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

FORM 10-K

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

For the fiscal year ended December 31, 2017

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

For the transition period from __________ to __________

Commission File Number: 001-36329

Recro Pharma, Inc.
(Exact name of registrant as specified in its charter)

Pennsylvania	**26-1523233**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
490 Lapp Road, Malvern, Pennsylvania	**19355**
(Address of principal executive offices)	**(Zip Code)**

(484) 395-2470
(Registrant's telephone number, including area code)

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

Title of Each Class	Name of Exchange on Which Registered
Common Stock, par value $0.01	**Nasdaq Capital Market**

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

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

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☒		

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

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

On the last business day of the most recently completed second fiscal quarter, the aggregate market value (based on the closing sale price of its common stock on that date) of the voting stock held by non-affiliates of the registrant was $111.6 million.

As of March 1, 2018, there were 19,156,851 shares of common stock outstanding, par value $0.01 per share.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates certain information by reference from the registrant's proxy statement for the 2018 annual meeting of shareholders to be filed no later than 120 days after the end of the registrant's fiscal year ended December 31, 2017.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents incorporated by reference herein contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K or the documents incorporated by reference herein regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward- looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K and the documents incorporated herein by reference include, among other things, statements about:

- our estimates regarding expenses, future revenue, capital requirements and timing and availability of and the need for additional financing;
- our ability to obtain and maintain regulatory approval of intravenous, or IV, meloxicam and our product candidates, and the labeling under any 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 required debt payments, and any milestone payments owing to Alkermes plc, or Alkermes, or our other licensing and collaboration partners;
- our ability to comply with the regulatory schemes applicable to our business and other regulatory developments in the United States and foreign countries;
- our ability to operate under increased leverage and associated lending covenants;
- the performance of third-parties upon which we depend, including third-party contract research organizations, or CRO’s, and third-party suppliers, manufacturers, distributers 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 and contracts with our key commercial partners;
- our ability to recruit or retain key scientific, technical, commercial, and management personnel or to retain our executive officers;
- our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including Good Manufacturing Practice, or cGMP, compliance and U.S. Drug Enforcement Agency, or DEA, compliance; and
- the effects of changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in the tax laws.

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

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

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

PART I

Item 1. Business

Overview

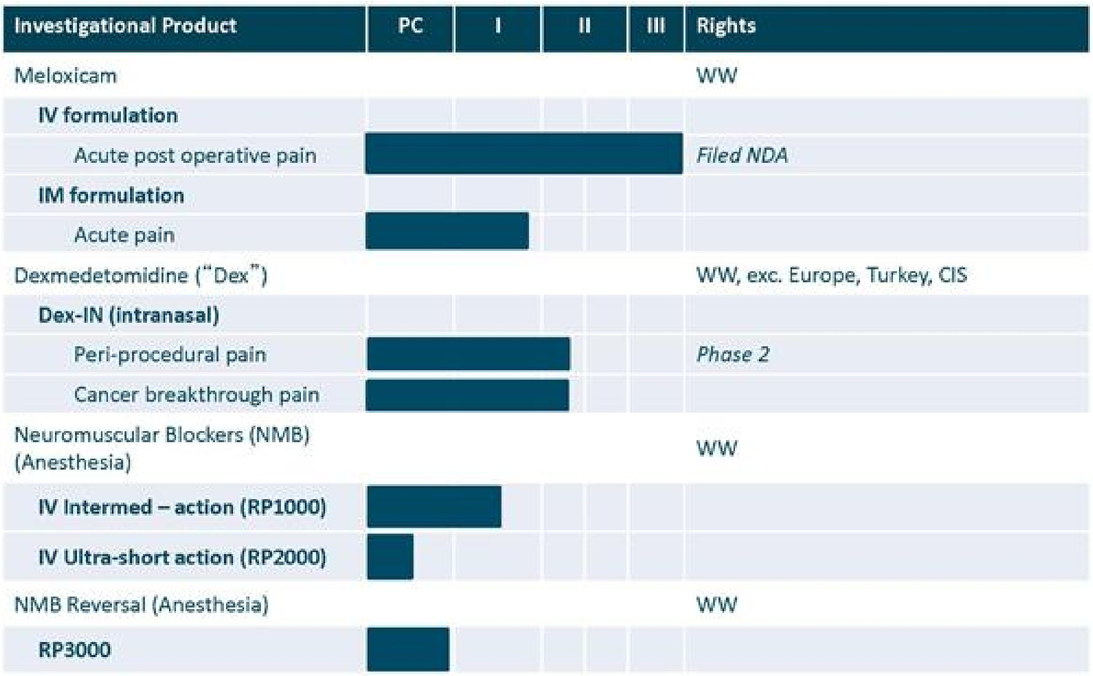
We are a specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating contract development and manufacturing, or CDMO division, through which we operate a revenue generating manufacturing facility in Gainesville, Georgia. We believe that 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, as well as through the ongoing contributions of our cash-flow positive CDMO division. In addition to our pipeline, we continue to evaluate acquisition and in-licensing opportunities.

Acute Care

Our Acute Care division is primarily focused on developing and commercializing innovative products for hospital and related acute care settings. 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 new drug application, or NDA, program included over 1,400 patients. In late July 2017, we submitted a NDA to the Food and Drug Administration, or FDA, for IV meloxicam 30mg for the management of moderate to severe pain. The FDA has accepted the NDA for review and set a date for decision on the NDA under the Prescription Drug User Fee Act, or PDUFA, of May 26, 2018. 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 Dex-IN, a proprietary intranasal formulation of dexmedetomidine, or Dex, an alpha-2 adrenergic agonist that we are evaluating for use in treatment of peri-procedural pain, and two novel neuromuscular blocking agents, or NMBs, and a related proprietary chemical reversal agent.

Pipeline



CDMO

Our CDMO division leverages formulation expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including manufacturing, royalties, profit sharing, and research and development, which support continued operations for our CDMO division and have contributed excess cash flow to be used for research and development in our Acute Care division. We operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia and we currently manufacture the following key products with our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR and Zohydro ER®, as well as supporting development stage products.

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 as well as through the ongoing contributions of our cash-flow positive CDMO division. In addition to our pipeline, we evaluate acquisition and in-licensing opportunities, especially those that can contribute additional revenue and cash flow. Our near-term goals include:

Complete regulatory approval of IV meloxicam. Our key 2018 goal is to receive FDA approval of IV meloxicam for the management of moderate to severe pain. In late July 2017, we submitted a NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. The FDA has accepted the NDA for review and set a PDUFA date of May 26, 2018.

Expand data supporting benefits of IV meloxicam. We are currently evaluating IV meloxicam in a number of programs including a Phase IIIb program that includes clinical trials in colorectal surgery patients and orthopedic surgery patients. We anticipate completing the Phase IIIb program by approximately the end of 2018.

Commercialize IV meloxicam in the United States independently or with third-parties. We believe IV meloxicam targets a group of specialists which would allow for successful marketing and commercialization by a company of our size. Assuming approval, we are currently preparing for a U.S. commercial launch of IV meloxicam and are establishing sales management, marketing and reimbursement functions to commercialize IV meloxicam in the United States.

Enter 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.

Leverage our development experience to progress our other pipeline product candidates. Our early-stage product pipeline includes proprietary product candidates for peri-procedural pain and for use in anesthesia (neuromuscular blocking and reversal). Our goal is to leverage our drug development expertise to develop these product candidates for use in hospital and acute care settings.

Expand our contract development and manufacturing business (CDMO). We are focused on the growth of our CDMO services. We intend to seek additional product and related development partnerships through ongoing business development efforts, as well as possibly through expansion of our proprietary drug delivery technologies, and current and new manufacturing service offerings.

Acute Care

Our Acute Care division is primarily focused on developing innovative products for hospital and related acute care settings.

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 and provides a rapid treatment of acute pain which lasts for approximately 24 hours.

Post-Operative Pain Market

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

While opioids provide effective analgesia for post-operative pain, their use is increasingly limited due to the known side effects of nausea, vomiting, constipation, respiratory depression, the development of tolerance and the potential for impact on addiction, misuse and abuse. Due to the potential for abuse, opioids are regulated as controlled substances and are listed on Schedule II and III by the DEA. According to a January 2016 article in the New England Journal of Medicine, overdose deaths from prescription painkillers (defined to mean opioid or narcotic pain relievers) have 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 Medicare and Medicaid, are quite 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.

Onset of pain relief. IV meloxicam results in rapid onset of pain relief as early as 10 minutes after administration.

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

Time to peak analgesic effect. Clinical data has demonstrated that IV meloxicam reaches peak analgesic effect within approximately 40 minutes of administration.

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 infuse.

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

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

Commercial Strategy

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

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

Overall, we plan to initially target approximately 1,500 hospitals and associated hospital outpatient departments, or HOPDs, and 600 ASCs, which together represent approximately 12.6 million patients across all settings of care. If IV meloxicam is approved by the FDA, we will complete the process of building a sales force and we plan to initially launch with approximately 50 representatives. In addition, we have medical, account-based and reimbursement teams. We believe this focused approach will help educate health care professionals, support formulary review processes and generate early adoption after launch with surgeons and anesthesiologists. We expect to reach full deployment of the sales organization in 2019, assuming FDA approval by our PDUFA date, at which time we expect to have a sales force of approximately 100 sales representatives who would market IV meloxicam to health care professionals at our called-on institutions.

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. At the end of July 2017, we submitted a NDA to the FDA for IV meloxicam 30mg for the management of moderate to severe pain. The FDA has accepted the NDA for review and set a PDUFA date of May 26, 2018. In addition, we are currently evaluating IV meloxicam in usage and pharmacoeconomic 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 institutional review board, or IRB, review.

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 completing the Phase IIIb program in 2018.

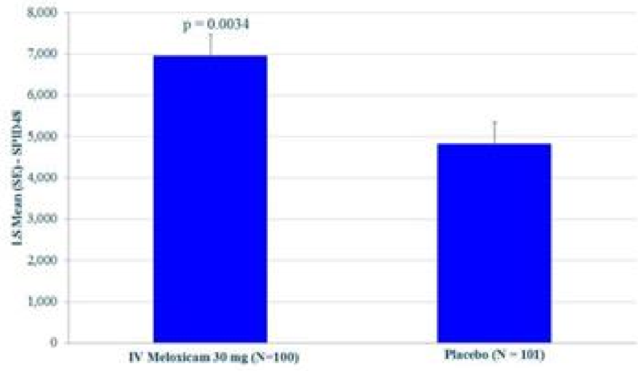
Phase III Clinical Trials

Study REC-15-016

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

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

Figure 1: SPID48



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

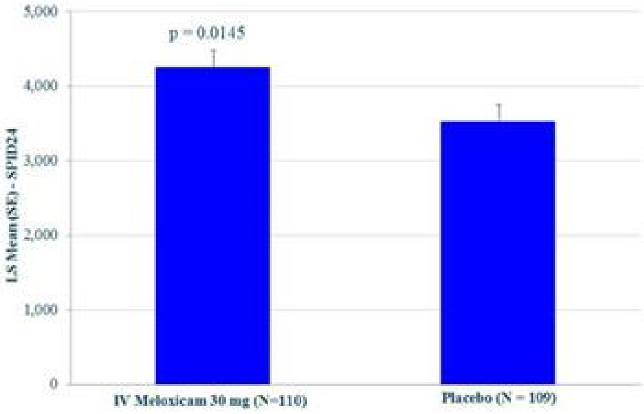
The safety results demonstrated that IV meloxicam was well tolerated with no serious adverse events, or SAEs, or bleeding events in the IV meloxicam-treated patients. The most common adverse events, or AEs, occurring in at least 3% of IV meloxicam-treated patients, were nausea, headache, pruritus, constipation, vomiting, dizziness, flushing and somnolence, and the incidence of these AEs was generally comparable to the placebo group. The IV meloxicam-treated patients experienced injection site pain and injection site erythema at a rate comparable to placebo. The majority of treatment emergent AEs, or TEAEs, were mild in nature and there were no discontinuations due to AEs. There were no meaningful differences between treatment groups in vital signs, electrocardiogram, or ECGs, or clinical lab assessments.

Study REC-15-015

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

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

Figure 2: SPID24



The study also achieved statistical significance for 10 of the secondary endpoints, including statistically significant differences in SPID12 ($p=0.0434$), time to perceptible pain relief ($p=0.0050$), subjects with ≥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 with no difference in SAEs related to bleeding for IV meloxicam treated patients versus placebo (1 each). There were two additional SAEs observed in the placebo group. The most common (at least 3% in the IV meloxicam group) AEs were nausea, headache, vomiting, and dizziness. The incidence of these events was lower than those observed in the placebo group. The majority of AEs were mild in nature and one patient in the placebo group discontinued treatment due to an adverse event of post-procedural bleeding. There were no meaningful differences between treatment groups in vital signs, ECGs or clinical lab assessments.

Safety Study

IV meloxicam has also successfully completed a double-blinded, 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 after approval, our pipeline also includes other earlier stage product candidates, including Dex-IN, intermediate and short-acting NMBs, and accompanying reversal agents, along with other product candidates that we may choose to develop for use in hospital or related settings.

NMBs

Neuromuscular blocking agents are used as muscle paralyzing agents to facilitate intubation and surgery. We are developing an intermediate-acting NMB, RP1000, an ultrashort-acting NMB, RP2000, and a reversal agent specific to our NMBs. The table below summarizes the predicted onset and duration of activity for each NMB based on currently available data, as well as the development status of each NMB:

Compound	**Onset Time**	**Duration of Activity**	**Status**
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 NMBs and reversal agent can reduce the time required for induction of anesthesia and the time needed to recover from NMB dosing post-procedure, while potentially enhancing patient safety and resulting in cost savings for the hospital or other provider. RP1000, the intermediate-acting NMB, as well as the reversal agent are subject to a clinical hold imposed by the FDA due to need for additional toxicity data at higher dose exposures, which we are working with the FDA to advance clinical development.

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

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 are exploring Dex-IN in peri-procedural pain. If approved, Dex-IN would also be the first approved peri-procedural pain product in its class of drugs.

CDMO Division

Through our contract development and manufacturing, CDMO, division, we leverage its formulation and development expertise to develop and manufacture pharmaceutical products using proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. Our manufacturing and development capabilities include formulation, product development from formulation through commercial manufacturing, and specialized capabilities for solid oral dosage forms, extended release and controlled substance manufacturing. In a typical collaboration, we work with our commercial partners to develop product candidates, or new formulations of existing product candidates, and may license certain intellectual property to such commercial partners. We also typically exclusively manufacture and supply clinical and commercial supplies of these proprietary products and product candidates. These collaborations may result in revenue streams including from manufacturing, royalties, profit sharing, and research and development, which support continued operations for our CDMO division as well as provide free cash flow to support research and development of proprietary product candidates in our Acute Care division.

The table below details the key products developed and/or manufactured with our key commercial partners:

Product	Indication	Technology	Territory	Revenue Source	Commercial Partner
Ritalin LA®	Attention Deficit Hyperactivity Disorder	OCR	Worldwide	Royalty / Manufacturing	Novartis Pharma AG
Focalin XR®	Attention Deficit Hyperactivity Disorder	OCR	Worldwide, except Canada	Royalty / Manufacturing	Novartis Pharma AG
Verelan PM®, SR & Verapamil PM	Hypertension	OCR	United States	Profit Sharing / Manufacturing	Lannett Company, Inc.
Verapamil SR	Hypertension	OCR	United States	Profit Sharing / Manufacturing	Teva Pharmaceutical Industries Ltd.
Zohydro ER®	Severe Pain	OCR	United States	Royalty / Manufacturing	Pernix Therapeutics, Inc.
			Canada	Royalty / Manufacturing	Paladin Labs, Inc.

In addition to these key products, we also develop and manufacture other development stage products. The manufacture of these products for clinical trials and commercial use is subject to cGMPs and other regulatory agency regulations. We own and operate a 97,000 square foot, DEA-licensed manufacturing facility in Gainesville, Georgia, which has been inspected by U.S., EU, Turkish and Brazilian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

With each product, we either purchase active drug substance from third parties or receive it from our commercial partners to formulate product using our technologies. Although some materials for our products are currently available from a single source or a limited number of qualified sources, we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements. We do not currently have any significant issues finding suppliers. However, there is no certainty that we will be able to obtain long-term supplies of our manufacturing materials in the future.

Permits and Regulatory Approvals

We hold various licenses for our CDMO division manufacturing activities. The primary licenses held are FDA Registrations of Drug Establishments and DEA Controlled Substance Registration. Due to certain U.S. state law requirements, we also hold certain state licenses for distribution activities throughout certain states. We also hold cGMP certifications for EU importation of products made in Gainesville for sale in the EU and an ANVISA certification for sale in Brazil.

In certain of our commercial partnerships, our commercial partner is the product authorization holder for products that have been developed on behalf of the commercial partner. In other commercial partnerships, we are the authorization holder. When our commercial partner holds the relevant authorization from the FDA or other national regulator, we support this authorization by furnishing a letter of reference to the Drug Master File, or the chemistry, manufacturing and related data to the relevant regulator or sponsor to provide adequate manufacturing support in respect of the product. We generally update this information annually with the relevant regulator.

We hold the approved NDAs for Verelan and Verapamil, which we license to Lanett Company, Inc. and Teva Pharmaceutical Industries, Inc., respectively.

Customer Agreements

We are party to agreements with each of our commercial partners governing the development, formulation and/or supply services we provide, as well as any applicable intellectual property licenses. Each commercial partner generally remains responsible for distributing, marketing and promoting their respective products. These collaborations result in revenue streams including royalties, profit sharing, etc., which support continued operations for our CDMO division and have contributed funds to be used in our research and development and pre-commercialization activities in our Acute Care division. We are dependent on a small number of commercial partners, with our four largest customers (Novartis Pharma AG, Teva Pharmaceutical Industries, Inc., Pernix Therapeutics, Inc., or Pernix, and Lannett Company, Inc.) having generated 98% of our revenues for the twelve months ended December 31, 2017, of which Teva Pharmaceutical Industries, Inc. generated 45% of our revenue under one customer agreement, and Novartis Pharma AG, generated 40% of our revenue combined under two separate customer agreements.

Intellectual Property

Acute Care

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 patent 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 NMBs and the related reversal agent under a worldwide, exclusive, sublicensable, royalty-bearing license from Cornell University. Under the license agreement, we are obligated to pay Cornell University (i) an annual license maintenance fee payment until the first commercial sale of a licensed compound; (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMB, of $5 million for U.S. regulatory approval and commercialization milestones and $3 million for European regulatory approval and commercialization milestones; and (iii) royalties on net sales of the NMBs and the related reversal agent at rates ranging from low to mid-single digits, depending on the applicable licensed compound and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. In addition, we will reimburse Cornell University 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 University upon our material breach, subject to a cure period, and upon our filing any claim asserting the invalidity of any of Cornell University'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 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 license our intellectual property rights related to injectable meloxicam and Dex to our Irish subsidiary, Recro Ireland Limited.

CDMO Division

We own various controlled release formulation patents, including patents in the United States, Canada, Europe, and Brazil, related to our proprietary delivery technologies that we utilize in our drug development, formulation and manufacturing business through our CDMO division. These patents are scheduled to expire between 2019 and 2026. We own patents and patent applications in the United States and Canada directed to the composition of, manufacturing of, and formulations of Zohydro ER®. We license our U.S. patents and patent applications to our commercial partner Pernix in the United States. We also own Canadian patents and patent applications relating to the same technology. The patent protection for Zohydro ER® formulation provides for protection of Zohydro ER® through 2019, subject to any extensions or disclaimers. In addition, we own several issued patents in the United States and several foreign patent applications for abuse resistant pharmaceutical compositions and methods of use related to Zohydro ER®, which provide patent protection through 2034, subject to any extensions or disclaimers.

Intellectual Property Protection Strategy

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

Our current intent is to develop and commercialize our product candidates in the United States while out-licensing development and commercialization rights for other territories outside the United States, for which we own the territorial rights. 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 establishing sales infrastructure, marketing and reimbursement functions to commercialize IV meloxicam, if approved, in the United States. While we plan to develop and commercialize our product candidates in the United States, we will consider potential strategic collaborations that could accelerate or enhance development and, upon approval, commercial success of our product candidates.

Manufacturing and Supply of our Acute Care Product Candidates

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 formulation. Pursuant to a Development, Manufacturing and Supply Agreement, or Supply Agreement, 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. The Supply Agreement may be terminated earlier (i) by us upon 180 days' written notice following the date of first generic entry; (ii) by either party upon twelve months' written notice following the first anniversary of the approval of the NDA for meloxicam; (iii) by either party upon written notice to the other party in the event of uncured material breach of the other party; and (iv) by Alkermes upon written notice in certain events of uncured non-payment.

Patheon UK Limited, or Patheon, provides sterile fill-finish of bulk injectable meloxicam formulation 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. We may terminate the Patheon Agreements upon prior notice if (i) a governmental authority prevents us from importing, exporting, purchasing or selling injectable meloxicam, (ii) injectable meloxicam is discontinued in the market or (iii) Patheon fails to timely deliver batches of injectable meloxicam. Patheon may terminate the Patheon Agreements if we assign any rights thereunder to a Patheon competitor or to a non-credit worthy substitute. In addition, either party may also terminate the Patheon Agreements for material, uncured breaches or in the event of the other party's bankruptcy.

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 initial term of the agreement is the later of 15 years from the first commercial sale and 15 years after the effective date of the agreement, and in each case, will be automatically extended for one or more periods of two years unless terminated. After the initial term, the agreement may be terminated upon six months' notice to the other party.

The single unit dose intranasal sprayer for Dex-IN is manufactured by a supplier of proprietary components and devices. We will continue to evaluate the option of entering a manufacturing agreement with the device originator or evaluate alternative devices prior to commercialization. Suppliers of components, subassemblies and other materials are located in Europe, Asia and the United States.

NMBs

Under our license agreement with Cornell University, we acquired certain materials relating to the API for our NMB product candidates. We are currently in the process of sourcing API for use in pre-clinical studies and clinical trials for these product candidates.

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 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, 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 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., Depomed, Inc. and Pacira 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., AcelRx Pharmaceuticals, 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.

The CDMO division competes with contract pharmaceutical formulation and manufacturing companies such as Catalent, Inc., Patheon Holdings Coôperatief U.A., Adare Pharmaceuticals, Inc., Metrics, Inc., a subsidiary of Mayne Pharma Group Limited, and other formulation, development and manufacture-related service providers.

Research and Development

Research activities represent a significant part of our businesses. In the years ended December 31, 2017, 2016 and 2015, respectively, we incurred research and development expenses of $33.1 million, $33.3 million and $12.3 million, respectively.

Information about Segment Revenue

Information about segment revenue is set forth in Note 17 to the Consolidated Financial Statements included in this Form 10-K.

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 Federal Food, Drug, and Cosmetic Act, or 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 current Good Clinical Practices, or 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 our CDMO division.

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, c ommonly referred to as the Orange Book. Specifically, the applicant must certify for each listed patent that, in relevant part, (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is not sought until after patent expiration; or (4) the listed patent is invalid, unenforceable or will not be infringed by the proposed new product. A certification that the new product will not infringe the previously approved product's listed patent or that such patent is invalid or unenforceable is known as a Paragraph IV certification. If the applicant does not challenge one or more listed patents through a Paragraph IV certification, the FDA will not approve the Section 505(b)(2) NDA until all the listed patents claiming the referenced product have expired.

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

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

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

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

The approval process is lengthy and difficult, and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response letter if the agency decides not to approve the NDA in its present form. The complete response letter 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 complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter 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 Risk Evaluation and Mitigation Strategy, or 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 abbreviated new drug application, or 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 quantities of our product candidates. FDA and state inspections may identify compliance issues at our site or 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.

The U.S. Drug Enforcement Administration

Certain products that we manufacture are regulated as a "controlled substance" as defined in the Controlled Substances Act of 1970, which establishes registration, security, recordkeeping, reporting, storage, distribution and other requirements administered and enforced by the DEA. The DEA is concerned with the control and handling of controlled substances, and with the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

The DEA regulates controlled substances by controlling them in five schedules. Schedule I and II controlled substances have a high potential for abuse, whereas Schedule III-V controlled substances have relatively decreasing potential for abuse. Therefore, the DEA imposes more stringent controls on Schedule I and II substances than Schedule III-V substances, including stricter security controls, quotas, and increased recordkeeping and reporting requirements. Certain of the products we manufacture and/or develop are regulated as Schedule II controlled substances. The DEA establishes annually an aggregate quota for how much certain controlled substances that we manufacture may be produced in total in the United States, based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce any Schedule II substance. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

The DEA requires facilities that manufacture controlled substances to adhere to certain security requirements. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Required security measures include background checks on employees and physical control of inventory through measures such as cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances and periodic reports must be made to the DEA, for example, distribution, acquisition, and inventory reports for Schedule I and II controlled substances, Schedule III substances that are narcotics and other designated substances. Reports must also be made for thefts or losses of any controlled substance and suspicious orders. In addition, special authorization and notification requirements apply to imports and exports.

Failure to maintain compliance with applicable requirements, particularly where noncompliance results in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations, or take other enforcement action. In certain circumstances, violations could result in criminal prosecution.

There is a risk that DEA regulations may interfere with the manufacture and supply of the drugs sold commercially, and thus with our ability to produce products in the volume needed to meet commercial demand.

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 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 Acute Care division 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 the Centers for Medicare and Medicaid Services, or 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, average manufacturer price, or AMP, and wholesale acquisition cost. The existing data for reimbursement based on these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates. CMS surveys and publishes retail community pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates. It may be difficult to project the impact of these evolving reimbursement mechanics on the willingness of payers to cover any products for which we receive regulatory approval.

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

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

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

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

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

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union member states. These countries include the United Kingdom, France, Germany and Sweden. The HTA process in the European Union member states is governed by the national laws of these countries. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of the use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the national healthcare system. Those elements of medicinal products are compared with other treatment options available on the market.

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

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

United States Healthcare Reform

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

In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs administered by physicians. CMS, the agency that administers the Medicare and Medicaid programs, also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payers often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payers.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the Affordable Care Act, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the pharmaceutical industry. The Affordable Care Act is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers, and impose additional health policy reforms. Among other things, the Affordable Care Act expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs, expanded the 340B program, and revised the definition of AMP, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the Affordable Care Act. These regulations became effective on April 1, 2016. There have been significant ongoing efforts to modify or eliminate the Affordable Care Act. For example, the Tax Cuts and Jobs Act, or 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, beginning in 2019. 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;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- state laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and

- the Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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

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 entered into force on May 24, 2016 and will apply from May 25, 2018. The EU Data Protection Regulation will increase the responsibility and liability in relation to personal data processed in the European Union and will also introduce 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.

Corporate Information

We were incorporated under the laws of the Commonwealth of Pennsylvania in November 2007. Our principal executive offices are located at 490 Lapp Road, Malvern, PA 19355, and our telephone number is (484) 395-2470.

Employees

We currently have 255 full-time employees and 1 temporary employee. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

Available Information

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

Item 1A. Risk Factors

The following risk factors and other information included in this Annual Report on Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page 4 of this Annual Report on Form 10-K for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. All references and risks related to the launch, commercialization or sale of injectable meloxicam or any of our other product candidates are predicated on such product candidates receiving the requisite marketing and regulatory approval in the United States and applicable foreign jurisdictions.

Risks Related to Our Finances and Capital Requirements

We have incurred net losses since inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

To date, we have focused primarily on developing our proprietary product candidates. We have incurred significant pre-tax losses in each year since our inception in November 2007, including pre-tax losses of approximately $52.0 million and $31.3 million for the years ended December 31, 2017 and 2016, respectively. As of December 31, 2017, we had an accumulated deficit of $111.3 million.

We have financed our operations through the sale of debt and equity securities, term loans made under our previous and existing credit facilities, including our current $100.0 million credit facility with Athyrium Opportunities III Acquisition LP, or Athyrium, and revenue generated by our CDMO division. We have used revenue generated by our CDMO division primarily to fund the operations of our CDMO division, to make payments under our previous credit facility and to partially fund our research and development and pre-commercialization activities. We believe that our CDMO division revenue will continue to contribute cash for general corporate purposes that may, to some extent, reduce the amount of external capital needed to fund development operations.

The size of our future net losses and our ability to achieve profitability will depend, in part, on the rate of future expenditures and our ability to successfully commercialize IV meloxicam, if approved, and our other current or future product candidates. To date, none of our product candidates have been commercialized, and revenues generated by our CDMO division do not cover our costs and may never be sufficient to achieve profitability. Our ability to generate future revenues from product sales depends heavily on our success in:

- obtaining regulatory approval for IV meloxicam for the management of moderate to severe pain;
- launching and commercializing IV meloxicam;
- developing a sufficient commercial organization capable of sales, marketing and distribution for IV meloxicam;
- establishing a commercially viable price for IV meloxicam;
- manufacturing commercial quantities of IV meloxicam at acceptable cost levels;
- effectively managing the levels of production, distribution and delivery of IV meloxicam through our supply chain and adequately adjusting such production and delivery to correspond to market demand;
- obtaining coverage and adequate reimbursement from third-parties, including government payers;
- obtaining and maintaining patent protection for IV meloxicam and our product candidates;
- completing the clinical development of our other product candidates; and
- our ability to generate increased revenue from our CDMO division.

We expect to continue to incur substantial and increased expenses as we continue our clinical, launch preparation and commercialization activities for IV meloxicam, and expand our research and development activities and advance our clinical programs for our other product candidates. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to predict the timing or amount of increased expenses, and when, or if, we will be able to achieve or maintain profitability.

If IV meloxicam or our other product candidates are not successfully developed or commercialized, or if revenues are insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval for IV meloxicam in the United States, our revenues are also dependent upon the size of the markets outside of the United States, as well as our ability to obtain market approval and achieve commercial success outside of the United States on our own or with a collaboration partner.

As a result of the foregoing, we expect to continue to incur significant and increasing losses from operations for the foreseeable future. Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations.

If we fail to obtain sufficient additional financing, we would be forced to delay, reduce or eliminate our product development and related commercialization programs or to significantly scale back or discontinue our manufacturing business.

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials and ramping up commercial manufacturing activities, is expensive. We expect our research and development expenses to increase in connection with our ongoing clinical and pre-commercialization activities, particularly as we advance our clinical programs and scale up our commercialization activities. If we obtain regulatory approval for IV meloxicam, we anticipate incurring significant costs of sales and general and commercialization expenses in connection with its launch and commercialization. In addition, maintaining our cGMP pharmaceutical manufacturing facility is expensive. While our CDMO division generates revenue and profit, that revenue and profit alone is not sufficient to support the development and commercialization of our product candidates. We will need to raise additional funds to support our future product development operations. In addition, we may also need to obtain additional financing if the capital requirements for operating and maintaining our manufacturing facility exceed our current expectations. Such financing may not be available to us on acceptable terms, or at all.

We expect our existing cash and cash equivalents and other expected financing sources will be sufficient to fund our operations over the next 12 months. If IV meloxicam is approved by the FDA, we will need to raise additional funding to satisfy the $45 million milestone payment due to Alkermes upon FDA approval of IV meloxicam, and to implement our commercial launch plans for IV meloxicam. In addition, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our pre-commercialization and commercialization activities for IV meloxicam may lead to additional, unexpected costs related to the commercial manufacture of IV meloxicam or the build out of our commercial sales organization. We may also encounter technical, enrollment or other difficulties that could increase our development costs more than we expect for our other product candidates. Additional funding will be needed to develop our other product candidates.

Securing additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates or to develop and maintain customer relationships. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of IV meloxicam or curtail the development programs for our other product candidates;
- seek collaboration partners for the development or commercialization of our product candidates at an earlier stage than otherwise would be desirable, on terms that are less favorable than might otherwise be available or for product candidates that we would otherwise plan to develop and commercialize on our own;
- relinquish or license, on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly scale back or discontinue our CDMO division.

Any of the above could have a material adverse effect on our business, operating results and prospects.

We may sell additional equity or debt securities to fund our operations, which would result in dilution to our shareholders and may impose restrictions on our business.

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. On December 29, 2017, we entered into a Sales Agreement, or the Sales Agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may sell from time to time, at our option, up to $40.0 million of shares of our common stock through Cowen, as our placement agent. On March 2, 2018, we entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement, Aspire Capital is committed to purchase, at our sole election, up to an aggregate of $20.0 million of our shares of common stock over the approximately 30-month term of the Purchase Agreement. To the extent that we raise additional capital through sales of common stock under the Sales Agreement or the Purchase Agreement, or the sale of equity or convertible debt securities by any other means, existing ownership interests will be diluted, and the terms of such financings may include liquidation or other preferences that adversely affect the rights of existing shareholders. Debt financings may be coupled with an equity component, such as warrants to purchase shares, which could also result in dilution of our existing shareholders' ownership. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

Our operating results may fluctuate significantly.

Our operating results may be subject to quarterly and annual fluctuations. Our operating results will be affected by numerous factors, including:

- the timing and amount of development and net sales milestones, royalties and earn-out payments payable by us under our existing license agreements and acquisition agreements;
- fluctuations in the revenues generated by our CDMO division, including the loss of a major customer or product;
- any delays in regulatory review and approval of IV meloxicam or our other product candidates in clinical development;
- variations in the level of expenses related to our development programs;
- the success of our clinical trials through all phases of clinical development;
- any newly identified side effects of IV meloxicam or our other product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;

- changes in the fair values of our warrants and contingent consideration li abilities;
- any intellectual property infringement lawsuit in which we may become involved;
- our ability to obtain and maintain patent protection;
- the success of our commercial launch preparations activities;
- our ability to establish an effective sales and marketing infrastructure;
- our dependency on third parties to supply and manufacture our product candidates and delivery devices;
- the level of market acceptance for IV meloxicam or any of our other product candidates, once approved, and underlying demand for that product and wholesalers' buying patterns;
- the amount of sales and other revenues from IV meloxicam or any of our other product candidates, once approved, including the selling prices for such potential products and the availability of adequate third-party coverage and reimbursement;
- competition from existing products or new products that may emerge;
- regulatory developments affecting our product candidates, which are not limited to but could include the imposition of a REMS program as a condition of approval;
- our execution of any additional collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; and
- our acquisition or in-licensing of new products or product candidates.

Due to the various factors mentioned above, and others, the results of any prior quarterly period should not be relied upon as an indication of our future operating performance. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

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

As of December 31, 2017, we had an outstanding balance under the credit agreement of $60.0 million. Upon entry into the credit agreement with Athyrium, we drew upon an initial $60.0 million term loan and have the ability to draw upon two additional tranches of terms loans, each in the aggregate original principal amount of $20.0 million, subject to certain timing and milestone restrictions.

Our indebtedness could have important consequences to our shareholders. For example, it:

- increases our vulnerability to adverse general economic or industry conditions;
- limits our flexibility in planning for, or reacting to, changes in our business or the industries in which we operate;
- makes us more vulnerable to increases in interest rates, as borrowings under our credit agreement with Athyrium are at variable rates;
- limits our ability to obtain additional financing in the future for working capital or other purposes; and
- places us at a competitive disadvantage compared to our competitors that have less indebtedness.

Any of the above listed factors could materially adversely affect our business, financial condition, results of operations and cash flows. Our credit agreement with Athyrium also contains certain financial and other covenants, including a minimum liquidity requirement and a trailing four quarter revenue requirement, maximum leverage ratios and includes limitations on, among other things, additional indebtedness, paying dividends in certain circumstances, acquisitions and certain investments. The credit agreement provides for certain mandatory prepayment events, including with respect to the proceeds of asset sales, extraordinary receipts, debt issuances and other specified events, based on the terms of the credit agreement with Athyrium. Any failure to comply with the terms, covenants and conditions of the credit agreement may result in an event of default under such agreement, may limit our ability to draw upon additional tranches of term loans, and could have a material adverse effect on our business, financial condition and results of operation.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law the Tax Act, which significantly changes the Internal Revenue Code of 1986, as amended. The Tax Act contains, among other things, significant changes to corporate taxation, including a permanent reduct ion to the corporate income tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Any federal net operating loss carryovers created in 2018 and thereafter will be carried forward indefinitely. As a result of the Tax Act, we have incurred a one-time net expense of $7.9 million related to the remeasurement of our deferred tax balances to the new statutory rate. We continue to examine the impact the Tax Act may have on our business. Any estimates we have made or will make regarding the impact of the Tax Act reflect certain assumptions based upon our current interpretation and analysis to date of the law. These assumptions may be subject to further refinement due to any future changes in interpretations or additional guidance that may be issued as a result of the Tax Act . Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain, and our business and financial condition could be adversely affected.

Changes in tax laws and unanticipated tax liabilities could adversely affect our effective income tax rate and ability to achieve profitability.

We are subject to income taxes in the United States and Ireland. Our effective income tax rate in the future could be adversely affected by a number of factors including changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws.

We regularly assess these matters to determine the adequacy of our tax provision, which is subject to discretion. If our assessments are incorrect, it could have an adverse effect on our business and financial condition. There can be no assurance that income tax laws and administrative policies with respect to the income tax consequences generally applicable to us or to our subsidiaries will not be changed in a manner which adversely affects our shareholders. Changes in tax laws and unanticipated tax liabilities could adversely affect our effective income tax rate and ability to achieve profitability.

<u>Risks Related to Clinical Development and Regulatory Approval</u>

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

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

We submitted an NDA for IV meloxicam for the management of moderate to severe pain in July 2017. Our NDA was subsequently accepted for filing and review by the FDA in September 2017 and a PDUFA date for was set for May 26, 2018. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase III clinical trials or other aspects of our NDA are not sufficient for regulatory approval and may issue a complete response letter instead of approval. If we receive a complete response letter, the FDA would outline deficiencies in our NDA and may request the submission of additional information, including CMC, preclinical and clinical data. The FDA is also in the process of auditing the third-party manufacturing facilities that we rely on for the manufacture of IV meloxicam for pre-approval inspections and may audit one or more of our clinical trial sites, and if any site or facility reveals anomalies or does not pass inspection, including, but not limited to, any issues related to our process validation batches, the FDA could delay or preclude approval of our NDA. In either case, our commercialization of IV meloxicam may be delayed and we may incur additional costs and be required to devote additional resources to address the FDA's concerns. If the FDA requires us to conduct additional clinical trials or pre-clinical studies or requires any of our manufacturers to improve or change their practices, our timeline for commercialization of IV meloxicam will be delayed and we will incur additional costs. Further, there can be no assurance that we will complete the other clinical and non-clinical studies or address manufacturing issues in a manner that is acceptable to the FDA. In addition, we are conducting Phase IIIb clinical trials for IV meloxicam in colorectal surgery patients and orthopedic surgery patients, and those clinical trials could fail or produce results that are adverse or inconclusive, which could have a negative impact on regulatory approval.

Any delay or setback in the development or regulatory approval of IV meloxicam could adversely affect our business and cause our stock price to decline. Should our recent Phase III clinical development program be insufficient to support regulatory approval, we may be forced to rely on our other product candidates, which are at an earlier development stage and will require additional time and resources to obtain regulatory approval and proceed with commercialization. We cannot assure you that we will be able to obtain approval for IV meloxicam from the FDA.

Even if the FDA grants approval of IV meloxicam, the terms of the approval may limit its commercial potential.

Even if IV meloxicam were to successfully obtain approval from the FDA, any such approval might significantly limit the approved indications for use, including limiting its use to a more limited patient populations, 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, REMS or surveillance as conditions of approval, or, through product labeling limit the claims that we may make, any of which may impede the successful commercialization of IV meloxicam. For example, the FDA may conclude that our Phase III clinical trials or other aspects of our NDA are not sufficient to support a product label with claims covering management of moderate to severe pain or 24 hour dosing intervals. If the approval of IV meloxicam contains significant limitations, our ability to market to our full target market will be reduced and our ability to realize the full market potential of IV meloxicam will be harmed and we may have to discontinue the commercialization of IV meloxicam or limit our sales and marketing efforts, which in turn could limit our ability to achieve profitability.

Our development and commercialization strategy for 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 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 product 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.

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 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.

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

AEs caused by IV meloxicam and our other 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 SAEs, as those terms are defined by the FDA in its regulations, and AEs or SAEs could be generated during the course of our on-going Phase IIIb clinical trials for IV meloxicam. Our ability to obtain regulatory approval for IV meloxicam and our other 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.

IV meloxicam or any of our other product candidates, if approved, may require REMS, which may significantly increase our costs.

IV meloxicam or any of our other 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 IV meloxicam or our other product candidates. Depending on the extent of the REMS requirements, our costs to commercialize IV meloxicam or our other product candidates may increase significantly and distribution restrictions could limit sales. 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 in 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 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.

Even if we obtain FDA approval for IV meloxicam or our other 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.

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 the course of 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 filing;
- 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.

With the exception of our recent NDA submission for IV meloxicam, we have not previously submitted an NDA or any similar drug approval filing to the FDA or any comparable foreign authority for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval. If we do not receive regulatory approval for 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.

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 agreement with the FDA or the equivalent regulatory authorities in other countries on final trial design or the scope of the development program;

- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or the equivalent regulatory authorities in other countries;

- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;

- delays in obtaining required IRB approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver a sufficient supply of clinical trial materials.

For example, the FDA has imposed a clinical hold on two of our early-stage product candidates, RP1000 and the reversal agent. We currently are scheduled to meet with the FDA regarding the process for resolving the holds, but we will be unable to proceed with clinical development on these product candidates until clinical hold is resolved. In addition, we initially studied Dex-IN for the treatment of post-operative pain. Based on clinical trial results and feedback from the FDA, we are exploring Dex-IN in peri-procedural pain. However, we cannot guarantee whether the FDA will accept a development path that leads to this indication. If we are unable to resolve these issues with the FDA, or if clinical trials for any of our other 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.

Although we commenced operations in 2007, our operations have been primarily limited to developing our technology and undertaking non-clinical studies and clinical trials for our product candidates. 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. Consequently, because our success is dependent on our ability to commercialize IV meloxicam, 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.

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:

- the results of our ongoing Phase IIIb clinical trials for IV meloxicam;
- our ability to consistently manufacture commercial quantities of IV meloxicam at 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;
- 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 IV meloxicam;
- 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 term;
- 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. 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 clinical indications for which each of our product candidates are approved, including any 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.

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 health care payers, we may not generate sufficient revenue and we may not become or remain profitable.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell IV meloxicam or our other product candidates, we may be unable to generate any revenue for IV meloxicam or our other product candidates.

In anticipation of the approval and commercialization of IV meloxicam, we have begun to build out our sales, marketing and distribution capabilities, and will need to continue to do so. We may discover that the cost of continuing to establish, expand and maintain such sales force may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must continue to build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. We intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States. We will also consider the option to enter into strategic partnerships for certain product candidates in the United States.

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 is to develop a specialty sales force and/or collaborate with third parties to promote the 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.

We are subject to intense competition and, if we are unable to compete effectively, injectable meloxicam or any of our other 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 and drug delivery devices developed, manufactured and marketed by others. We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations.

In the post-operative pain relief setting, we believe patients are prescribed injectable acetaminophen, 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 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., Depomed, Inc. and Pacira 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., AcelRx Pharmaceuticals, Inc., Durect Corporation, Heron Therapeutics, Inc., Innocoll Holdings plc, Sandoz AG, Trevena, Inc. and Cara Therapeutics, Inc. are currently developing post-operative pain therapeutics that could compete with us 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, 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 may also be more successful than us 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.

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

Some of the contract manufacturers of our lead product candidate injectable meloxicam manufacture and source raw materials outside the United States and we may, in the future, use manufacturers outside the United States for our other product candidates. 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 shipment delays relating to the import or export of our products or the delivery of our products by means of additional third-party vendors;
- difficulties obtaining export or import licenses for our products;
- compliance with the U.S. Foreign Corrupt Practices Act and other laws and regulations governing international trade;
- fluctuations in foreign currency exchange rates;
- changes to U.S. and foreign trade policies, including the enactment of tariffs on goods imported into the United States.; and
- imposition of domestic and international customs and tariffs, withholding or other taxes, including any value added taxes.

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

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

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

- a covered benefit under its health plan;

- appropriate and medically necessary for the specific condition or disease;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for IV meloxicam or our other 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 IV meloxicam or our other product candidates to each government authority or other third-party payer. For example, if our ongoing Phase IIIb clinical trials for IV meloxicam in colorectal surgery patients and orthopedic surgery patients do not show improved outcomes relative to the current standard of care, obtaining payer coverage could be more difficult. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement.

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 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 IV meloxicam or our other product candidates, which in turn, could negatively impact pricing. If patients are not adequately reimbursed for IV meloxicam or our other product candidates, they may reduce or discontinue purchases of it, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition.

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 IV meloxicam or other 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; and

- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

Our current and future operations with respect to the commercialization of IV meloxicam and our other 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 IV meloxicam or our other product candidates, and other parties through which we market, sell and distribute IV meloxicam or our other 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;

- 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.

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 increase 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 begun to enact new 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 is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

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

If we are able to successfully commercialize IV meloxicam or our other 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 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 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 under other similar government pricing programs. These programs are described in greater detail in the section below under “Business — Government Regulation — 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 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 (VA, DOD, Public Health Service, and U.S. Coast Guard). The Federal Ceiling Price is based on the Non-Federal Average Manufacturer Price, which we calculate and report to the VA on a quarterly and annual basis. If we overcharge the government in connection with our FSS contract or Section 703 Agreement, whether due to a misstated Federal Ceiling Price or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the U.S. civil False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Affordable Care Act and any changes in healthcare law may increase the difficulty and cost for us to commercialize IV meloxicam or our other 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 IV meloxicam or our other product candidates or restrict or regulate post-approval activities and affect our ability to profitably sell IV meloxicam or our other 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 IV meloxicam or our other 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, beginning in 2019. 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.

Risks Related to Our Reliance on Third Parties

We rely on limited sources of supply and manufacturing for injectable meloxicam and our other product candidates, and if we encounter any issues with our contract manufacturers or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply injectable meloxicam.

We do not own facilities for clinical-scale or commercial manufacturing of injectable meloxicam and our other 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 Patheon provides sterile fill and finish services. Currently, Alkermes is the only established supplier of bulk injectable meloxicam formulation, and we have committed to purchase a certain percentage of our annual requirements of sterile fill and finish services from Patheon. 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.

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 injectable meloxicam and our other product candidates. Although we have agreements pertaining to the manufacture, testing, supply, storage and distribution of product supplies of injectable meloxicam, upon commercialization, it is possible that our manufacturing requirements may exceed the available supply allotments under our existing agreements. We currently rely on Alkermes and Patheon to manufacture, test and supply injectable meloxicam. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any;

- 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 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 the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or 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 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 IV meloxicam or their performance is substandard, our product launch may be delayed and our costs may be higher than expected.

Our reliance on third-party service providers, including carriers, logistics providers and distributors exposes us to risks which could delay or impair the commercialization of IV meloxicam or our other 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 IV meloxicam or our other 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 IV meloxicam or our other product candidates.

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.

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

As we scale up manufacturing of IV meloxicam or our other 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 IV meloxicam or our other 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.

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 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 cGCPs, which are regulations and guidelines enforced by the FDA and equivalent regulatory authorities in other countries for all of our product candidates in clinical development. The FDA and the equivalent regulatory authorities in other countries enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our contractors fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials for IV meloxicam and our other 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 CDMO Division

Revenues from our development, formulation and manufacturing business are dependent on a small number of commercial partners, and the loss of one of these partners, or a decline in their orders, may adversely affect our business.

Our CDMO division is dependent on our relationships with a small number of commercial partners, with our four largest customers (Novartis AG, Teva Pharmaceutical Industries, Inc., Pernix and Lannett Company, Inc.) having generated 98% of our revenues for the year ended December 31, 2017, of which Teva Pharmaceutical Industries, Inc. generated 45% of our revenue under one customer agreement and Novartis Pharma AG generated 40% of our revenue combined under two separate customer agreements. Our contracts with our commercial partners are for a short term, generally one year. If any one or more of these commercial partners fails to renew their contract, adjusts pricing, significantly reduces their purchasing volume or experiences financial difficulties such as bankruptcy, our revenues could be adversely affected. We are actively seeking to develop new customer relationships but there can be no guarantee that we will be able to expand our customer base.

Our royalty, profit sharing and manufacturing revenues from this business also depend on the ability of our commercial partners to effectively market and sell their products to their customers. A commercial partner may choose to devote its efforts to its other products or reduce or fail to devote the necessary resources to provide effective sales and marketing support of the products we manufacture and supply. Our commercial partners face competition from other pharmaceutical companies for sales of products to end users. Competition from sellers of generic drugs is a major challenge for our commercial partners, and the loss or expiration of intellectual property rights for the products we manufacture can have a significant adverse effect on their sales volume. This and any other significant reduction, delay or cancellation of orders from our commercial partners could adversely affect our revenues.

In addition, the financial covenants in our credit agreement with Athyrium include minimum revenue targets for our CDMO division, and any significant reduction, delay or cancellation of orders from our commercial partners may cause us to fail to meet such targets, which may result in an event of default under the credit agreement with Athyrium and could have a material adverse effect on our business, financial condition and results of operation.

We are subject to risks related to large-scale commercial manufacturing.

Manufacturing pharmaceuticals, especially in large quantities, is complex. The products we manufacture for our commercial partners require several manufacturing steps and may involve complex techniques to assure quality and sufficient quantity. Our manufactured products must be made consistently and in compliance with a clearly defined manufacturing process. Slight deviations anywhere in the manufacturing process, including obtaining materials, equipment malfunctions, filling, labeling, packaging, storage, shipping, regulatory compliance, quality control and testing, some of which all pharmaceutical manufacturing companies experience from time to time, may result in lot failures, delay in the release of lots, product recalls or spoilage. Success rates can vary dramatically at different stages of the manufacturing process, which can lower yields and increase costs.

In addition, some of the raw materials needed for the manufacture of our products are currently available from a single source or a limited number of qualified sources of these products. Although we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements, there is no certainty that we will be able to obtain long-term supplies of our manufacturing materials in the future. We may also experience deviations in the manufacturing process or interruptions in our supply chain that may take significant time and resources to resolve and, if unresolved, may affect manufacturing output and/or cause us to fail to satisfy customer orders or contractual commitments or result in litigation or regulatory action.

Our manufacturing facility also requires specialized personnel and is expensive to operate and maintain. Any suspension of the sale of products of our commercial partners to be manufactured in our facility may cause operating losses as we continue to operate the facility and retain specialized personnel. In addition, any interruption in manufacturing could result in delays in meeting our contractual obligations and could damage our relationships with our commercial partners, including the loss of manufacturing and supply rights.

Our development and formulation services projects are typically for a shorter term than our manufacturing projects, and any failure by us to maintain a high volume of development and formulation services projects, including due to lower than expected success rates of the products for which we provide services, could have a material adverse effect on our business, results of operations and financial condition.

Our pharmaceutical development services business contracts are generally shorter in term than our manufacturing contracts and typically require us to provide development services within a designated scope. Since our development and formulation services focus on products that are still in developmental stages, their viability depends on the ability of such products to reach their respective subsequent development phases. In many cases, such products do not reach subsequent development phases and, as a result, the profitability of the related pharmaceutical development service project may be limited. Even if a customer wishes to proceed with a project, the product we are developing on such customer's behalf may fail to receive necessary regulatory approval or may have its development hindered by other factors, such as the development of a competing product.

If we are unable to continue to obtain new projects from existing and new customers, our development and formulation services business could be adversely affected. Furthermore, although our development and formulation services business acts as a pipeline for our manufacturing services business, we cannot predict the conversion rate of our development and formulation services projects to commercial manufacturing services projects, or how successful we will be in winning new projects that lead to a viable product. As such, an increase in the turnover rate of our development and formulation services projects may negatively affect our manufacturing services business at a later time. In addition, the discontinuation of a project as a result of our failure to satisfy a customer's requirements may also affect our ability to obtain future projects from such customer, as well as from new customers. Any failure by us to maintain a high volume of development and formulation services projects could have a material adverse effect on our business, results of operations and financial condition.

If we fail to meet the stringent requirements of governmental regulation in the manufacture of pharmaceutical products, we could incur substantial costs and a reduction in revenues.

We are required to maintain compliance with cGMP, and our manufacturing facility is subject to inspections by the FDA and other global regulators to confirm such compliance. Changes of suppliers or modifications of methods of manufacturing may require amending our application(s) to the FDA and acceptance of the change by the FDA prior to release of our manufactured products. Because we produce multiple products at our manufacturing facility, there are increased risks associated with cGMP compliance. On January 24, 2018, following a six day inspection of our manufacturing facility, the FDA issued a Form 483 containing four observations relating to good documentation practices and data integrity. We have promptly responded to these observations as a part of our ongoing obligations under the FDA's quality system regulation and have implemented corrective and preventative actions to ensure these type of observations do not occur in the future While we remain committed to continuous improvement and strengthening our quality system and ensuring that all aspects of the system are in full compliance, we can provide no assurance that our remediation efforts will be successful to a degree acceptable by the FDA.

Our inability to demonstrate ongoing cGMP compliance, including the remediation of the observations in the recent Form 483, could require us to engage in additional lengthy and expensive remediation efforts, withdraw or recall products and/or interrupt commercial supply of any products. Any delay, interruption or other issue that arises in the manufacture, fill/finish, packaging, or storage of any drug product as a result of a failure of our facility to pass any regulatory agency inspection or maintain cGMP compliance or remediate the observations from the recent Form 483 could significantly impair our relationships with our commercial partners, which would substantially harm our business, prospects, operating results and financial condition. Any ongoing or additional findings of non-compliance could also increase our costs and cause us to lose revenue from manufactured products, which could be seriously detrimental to our business, prospects, operating results and financial condition.

Additionally, our manufacturing activities are subject to the Controlled Substances Act and the regulations of the DEA. Accordingly, we must adhere to a number of requirements with respect to controlled substances, including registration, recordkeeping and reporting requirements; labeling and packaging requirements; security controls, procurement and manufacturing quotas; and certain restrictions on refills. Failure to maintain compliance with applicable requirements can result in enforcement action that could have a material adverse effect on our business, financial condition, operating results and cash flows. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could result in criminal proceedings.

We may not be able to successfully offer new services.

In order to successfully compete, we will need to offer and develop new services. Without the timely introduction of enhanced or new services, our services and capabilities may become obsolete over time, in which case, our revenues and operating results would suffer. The related development costs may require a substantial investment before we can determine their commercial viability, and we may not have the financial resources to fund such initiatives.

In addition, the success of enhanced or new services will depend on several factors, including but not limited to our ability to:

- properly anticipate and satisfy customer needs, including increasing demand for lower cost services;
- enhance, innovate, develop and manufacture new offerings in an economical and timely manner;
- differentiate our offerings from competitors' offerings;
- meet quality requirements, authorization requirements, and other regulatory requirements of government agencies;
- obtain valid and enforceable intellectual property rights; and
- avoid infringing the proprietary rights of third parties.

Even if we were to succeed in creating enhanced or new services, those services may not result in commercially successful offerings or may not produce revenues in excess of the costs of development and capital investment and may be quickly rendered obsolete by changing customer preferences or by technologies or features offered by our competitors. In addition, innovations may not be accepted quickly in the marketplace due to, among other things, entrenched patterns of clinical practice, the need for regulatory clearance and uncertainty over market access or government or third-party reimbursement.

Technological change may cause our offerings to become obsolete over time. A decrease in our customers' purchases of our offerings could have a material adverse effect on our business, results of operations and financial condition.

The healthcare industry is characterized by rapid technological change. Demand for our services may change in ways that we may not anticipate because of evolving industry standards or as a result of evolving customer needs that are increasingly sophisticated and varied or because of the introduction by competitors of new services and technologies. In addition, we require capital and resources to support the maintenance and improvement of our facilities, including replacing or repairing aging production equipment and updating overall facility master plans. If we are unable to maintain and improve our facilities, we may experience unscheduled equipment downtime and unpredicted machinery failure and become unable to supply our customers with products or services which may affect business continuity. Any such incident or disruption in business continuity could have a material adverse effect on our business, results of operations and financial condition.

We may be adversely affected by natural disasters or other events that disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our manufacturing facility is located in Gainesville, Georgia, where natural disasters or similar events, like hurricanes, blizzards, tornadoes, fires, floods or explosions or large-scale accidents or power outages, could severely disrupt our operations and have a material adverse effect on our business, prospects, results of operations and financial condition. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our Gainesville facility, damaged critical infrastructure, such as manufacturing resource planning and enterprise quality systems, or otherwise disrupted operations at that location, it may be difficult or, in certain cases, impossible for us to continue our development, formulation and manufacturing business for a substantial period of time.

Currently, we maintain insurance coverage against damage to our property and equipment, and to cover business interruption expenses, in an amount we believe is sufficient for our development, formulation and manufacturing operations. However, there can be no assurance that such insurance will continue to be available on acceptable terms or that such insurance will provide adequate protection against actual losses. Even if we maintain adequate insurance coverage, claims could have a material adverse effect on our financial condition, liquidity and results of operations and on our ability to obtain suitable, adequate or cost-effective insurance in the future.

We must comply with environmental and health and safety laws and regulations, which can be expensive and restrict how we do business.

In connection with our CDMO division, we are subject to federal, state and local laws, rules, regulations and policies concerning the environment and the health and safety of our employees. Although we believe that we have complied with the applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

In addition, our business conducted by our CDMO division involves the use, generation and disposal of hazardous materials, including chemicals, solvents, agents and biohazardous materials. As a result, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that our safety procedures for storing, handling and disposing of such materials comply with the standards prescribed by those regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. We currently contract with third parties to dispose of these substances that we generate, and we rely on these third parties to properly dispose of these substances in compliance with applicable laws and regulations. If these third parties do not properly dispose of these substances in compliance with applicable laws and regulations, we may be subject to legal action by governmental agencies or private parties for improper disposal of these substances. The costs of defending such actions and the potential liability resulting from such actions are often very large. In the event we are subject to such legal action or we otherwise fail to comply with applicable laws and regulations governing the use, generation and disposal of hazardous materials and chemicals, we could be held liable for any damages that result, and any such liability could exceed our resources.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

Risks Related to Our Business Operations and Industry

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

We are highly dependent on the principal members of our executive team and, in particular, the services of Gerri A. Henwood, our President and Chief Executive Officer, the loss of whose services would adversely impact the achievement of our objectives. We have 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 will need to continue to grow the size of our organization, and we may experience difficulties in managing this growth.

We have begun to grow the size of our managerial, operational, sales, marketing, financial and other resources as we prepare for the potential approval and commercialization of IV meloxicam and the ongoing development of our other product candidates. However, our management, personnel and systems currently in place may not be adequate to support this growth or assist us with the potential growth into a commercial stage pharmaceutical company. As we continue to expand, we may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Additional future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of any FDA-approved product candidates;
- overseeing our ongoing clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any additional sales and marketing personnel engaged in connection with the commercialization of any approved product, on terms that are favorable to us if at all;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and financial systems and procedures; and
- expanding our facilities.

As our operations expand, we will need to manage additional relationships with various collaboration partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

As part of our business strategy, we may pursue acquisitions of assets, including preclinical, clinical or commercial stage products or product candidates, businesses or strategic alliances and collaborations, to expand our existing technologies and operations. 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. On April 10, 2015, we completed the acquisition from Alkermes of certain assets, including the worldwide rights to injectable meloxicam and the development, formulation and manufacturing business that comprised our CDMO division, which we refer to as the Gainesville Transaction. While we have successfully integrated the assets that we purchased in the Gainesville Transaction into our infrastructure, we cannot assure that the experience would be the same for future acquisitions. We may not be able to find suitable strategic alliance or collaborators or identify other investment opportunities, and we may experience losses related to any such investments.

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

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

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

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

The use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. In addition, our CDMO division exposes us to potential toxic tort and other types of product liability claims that are inherent in the manufacture of pharmaceutical products. 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 current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for our product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts.

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

We incur increased costs and demands upon our management as a result of complying with the laws and regulations affecting public companies, which could harm our operating results.

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

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

The 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. Such 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.

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. As of December 31, 2017, 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 patent and patent applications (specifically directed to the prevention of flake like substances) which expire in 2030. As of December 31, 2017, we own or license a total of five issued U.S. patents and 4 U.S. pending patent applications, and 50 issued foreign patents (including European validation countries) and 5 pending foreign applications related to meloxicam. As of December 31, 2017, we own six issued U.S. patents relating to Zohydro-ER®, two of which expire on November 1, 2019, and four of which expire on September 12, 2034. We also own Canadian patent applications that are pending relating to the same technology, which we license to our commercial partner, Paladin Labs Inc., in Canada. As of December 31, 2017, we are the owner of record of one issued U.S. patent and ten issued foreign patents to Dex. As of December 31, 2017, we are also the owner of record and are prosecuting one U.S. non-provisional patent application and 34 foreign patent applications related to certain product pipeline candidates. In addition, we have recently 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 in 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 composition of matter patents for Dex are licensed from Orion. The composition of matter patent for Dex expired in January 2014. If no additional patent protection is obtained, patent expirations will impact our ability to prevent third parties from marketing generic equivalents.

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. On September 16, 2011, the Leahy Smith America Invents Act, or the Leahy Smith Act, was signed into law. The Leahy Smith Act includes a number of significant changes to United States patent law. 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, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy Smith Act will have on the operation of our business. However, the Leahy Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patent, all of which could have a material adverse effect on our business and financial condition.

We do not own worldwide rights to all of our product candidates or the exclusive rights to all formulations.

We own worldwide rights to injectable meloxicam. We have an exclusive license from Orion for the development and, subsequent to approval, the commercialization of Dex-IN for use in the treatment of pain in humans the licensed dosage forms, but specifically excluding delivery vehicles for administration by injection or infusion, in the Territory. Orion retains the rights to develop and commercialize Dex for all uses and indications other than pain in humans and for use in combination products in that field, and we have granted Orion a license to use our clinical trial data, patents and know-how for such purpose; provided, however that Orion cannot undertake development activities in the United States, Australia or South Africa with respect to treatment of pain in humans in any licensed dosage form until four years after our first product is granted regulatory approval in the United States. It is possible, therefore, that Orion may develop and commercialize competing products in the territories retained by it and/or combination products for Dex in the Territory. We are unaware of any such programs at Orion at this time. We have a right of first refusal to commercialize any such product developed by Orion in the Territory. However, there is no guarantee that we would have the resources to exercise this right or, if we did, that we would be able to reach mutually agreeable terms with Orion.

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 ANDA application (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.

We and our commercial partners have been involved in Paragraph IV litigation in the United States involving some of our patents in respect of Zohydro ER®. These litigations have been, and any other Paragraph IV litigation may be, expensive, distracting to management and protracted. Although we and our commercial partners have successfully settled our Paragraph IV litigation, any future Paragraph IV litigation could result in new or additional generic competition to Zohydro ER®. The introduction of a generic version of Zohydro ER® could cause a reduction in revenue for our manufacturing business, which could have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, we were previously involved in an interference in front of the United States Patent and Trademark Office with another party, which involved a patent application relating to Zohydro ER®, for which we ultimately were successful on appeal. However, any future interference claims could arise, and if successful, result in the issuance of a patent that could limit our freedom to operate in respect to Zohydro ER®, which could also cause a reduction in revenue for our manufacturing business and have a material adverse effect on our business, prospects, results of operations and financial condition.

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 upon 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.

Our ability to manufacture products for our commercial partners may be impaired if any of our manufacturing activities, or the activities of third parties involved in our manufacture and supply chain, are found to infringe patents of others.

Our ability to continue to manufacture Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR and Zohydro ER® for our commercial partners, to utilize third parties to supply raw materials or other products, or to perform fill/finish services or other steps in our manufacture and supply chain, depends on our and their ability to operate without infringing the patents and other intellectual property rights of others. Other parties may allege that our manufacturing activities, or the activities of third parties involved in our manufacturing and supply chain, infringe patents or other intellectual property rights. A judicial decision in favor of one or more parties making such allegations could preclude the manufacture of the products to which those intellectual property rights apply, which could materially harm our business, operating results and financial condition.

<u>Risks Relating to Our Securities</u>

If securities or industry analysts do not continue to publish research or reports, or if they publish unfavorable research or reports, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. We currently have limited research coverage by securities and industry analysts. If additional securities or industry analysts do not commence coverage of our company, the trading price for our stock could be negatively impacted. In the event we obtain securities or industry analyst coverage, if one or more of the analysts who covers us downgrades our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline.

We have never paid dividends on our common stock and do not intend to do so for the foreseeable future.

We have never paid dividends on our common stock and we do not anticipate that we will pay any dividends on our common stock for the foreseeable future. Accordingly, any return on an investment in our common stock will be realized, if at all, only when shareholders sell their shares. In addition, our failure to pay dividends may make our stock less attractive to investors, adversely impacting trading volume and price.

The concentration of our capital stock ownership with our directors and their affiliated entities and our executive officers will limit shareholders' abilities to influence certain corporate matters.

Our directors and their affiliated entities, and our executive officers, beneficially own, in the aggregate, approximately 17% of our outstanding common stock as of December 31, 2017. As a result, these shareholders are collectively able to influence matters requiring approval of our shareholders, including the election of directors and approval of significant corporate transactions, such as mergers, consolidations or the sale of all or substantially all of our assets. Such influence may delay, prevent or deter a change in control of our company, even when such a change may be in the best interests of some shareholders, impede a merger, consolidation, takeover or other business combination involving us, or could deprive our shareholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might adversely affect the prevailing market price of our common stock.

The market price and trading volume of our common stock has been and may continue to be volatile, which could result in rapid and substantial losses for our shareholders.

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

- regulatory approval of IV meloxicam or our other product candidates;
- FDA, state or international regulatory actions, including actions on regulatory applications for any of our product candidates;
- legislative or regulatory changes;
- judicial pronouncements interpreting laws and regulations;
- changes in government programs;
- announcements of new products, services or technologies, commercial relationships, acquisitions or other events by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- fluctuations in stock market prices and trading volumes of similar companies;
- changes in accounting principles;
- litigation or public concern about the safety of our product candidates or similar product candidates;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders; and
- actions by institutional shareholders.

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

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

We are an "emerging growth company," as defined in the JOBS Act. We will remain an emerging growth company until the earliest of (1) the beginning of the first fiscal year following the fifth anniversary of our initial public offering, or January 1, 2020, (2) the beginning of the first fiscal year after our annual gross revenue is $1.07 billion or more, (3) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt securities and (4) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded $700 million as of the end of the second quarter of that fiscal year.

For as long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, Section 102(b)(1) of the JOBS Act also 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 of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to "opt out" of such extended transition period and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 102(b)(1) of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We cannot predict if investors will find our common stock less attractive because we may rely on some of these exemptions. 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. Our reduced disclosure may make it more difficult for investors and securities analysts to evaluate us and may result in less investor confidence.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of shares by these shareholders could have a material adverse effect on the trading price of our common stock.

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.

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 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;
- 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, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our shareholders. Under Pennsylvania law, a corporation may not, in general, engage in a business combination with any holder of 20% or more of its capital stock unless the holder has held the stock for five years or, among other things, the board of directors has approved the transaction. Any provision of our articles of incorporation or bylaws or Pennsylvania law that has the effect of delaying or deterring a change in control could limit the opportunity for our shareholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices, primarily used by our Acute Care Segment 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. The Acute Care Segment also leases a 4,145 square foot office space in Dublin, Ireland pursuant to a three-year lease. We currently own and our CDMO segment operates a 97,000 square foot, DEA-licensed facility in Gainesville, Georgia.

Item 3. Legal Proceedings

As part of the Gainesville Transaction, we acquired the rights to Zohydro ER®, which we license to our commercial partner Pernix, in the United States, and which is subject to ongoing intellectual property litigation and proceedings.

Zohydro ER® has been subject to four paragraph IV certifications with Actavis plc, or Actavis, one of which was filed in 2014 regarding the filing of Abbreviated NDAs, or ANDAs, with the FDA for a generic version of Zohydro ER®, one of which was filed in April 2015 regarding the filing of a supplemental ANDA, or sANDA, and another two of which were filed in November 2015 and October 2016 regarding one of our recently issued patents relating to a formulation of Zohydro ER®. These certification notices allege that the three U.S. patents listed in the FDA's Orange Book for Zohydro ER®, with an expiration date in November 2019 or September 2034, will not be infringed by Actavis' proposed products, are invalid and/or are unenforceable. In 2014, Daravita Limited (a subsidiary of Alkermes and our predecessor in interest) filed suit against Actavis in the U.S. District Court for the District of Delaware based on the ANDAs, and, in 2015, we filed suit against Actavis in the U.S. District Court for the District of Delaware based on the sANDA. In February 2017, the District Court in the Actavis case ruled in our favor and enjoined Actavis from selling the proposed generic version of Zohydro ER®. Actavis has appealed this decision to the U.S. Court of Appeals for the Federal Circuit. In October 2017, we filed suit against Actavis in the U.S. District Court for the District of Delaware based upon another recently issued patent relating to a formulation of Zohydro ER®. Under our license agreement with Pernix, we have the right to control the enforcement of our patents and related proceedings involving Zohydro ER® and any prospective generic entrant, and Pernix has the obligation to reimburse us for all reasonable costs of such actions. The litigations with Actavis settled in January 2018 via a multi-party settlement agreement with Pernix and Actavis, in which Actavis was granted a license to begin selling a generic version of Zohydro® ER on March 1, 2029, or earlier under certain circumstances.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock is traded on the NASDAQ Capital Market under the symbol "REPH." The following table sets forth the high and low sales price of our common stock, as reported by the NASDAQ Capital Market for the periods indicated:

	High	Low
Year Ended December 31, 2017		
Fourth Quarter	$10.59	$8.19
Third Quarter	$9.21	$6.68
Second Quarter	$8.94	$5.81
First Quarter	$8.88	$6.80
Year Ended December 31, 2016		
Fourth Quarter	$10.17	$5.89
Third Quarter	$12.50	$7.51
Second Quarter	$8.78	$5.95
First Quarter	$9.20	$5.59

Holders of Common Stock

As of March 1, 2018, there were 8 holders of record of our common stock. We believe that the number of beneficial owners of our common stock at that date was substantially greater.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and our ability to pay cash dividends is currently prohibited by the terms of our credit facility with Athyrium. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, anticipated cash needs and plans for expansion.

Issuer Repurchases of Equity Securities

None.

Securities Authorized for Issuance Under Equity Compensation Plans

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

Recent Sales of Unregistered Securities

Other than the issuance of warrants to Athyrium, as disclosed on our Form 8-K filed with the SEC on November 20, 2017, there were no unregistered sales of equity securities during the period.

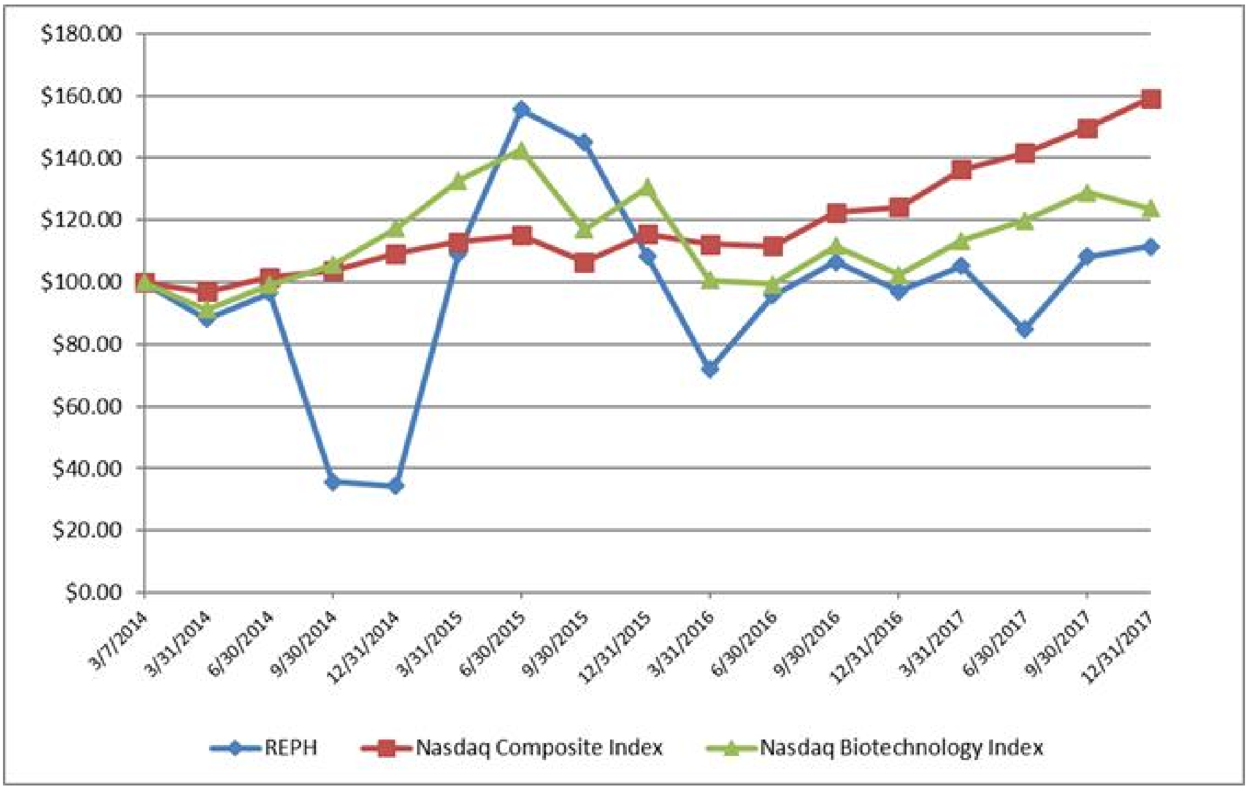
Use of Proceeds

None.

Performance Graph

This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act.

The following graph illustrates a comparison of the total cumulative stockholder return for our common stock since March 7, 2014, which is the first trading day for our stock, to two indices: the NASDAQ Composite Index and the NASDAQ Biotechnology Index. The graph assumes an initial investment of $100 on March 7, 2014, in our common stock, the stocks comprising the NASDAQ Composite Index, and the stocks comprising the NASDAQ Biotechnology Index. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.



Item 6. Selected Financial Data

The following tables present our selected financial data for the periods indicated. The consolidated statements of operations data for the years ended December 31, 2017, 2016 and 2015 and the selected consolidated balance sheet data as of December 31, 2017 and 2016 have been derived from our audited financial statements included elsewhere in this Annual Report on Form 10-K. The consolidated statements of operations data for the years ended December 31, 2014 and 2013 and the consolidated balance sheet data as of December 31, 2015, 2014 and 2013 have been derived from audited financial statements not included in this Annual Report on Form 10-K. Our historical results are not necessarily indicative of the results that may be expected in the future. The selected financial data below should be read in conjunction with the information contained in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” the consolidated financial statements and notes thereto, and other financial information included elsewhere in this Annual Report on Form 10-K.

	Year ended December 31,				
	2017	2016	2015	2014	2013
	(in thousands, except share and per share data)				
Consolidated Statements of Operations Data:					
Revenue	$ 71,834	$ 69,337	$ 51,952	$ —	$ —
Operating expenses:					
Cost of sales (excluding amortization of intangible assets)	38,193	37,152	28,054	—	—
Research and development	33,095	33,278	12,281	7,874	544
General and administrative	25,426	12,742	13,017	3,998	546
Amortization of intangible assets	2,583	2,583	1,884	—	—
Change in warrant valuation	9	(373)	(1,560)	—	—
Change in contingent consideration valuation	12,839	9,728	5,246	—	—
Total operating expenses	112,145	95,110	58,922	11,872	1,090
Operating loss	(40,311)	(25,773)	(6,970)	(11,872)	(1,090)
Other income (expense):					
Interest income	385	49	12	11	—
Interest expense	(12,034)	(5,588)	(5,560)	(4,273)	(868)
Loss before income taxes	(51,960)	(31,312)	(12,518)	(16,134)	(1,958)
Income tax benefit	1,880	1,107	15,551	—	—
Net income (loss)	(50,080)	(30,205)	3,033	(16,134)	(1,958)
Accretion of redeemable convertible preferred stock and deemed dividend	—	—	—	(1,270)	(440)
Net income (loss) applicable to common shareholders	$ (50,080)	$ (30,205)	$ 3,033	$ (17,404)	$ (2,398)
Basic net income (loss) per common share	$ (2.63)	$ (2.82)	$ 0.36	$ (2.79)	$ (15.41)
Diluted net income (loss) per common share	$ (2.63)	$ (2.82)	$ 0.21	$ (2.79)	$ (15.41)
Weighted average basic common shares outstanding	19,070,983	10,721,928	8,491,025	6,238,581	155,600
Weighted average diluted common shares outstanding	19,070,983	10,721,928	8,749,234	6,238,581	155,600

	As of December 31,				
	2017	2016	2015	2014	2013
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 64,482	$ 64,483	$ 19,779	$ 19,682	$ 13
Working capital	37,379	68,497	29,189	18,928	(12,080)
Total assets	186,226	182,997	138,697	20,374	851
Debt, net	53,598	24,388	29,760	—	—
Convertible notes payable	—	—	—	—	11,907
Total liabilities	157,378	111,384	98,347	1,446	12,931
Series A redeemable convertible preferred stock	—	—	—	—	5,880
Total shareholders’ equity (deficit)	28,848	71,613	40,350	18,928	(17,960)

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included in Part I, Item 1A of this Annual Report on Form 10-K.

Overview

We are a specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating CDMO division. Each of these divisions are deemed to be reportable segments for financial reporting purposes.

Our Acute Care segment is primarily focused on developing innovative products for commercialization in hospital and other acute care settings. Our lead product candidate, IV meloxicam, has successfully completed three Phase III clinical trials, two pivotal efficacy trials, 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. 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. The FDA has accepted the NDA for review and set a PDUFA date of May 26, 2018. Our Acute Care segment has no revenue and our costs consist primarily of expenses incurred in conducting our clinical trials and preclinical studies, manufacturing scale-up, regulatory activities, pre-commercialization of meloxicam and personnel costs.

Our CDMO segment leverages our formulation expertise to develop and manufacture pharmaceutical products using our proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. These collaborations result in revenue streams including royalties, profit sharing, research and development and manufacturing, which support continued operations for our CDMO segment and have contributed funds to be used in our research and development and pre-commercialization activities in our Acute Care segment. We operate a 97,000 square-foot, DEA-licensed manufacturing facility in Gainesville, Georgia, and we currently develop and/or manufacture the following key products with our commercial partners: Ritalin LA®, Focalin XR®, Verelan PM®, Verelan SR®, Verapamil PM, Verapamil SR and Zohydro ER®, as well as development stage products. Our CDMO segment's revenue streams are derived from manufacturing, royalty and profit sharing revenues, as well as our research and development of services performed for commercial partners.

We have incurred losses and generated negative cash flows from operations since inception, and expect to continue to incur significant and increasing operating losses for the foreseeable future. Substantially all of our operating losses resulted from costs incurred in connection with our development programs, including our non-clinical and formulation development activities, manufacturing, clinical trials and pre-commercialization activities. We have used revenue generated by our CDMO segment primarily to fund operations at our Gainesville, Georgia manufacturing facility, to make payments under our previous credit facility and to partially fund our development and pre-commercialization activities of our Acute Care segment. We believe our CDMO segment's revenue will continue to contribute cash for general corporate purposes that may, to some extent, reduce the amount of external capital needed to fund development and commercial operations. We expect to incur increasing expenses over the next several years to commercialize IV meloxicam, if approved, including continued pre-commercialization and commercialization activities for IV meloxicam, and to develop our other current and future product candidates.

On April 10, 2015, we completed the Gainesville Transaction, which transformed our business through the addition of a revenue-generating business and the increase in our workforce as a result of the addition of the employees at our Gainesville, Georgia manufacturing facility. The consideration paid consisted of $50.0 million cash, a $4.0 million working capital adjustment and a seven-year warrant to purchase 350,000 shares of our common stock at an exercise price of $19.46 per share. In addition, we may be required to pay up to an additional $125.0 million in milestone payments including $45 million upon regulatory approval of IV meloxicam, as well as net sales milestones and a royalty percentage of future product net sales related to IV meloxicam.

We funded the up-front payment of the Gainesville Transaction with borrowings under our previous credit facility with OrbiMed Royalties, II, LP, or OrbiMed, and cash on hand. Pursuant to the credit facility with OrbiMed, we issued OrbiMed a warrant to purchase an aggregate of 294,928 shares of our common stock at an exercise price of $3.28 per share, subject to certain adjustments.

In November 2017, we entered into our credit agreement with Athyrium, pursuant to which we drew upon an initial $60.0 million term loan and have the ability to draw upon two additional tranches of terms loans, each in the aggregate original principal amount of $20.0 million, subject to certain timing and milestone restrictions. We used the proceeds from the initial term loan to repay in full all outstanding indebtedness and transaction fees under the previous credit facility with OrbiMed. The interest rate under the credit agreement with Athyrium is equal to three-month LIBOR plus 9.75%, with a 1.0% LIBOR floor. Pursuant to the credit agreement with Athyrium, we issued Athyrium a warrant to purchase an aggregate of 348,664 shares of our common stock at an exercise price of $8.6043 per share, subject to certain adjustments.

Financial Overview

Revenues

During the twelve months ended December 31, 2017, 2016 and 2015 we recognized revenues in four categories: manufacturing revenue, royalty, profit sharing and research and development revenue. All revenue is generated from our CDMO segment.

Manufacturing revenue

We recognize manufacturing revenue from the sale of products we manufacture for our commercial partners. Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, shipment has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured.

***Royalty* revenue**

We recognize royalty revenue related to the sale of products by our commercial partners that incorporate our technologies. Royalties are earned under the terms of a license, development and/or supply agreement in the period the products are sold by a commercial partner and collectability is reasonably assured.

Profit sharing revenue

We recognize revenue from profit sharing related to the sale of certain of our manufactured products by our commercial partners. Profit sharing revenue is earned under the terms of a license, development and/or supply agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

Research and development revenue

Research and development revenue consists of funding that compensates us for formulation, and preparation of pre-clinical and clinical testing drug product materials prepared by our CDMO segment under research and development arrangements with commercial partners. We generally bill our commercial partners under research and development arrangements using a full-time equivalent or hourly rate, plus direct external costs, if any. To the extent that the agreements specify services are to be performed on a fixed basis, revenues are recognized consistent with the pattern of the work performed. In agreements which specify milestones, we recognize revenue from non-refundable milestone payments when the earnings process is complete and the payment is reasonably assured. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations would be deferred and recognized over the period of performance.

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 materials and manufacturing services;
- costs related to facilities, depreciation and other allocated expenses;
- acquired in process research and development;
- costs associated with non-clinical and regulatory activities;
- salaries and related costs for personnel in research and development and regulatory functions;

- costs associated with pre-commercialization activities for IV meloxicam, including manufacturing costs of pre-commercial inventory; and
- costs related to scale up and validation for IV meloxicam.

The majority of our external research and development costs relate 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 our product candidates is highly uncertain and subject to a number of risks, including, but not limited to:

- the costs, timing and outcome of regulatory review of a product candidate;
- the duration of clinical trials, which varies substantially according to the type, complexity and novelty of the product candidate;
- substantial requirements on the introduction of pharmaceutical products imposed by the FDA and comparable agencies in foreign countries, which require lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures;
- the possibility that data obtained from pre-clinical and clinical activities at any step in the testing process may be adverse and lead to discontinuation or redirection of development activity or may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval;
- risk involved with development of manufacturing processes, FDA pre-approval inspection practices and successful completion of manufacturing batches for clinical development and other regulatory purposes;
- the costs, timing and outcome of regulatory review of a product candidate;
- the emergence of competing technologies and products and other adverse market developments, which could impede our commercial efforts; and
- the other risks disclosed in the section titled “Risk Factors” of this Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

Development timelines, probability of success and development costs vary widely. As a result of the uncertainties discussed above, we anticipate that we will make determinations as to which additional programs to pursue and how much funding to direct to each program on an ongoing basis in response to the scientific and clinical data of each product candidate, as well as ongoing assessments of such product candidate’s commercial potential and available capital resources. Accordingly, we cannot currently estimate with any degree of certainty the amount of time or costs that we will be required to expend in the future on our product candidates to complete current or future clinical or pre-commercial stages prior to their regulatory approval, if such approval is ever granted. As a result of these uncertainties surrounding the timing and outcome of any approvals, we are currently unable to estimate precisely when, if ever, any of our other product candidates will generate revenues and cash flows.

We expect our research and development costs to primarily relate to injectable meloxicam for the foreseeable future as we advance this product candidate through the pre-commercialization scale-up, clinical and other pre-approval activities. We also expect to have expenses as we initiate clinical trials and related work for our other product candidates. We may elect to seek out 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. We expect our research and development costs to continue to increase as we continue clinical and pre-commercialization manufacturing activities for IV meloxicam, and engage in pipeline development activities.

In addition, research and development expenses consist of costs incurred by our CDMO segment for its product and formulation development activities, including regulatory support. We expense research and development costs as incurred. Advanced payments for goods and services that will be used in future research and development activities are initially recorded as prepaid expenses and expensed as the activity is performed or when the goods have been received.

General and Administrative Expenses

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

We expect our general and administrative expenses to continue to increase as we build our Acute Care commercialization team and engage in pre-commercialization IV meloxicam marketing, sales, market access and medical affairs activities. In addition, we will continue to incur costs relating to our operations as a public company, including increased headcount and increased salary, consulting, legal, patent and compliance, accounting, insurance and investor relations costs.

Amortization of Intangible Assets

We recognize amortization expense related to the intangible asset for our contract manufacturing relationships on a straight-line basis over an estimated useful life of six years. The intangible asset related to injectable meloxicam represents in process research and development, or IPR&D, which is considered an indefinite-lived intangible asset that is assessed for impairment annually or more frequently if impairment indicators exist.

Change in Fair Value of Contingent Consideration

In connection with the acquisition of injectable meloxicam in the Gainesville Transaction, we are required to pay up to an additional $125.0 million in milestone payments, including $45 million upon regulatory approval of IV meloxicam, 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 since reevaluated and as of December 31, 2017 recorded a $82.0 payment obligation, representing the estimated probability adjusted fair value, and we expect, at a minimum, the current portion of $32.0 million will further increase by approximately $15 million to $20 million as we approach the PDUFA date, and potential approval of IV meloxicam, which will trigger the $45 million milestone payment due to Alkermes. Each reporting period, we revalue this estimated obligation with changes in fair value recognized as a non-cash operating expense or income.

Change in Fair Value of Warrants

We have classified as liabilities certain warrants outstanding which contain a contingent net cash settlement feature, upon a change in control. The fair value of these warrants are remeasured through settlement or expiration with changes in fair value recognized as a period charge within the Consolidated Statements of Operations and Comprehensive Income (Loss).

Interest Expense, net

Interest expense, net for the twelve months ended December 31, 2017 was a result of interest expense incurred on our OrbiMed and Athyrium senior secured term loans and the amortization of the related financing costs and one-time charges for fees related to early extinguishment of the OrbiMed debt and the non-cash write-off of OrbiMed deferred financing costs. Interest expense for the twelve months ended December 31, 2016 and 2015 was a result of interest expense incurred on our OrbiMed senior secured term loan and the amortization of the related financing costs.

Net Operating Losses and Tax Carryforwards

As of December 31, 2017, we had approximately $9.0 million of federal net operating loss carryforwards. We also had federal and state research and development tax credit carryforwards of $3.4 million available to offset future taxable income. U.S. tax laws limit the time during which these carryforwards may be utilized against future taxes. These federal and state net operating loss and federal and state tax credit carryforwards will begin to expire at various dates beginning in 2028, if not utilized. Based on our projected future taxable income we expect to be able to utilize all federal and state net operating losses. We have also generated foreign net operating loss carryforwards in Ireland. We currently do not believe it is more likely than not we will use any of these net operating losses and as a result have recorded a full valuation allowance against the deferred tax asset related to the losses.

Under the Tax Reform Act of 1986, or the Act, the utilization of a corporation's net operating loss and research and development tax credit carryforwards is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. We determined that we have experienced ownership changes, as defined by the Act, during the 2008, 2014 and 2016 tax years as a result of past financings; accordingly, our ability to utilize the aforementioned carryforwards will be limited. Although the carryforwards will be limited, we have determined that none of the net operating losses will expire prior to being utilized as a result of the changes. In addition, state net operating loss carryforwards may be further limited, including in Pennsylvania, which has a limitation of 30%, 35% or 40% of taxable income after modifications and apportionment on state net operating losses utilized in any one year during tax years beginning during 2017, 2018 or 2019 going forward respectively. In addition, since we will need to raise substantial additional funding to finance our operations, we may undergo further ownership changes in the future, including changes to our organizational structure relating to foreign operations, purchases, sales and licenses, which could further limit our ability to use net operating loss carryforwards. As a result, if we generate taxable income, our ability to use some of our net operating loss carryforwards to offset U.S. federal and state taxable income may be subject to limitations, which could result in increased future tax liabilities to us.

As discussed in Note 18 to the Financial Statements, in December 2017, the federal government enacted numerous amendments to the Internal Revenue Code of 1986 pursuant to the Tax Act. The Tax Act will impact our income tax expense/(benefit) from operations 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.
- Our results for the fourth quarter of 2017 included a one-time net expense of $7.9 million, as a result of remeasuring our deferred tax balances to the new statutory rate.
- We 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.

Results of Operations

Comparison of the Twelve Months Ended December 31, 2017 and 2016

	Year ended December 31,	
	2017	2016
	(amounts in thousands)	
Revenue	$ 71,834	$ 69,337
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	38,193	37,152
Research and development	33,095	33,278
General and administrative	25,426	12,742
Amortization of intangible assets	2,583	2,583
Change in warrant valuation	9	(373)
Change in contingent consideration valuation	12,839	9,728
Total operating expenses	112,145	95,110
Operating loss	(40,311)	(25,773)
Other income (expense):		
Interest expense, net	(11,649)	(5,539)
Loss before income taxes	(51,960)	(31,312)
Income tax benefit	1,880	1,107
Net loss	$ (50,080)	$ (30,205)

Revenue and costs of sales. Our revenues were $71.8 million and $69.3 million and cost of sales were $38.2 million and $37.2 million for the twelve months ended December 31, 2017 and 2016, respectively. Excluding the $2.3 million, one-time, contractually based manufacturing revenue amount from one of our commercial partners in the twelve months ended December 31, 2016, the $4.8 million increase in 2017 revenue versus 2016 was primarily due to higher profit share revenue as a result of stronger sales volumes and pricing of Verapamil as well as increased manufacturing revenue. These increases were partially offset by decreased royalty revenue due to a change in the mix of generic and brand sales by another of our commercial partners. Costs of sales were $38.2 million and $37.2 million for the twelve months ended December 31, 2017 and 2016, respectively. The increase in cost of sales of $1.0 million was primarily due to changes in the product mix.

Research and Development. Our research and development expenses were $33.1 million and $33.3 million for the twelve months ended December 31, 2017 and 2016, respectively. The decrease of $0.2 million in 2017 was primarily due to lower IV meloxicam clinical trial expenses offset by increases in pre-commercialization IV meloxicam product validation, manufacturing and support costs, NDA filing fees and development costs for our other pipeline products.

General and Administrative. Our general and administrative expenses were $25.4 million and $12.7 million for the twelve months ended December 31, 2017 and 2016, respectively. The increase of $12.7 million was primarily due to building of the commercial team and its related infrastructure, and pre-commercial activities for IV meloxicam.

Amortization of Intangible Assets. Amortization expense was $2.6 million for the twelve months ended December 31, 2017 and 2016 which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its estimated useful life.

Interest Expense, net. Interest expense, net was $11.6 million and $5.5 million during the twelve months ended December 31, 2017 and 2016, respectively. The increase in interest expense, net, was due to the refinancing of our prior credit agreement with OrbiMed in 2017 which resulted in a one-time charge totaling approximately $6.8 million for fees related to early extinguishment of debt and the non-cash write-off of related deferred financing costs. Additionally, the higher principal balance on our Athyrium senior secured term loan and amortization of the related financing costs contributed to an increase in interest expense, net.

Income Tax Benefit. Income tax benefit was $1.9 million and $1.1 million for the twelve months ended December 31, 2017 and 2016, respectively. The increase in income tax benefit was primarily due to the increase in net loss before income. As a result of the Tax Cuts and Jobs Act of 2017, included within income tax benefit for the year ended December 31, 2017 was a non-cash adjustment of $7.9 million for the remeasurement of the net deferred tax items using the recently enacted 21% statutory tax rate. We believe that it is more likely than not that the deferred income tax assets associated with our foreign operations will not be realized, and as such, there is a full valuation allowance against our foreign deferred tax assets.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO segment's revenues were $71.8 million and $69.3 million and cost of sales were $38.2 million and $37.2 million for the twelve months ended December 31, 2017 and 2016, respectively. Excluding the $2.3 million, one-time, contractually based manufacturing revenue amount from one of our commercial partners in the twelve months ended December 31, 2016, the $4.8 million increase in revenue versus prior year was primarily due to increased profit share revenue as a result of increased sales volumes and pricing by one of our commercial partners as well as increased manufacturing revenue. These increases were partially offset by decreased royalty revenue due to a change in the mix of generic and brand sales by one of our commercial partners. Costs of sales were $38.2 million and $37.2 million, respectively. The increase in cost of sales of $1.0 million was primarily due to changes in the product mix.

Our CDMO segment's operating expenses (including cost of sales) increased by $1.9 million, from $46.1 million in the twelve months ended December 31, 2016 to $48.0 million in the twelve months ended December 31, 2017. Research and development expenses increased by $1.3 million due to expanded investment in our formulation and development capabilities and general and administration expenses decreased by $0.1 million. All of the above contributed to our CDMO segment's operating income of $25.4 million for the twelve months ended December 31, 2017, which included non-cash charges of $7.4 million for depreciation and amortization and $1.0 million for stock-based compensation.

Acute Care Segment-

Our Acute Care segment's operating expenses increased $12.2 million from $40.7 million in the twelve months ended December 31, 2016 to $52.9 million in the twelve months ended December 31, 2017. Research and development expenses increased $0.1 million as a result of increased IV meloxicam pre-commercialization manufacturing costs, NDA filing fees and increased headcount, which was partially offset by a decrease in our IV meloxicam clinical trial expenses. General and administrative costs increased by $12.1 million as a result of increased headcount and increased pre-commercialization marketing expenses. The non-cash charge for contingent consideration increased by $3.1 million. All of the above contributed to our Acute Care segment's operating loss of $65.7 million for the twelve months ended December 31, 2017, which also included non-cash charges of $4.6 million for stock-based compensation, depreciation and amortization.

Comparison of the Years Ended December 31, 2016 and 2015

	Year ended December 31,	
	2016	**2015**
	(amounts in thousands)	
Revenue	$ 69,337	$ 51,952
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	37,152	28,054
Research and development	33,278	12,281
General and administrative	12,742	13,017
Amortization of intangible assets	2,583	1,884
Change in warrant valuation	(373)	(1,560)
Change in contingent consideration valuation	9,728	5,246
Total operating expenses	95,110	58,922
Operating loss	(25,773)	(6,970)
Other income (expense):		
Interest expense, net	(5,539)	(5,548)
Loss before income taxes	(31,312)	(12,518)
Income tax benefit	1,107	15,551
Net loss	$ (30,205)	$ 3,033

Revenue and costs of sales. Our revenues were $69.3 million and $52.0 million and cost of sales were $37.2 million and $28.1 million for the twelve months ended December 31, 2016 and 2015, respectively. The increase of $17.3 million in revenue and $9.1 million in cost of sales was primarily the result of including a full year of operation of our CDMO segment in the twelve months ended December 31, 2016, compared to the inclusion of approximately nine months of operations for the twelve months ended December 31, 2015 (following the closing of the Gainesville Transaction early in the second quarter of 2015). In the twelve months ended December 31, 2016 revenues also included $2.3 million related to a one-time contractually based manufacturing revenue payment from one of our commercial partners and approximately $1.1 million in higher profit-share revenue from another commercial partner's new customer base.

Research and Development. Our research and development expenses were $33.3 million and $12.3 million for the twelve months ended December 31, 2016 and 2015, respectively, an increase of $21.0 million from December 31, 2015, primarily due to an increase of $19.5 million in our IV meloxicam clinical expenses and $2.5 million in increased salaries and benefits expense due to increased headcount partially offset by a decrease in pre-commercial manufacturing costs and other pipeline clinical expenses.

General and Administrative. Our general and administrative expenses were $12.7 million and $13.0 million for the twelve months ended December 31, 2016 and 2015, respectively, a decrease of $0.3 million from December 31, 2015 primarily due to lower professional fees (due to expenses incurred in the 2015 Gainesville Transaction), partially offset by higher headcount and pre-commercialization expenses in 2016.

Amortization of Intangible Assets. Amortization expense was $2.6 million and $1.9 million for the twelve months ended December 31, 2016 and 2015, respectively, which was exclusively related to the amortization of our royalties and contract manufacturing relationships intangible asset over its six year estimated useful life. The amortization recorded during the twelve months ended December 31,2015 represents a partial year.

Interest Expense, net. Interest expense, net was $5.5 million during the twelve months ended December 31, 2016 and 2015, as a result of interest expense incurred on our OrbiMed senior secured term loan and amortization of the related financing costs. Though the principal amount of the debt was paid down significantly in the twelve months ended December 31, 2016, interest expense in the twelve months ended December 31, 2016 was equal to the interest expense for the twelve months ended December 31, 2015 as the interest for the twelve months ended December 31, 2015 was over a nine month period as compared to a full year for the twelve months ended December 31, 2016. The interest rate under the credit agreement with OrbiMed is equal to LIBOR plus 14.0%, with a 1.0% LIBOR floor.

Income Tax Expense. Income tax benefit was $1.1 million for the twelve months ended December 31, 2016 due to income tax related to our US operations offset by our federal research and development credits. There was a full valuation allowance against our foreign deferred tax assets for the twelve months ended December 31, 2016. As there was a full valuation allowance against our net deferred tax assets as of December 31, 2015, there was no income tax expense recorded for the twelve months ended December 31, 2015.

Operating Income (Loss) per Segment.

CDMO Segment-

Our CDMO segment's revenues were $69.3 million and $52.0 million and cost of sales were $37.2 million and $28.1 million for the twelve months ended December 31, 2016 and 2015, respectively. The increase of $17.3 million in revenue and $9.1 million in cost of sales was primarily the result of including a full year of operation of our CDMO segment in the twelve months ended December 31, 2016, compared to the inclusion of approximately nine months of operations for the twelve months ended December 31, 2015 (following the closing of the Gainesville Transaction early in the second quarter of 2015). In the twelve months ended December 31, 2016 revenues also included $2.3 million related to a one-time contractually based manufacturing revenue payment from one of our commercial partners and approximately $1.1 million in higher profit-share revenue from another commercial partner's new customer base.

Our CDMO segment's operating expenses (including cost of sales) increased by $9.8 million, from $36.2 million in 2015 to $46.0 million in 2016. Research and development expenses increased by $1.9 million due to 2016 representing a full year of operation of our CDMO segment, which was only included for approximately nine months of 2015 due to the closing of the Gainesville Transaction early in the second quarter of 2015 and due to increases in formulation expenses and rent allocation expenses in 2016. General and administration expenses decreased by $1.0 million due to a decrease in patent costs, and partially offset by an increase in stock-based compensation and business development expenses. Amortization of intangibles increased by $0.7 million.

All of the above contributed to our CDMO segment's operating income of $24.2 million for 2016, which included non-cash charges of $5.0 million for depreciation and amortization and $ 0.8 million for stock-based compensation.

Acute Care Segment-

Our Acute Care segment's operating expenses increased $25.5 million from $24.5 million in 2015 to $50.0 million in 2016. Research and development expenses increased $19.1 million as a result of the costs of two Phase III clinical studies and a safety study conducted in 2016 and increased salaries and benefits due to additional headcount. General and administrative costs increased by $0.7 million as a result of increased salaries and benefits due to headcount, and increased pre-commercialization expenses. The warrant valuation decreased $0.4 million and contingent consideration increased by $9.7 million.

All of the above contributed to our Acute Care segment's operating loss of $50.0 million for 2016 which included non-cash charges of $0.04 million for depreciation and amortization and $3.1 million for stock-based compensation.

Liquidity and Capital Resources

As of December 31, 2017, we had $64.5 million in cash and cash equivalents and short-term investments.

Since inception through December 31, 2017, we have financed our product development, operations and capital expenditures primarily from sales of equity and debt securities, including sales of our common stock with net proceeds of $116.4 million, and term loans made under our previous and existing credit facilities, including our current $100 million credit facility with Athyrium. Revenues from our CDMO segment are used primarily to fund operations at our Gainesville, Georgia manufacturing facility, to make payments under our credit facility and to partially fund the development and pre-commercialization activities of our Acute Care segment. During the twelve months ended December 31, 2017, our capital expenditures were $6.2 million.

We will need to raise substantial additional funds in order to fund the payments which may become due, including milestone payments owed to Alkermes or other licensing partners, to continue our clinical trials of our product candidates, to commercialize any approved product candidates or technologies and to enhance our sales and marketing efforts for additional products we may acquire. Insufficient funds may cause us to delay, reduce the scope of or eliminate one or more of our development, commercialization or expansion activities. Our future capital needs and the adequacy of our available funds will depend on many factors, including the cost of clinical studies and other actions needed to obtain regulatory approval of our products in development, the timing of approval of IV meloxicam, the level of market acceptance of IV meloxicam and the costs of commercialization activities for IV meloxicam, if approved, the continued profitability of our CDMO segment, and our ability to access additional tranches under our credit agreement with Athyrium. We may raise such additional funds through debt refinancing, bank or other loans, through strategic research and development, licensing, including out-licensing activities, 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.

On March 7, 2015, in connection with the Gainesville Transaction, we, through a wholly owned subsidiary, entered into a credit agreement with OrbiMed. Pursuant to the credit agreement, OrbiMed provided us with a term loan in the original principal amount of

$50.0 million on April 10, 2015, which amount was used to fund the Gainesville Transaction . On November 17, 2017, we entered into our credit agreement with Athyrium, pursuant to which we drew upon an initial $60.0 million term loan and have the ability to draw upon two additional tranches of terms loans, each in the aggregate original principal amount of $20.0 million. Pursuant to the terms of the credit agreement, we may draw upon the second $20.0 million tranche on or before December 31, 2018, provided that we receive regulatory approval for IV meloxicam and retain at least $20.0 million in unrestricted cash following payment of the $45.0 million milestone payment to Alkermes. We may draw upon the final $20.0 million tranche on or prior to March 31, 2020, provided that we have drawn on the second tranche and have achieved net sales for IV Meloxicam of $20.0 million in the most recent trailing twelve month period. We used the proceeds from the initial term loan to (i) repay in full all outstanding indebtedness under our credit facility with OrbiMed of approximately $31.7 million, which included the remaining debt principal balance of $27.3 million and early termination charges of $4.4 million and (ii) pay transaction fees associated with the credit facility with Athyrium of approximately $4.2 million. As of December 31, 2017, we had $60.0 million outstanding principal under our credit agreement with Athyrium.

Sources and Uses of Cash

Cash (used in)/provided by operations was ($17.0) million, ($3.2) million and $8.5 million for the twelve months ended December 31, 2017, 2016 and 2015, respectively, which represents our operating losses less our stock-based compensation, depreciation, non-cash interest expense, loss on early extinguishment of debt, acquired IPR&D, changes in fair value of warrants and contingent consideration and amortization of intangibles, as well as changes in operating assets and liabilities.

Cash used in investing activities was $10.3 million, $3.8 million and $55.1 million for the twelve months ended December 31, 2017 and 2016 and 2015, respectively, and reflected cash used for the purchase of short-term investments offset by maturities/redemption of investments in 2017 and for the purchase of property and equipment in 2017 and 2016. Our short-term investments are classified as available for sales securities with maturities of less than one year. Cash used in investing activities for 2015 includes the Gainesville Transaction investment of $52.7 million.

There was $23.9 million of cash provided by financing activities in the twelve months ended December 31, 2017 from proceeds from issuance of long-term debt from Athyrium of $60 million offset by repayment of long term debt for the payoff of the OrbiMed debt of $27.3 million, fees related to early extinguishment of debt paid to OrbiMed of $4.4 million and deferred financing costs from the Athyrium transaction of $4.2 million. Cash provided by financing activities was $51.7 million for the twelve months ended December 31, 2016, primarily as a result of the sale of common stock raising net proceeds of $58.1 million, $7.8 million in proceeds from the sale of shares of common stock through our common stock purchase agreement with Aspire Capital, offset by excess cash flow payments of $6.3 million made related to the OrbiMed credit agreement. Cash provided by financing activities was $46.7 million for the twelve months ended December 31, 2015, primarily as a result of the credit agreement with OrbiMed for $50.0 million, net of the payment of $1.7 million of issuance costs incurred in conjunction with the agreement, the closing on $14.8 million of net proceeds from a private placement of our common stock offset by a principal payment of $16.3 million made on the OrbiMed credit agreement.

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

- the timing and outcome of the FDA's review of an NDA for IV meloxicam;
- the timing and outcome of our Phase IIIb clinical trials for IV meloxicam in colorectal surgery patients and orthopedic surgery patients;
- the extent to which the FDA may require us to perform additional preclinical studies, clinical trials or pre-commercial manufacturing of injectable meloxicam or our other product candidates;
- the timing of the Gainesville Transaction regulatory milestone payments and other contingent consideration;
- the costs of our commercialization activities, if our product candidates are approved by the FDA;
- the cost of manufacturing scale-up, acquiring drug product and other capital equipment for our product candidates;
- the level of market acceptance of IV meloxicam, if approved;
- the scope, progress, results and costs of development for our other product candidates;
- the cost, timing and outcome of regulatory review of our other product candidates;
- the extent to which we in-license, acquire or invest in products, businesses and technologies;
- the timing and extent of our manufacturing and capital expenditures related to our CDMO division;
- our ability to maintain our relationships and contracts with our commercial partners;

- our ability to comply with stringent U.S. & foreign government regulation in the manufacture of pharmaceutical products, including cGMP and U.S. DEA requirements;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for product candidates;
- our ability to access additional tranches of term loans under our credit agreement with Athyrium;
- our ability to raise additional funds through equity or debt financings;
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims; and
- the effect of any changes in our effective tax rate due to changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws.

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

Contractual Commitments

The table below reflects our contractual commitments as of December 31, 2017:

	Payments Due by Period (in 000s)				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Long-Term Debt Obligations (1):					
Athyrium Debt	$ 60,600	$ —	$ —	$ 60,600	$ —
Interest on Debt	$ 34,408	7,091	14,106	13,210	—
Purchase Obligations (2):	$ 25,298	22,598	1,300	—	—
Operating Leases (3)	$ 2,213	568	910	735	—
Other Long-Term Liabilities:					
Other License Commitments and Milestone payments (4), (5)	$ 56,155	15	65	130	395
Alkermes Payments (6)	$ 125,000	—	—	—	—
Employment Agreements (7)	$ 858	858	—	—	—
Other Non-Current Liabilities (8)	$ 109	—	82	—	—
Total Contractual Obligations	$ 304,641	$ 31,130	$ 16,463	$ 74,675	$ 395

(1) The long-term debt obligations consist of principal, an exit fee of 1% of the principal, and interest on the initial $60.0 million of our $100 million credit facility with Athyrium as of December 31, 2017. The debt bears interest at a rate of LIBOR plus 9.75% per annum. Due to fluctuations of the future LIBOR interest rate, it has been set at the rate as at December 28, 2017 to calculate the obligation. In accordance with U.S. GAAP, the future interest obligations are not recorded on our Consolidated Balance Sheet. See Note 12 to the Consolidated Financial Statements included in this Form 10-K.

(2) These obligations consist of cancelable and non-cancelable purchase commitments related to inventory, capital expenditures and other goods or services. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 13 to the Consolidated Financial Statements included in this Form 10-K.

(3) We have become party to certain operating leases, for the leased space in Malvern, Pennsylvania, Gainesville, Georgia and Dublin, Ireland, as well as for office equipment, for which the minimum lease payments are presented.

(4) We are party to exclusive licenses with Orion for the development and commercialization of certain pipeline product candidates, under which we may be required to make certain milestone and royalty payments to Orion. See Note 5 and Note 13(a) to the Consolidated Financials Statements included in the Form 10-K. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets.

(5) We license the NMBs from Cornell University pursuant to a license agreement under which we are obligated to make annual license maintenance fee payments, milestone payments and patent cost payments and to pay royalties on net sales of the NMBs. The amount reflects only payment obligations that are fixed and determinable. We are unable to reliably estimate the timing of certain of these payments because they are dependent on the type and complexity of the clinical studies and intended uses of the products, which have not been established. In accordance with U.S. GAAP, certain of these obligations are not recorded on our Consolidated Balance Sheets. See Note 5 and 13(a) to the Consolidated Financial Statements included in this Form 10-K.

(6) 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 are recorded as contingent consideration on our Consolidated Balance Sheets. See Note 4 and Note 13(b) to the Consolidated Financial Statements included in this Form 10-K.

(7) We have entered into employment agreements with certain of our named executive officers. As of December 31, 2017, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than this amount, from that date through calendar year 2018. In accordance with U.S. GAAP, these obligations are not recorded on our Consolidated Balance Sheets. See Note 13 (f) to the Consolidated Financial Statements included in this Form 10-K.

(8) This value represents the deferred rent and non-current portion of payments due to Cornell University for past patent costs associated with the license agreement for the NMBs. In accordance with U.S. GAAP, these liabilities are recorded on our Consolidated Balance Sheets. See Note 5 and 13(a) to the Consolidated Financial Statements included in this Form 10-K.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Estimates

This management's discussion and analysis of our financial condition and results of operations is based on our consolidated 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, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, revenue recognition, 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 two-step goodwill impairment test consists of the following steps. The first step compares a reporting unit's fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit's goodwill impairment loss, if any. Step two requires an assignment of the reporting unit's fair value to the reporting unit's assets and liabilities to determine the implied fair value of the reporting unit's goodwill. The implied fair value of the reporting unit's goodwill is then compared with the carrying amount of the reporting unit's goodwill to determine the goodwill impairment loss to be recognized, if any. 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 amortizing intangible assets for recoverability whenever events occur or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. The impairment test is a two-step test. Under step one we assess the recoverability of an asset (or asset group). The carrying amount of an asset (or asset group) is not recoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset (or asset group). The impairment loss is measured in step two as the difference between the carrying value of the asset (or asset group) and its fair value. Assumptions and estimates used in the evaluation of impairment are subjective and changes in these assumptions may negatively impact projected undiscounted cash flows, which could result in impairment charges in future periods. 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.

Revenue Recognition—We generate revenues from development, formulation, manufacturing, and related services for multiple pharmaceutical companies. The agreements we have with our commercial partners provide for manufacturing revenues, royalties and/or profit sharing components, and research and development revenue.

Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, shipment has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured.

In addition to manufacturing revenue, our customer agreements have royalties and/or profit sharing payments, computed on the net product sales of the applicable commercial partner. Royalties are earned under the terms of a license and supply agreement in the period the products are sold by a commercial partner and collectability is reasonably assured. Profit sharing revenue is earned under the terms of a license and supply agreement in the period the products are sold and expenses are incurred by our commercial partner and collectability is reasonably assured.

Research and development revenue consists of funding that compensates us for formulation, pre-clinical and clinical testing performed by our CDMO segment under research and development arrangements with commercial partners. We generally bill our commercial partners under research and development arrangements using a full-time equivalent, or FTE, or hourly rate, plus direct external costs, if any. In agreements which specify milestones, we recognize revenue from non-refundable milestone payments when the earnings process is complete and the payment is reasonably assured. Non-refundable milestone payments related to arrangements under which we have continuing performance obligations would be deferred and recognized over the period of performance.

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

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

We continue to maintain a valuation allowance against certain other deferred tax assets where realizability is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowances to the extent we believe a portion will not be realized. This determination depends on a variety of factors, some of which are subjective, including our current year taxable income in the United States, expectations of future taxable income, impact of tax reform, achievement of milestones, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. If we determine that the deferred tax assets are not realizable in a future period, we would record material changes to income tax expense in that period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations. At December 31, 2017, we had approximately $42.5 million invested in money market instruments and government and agency bonds. We believe our policy of investing in highly-rated securities, whose liquidities are, at December 31, 2017, all less than one year, minimizes such risks. Due to the short-term duration of our investment portfolio and the low-risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio. We do not enter into investments for trading or speculative purposes. Our Athyrium secured term loan interest expense is based on the current committed rate of three-month LIBOR plus 9.75% with a 1.0% LIBOR floor. A fluctuation in LIBOR of 0.25% would result in a charge of $0.2 million of interest expense.

We have license agreements with Orion for certain product pipeline candidates which require the payment of milestones upon the achievement of certain regulatory and commercialization events and royalties on product sales, which are required to be made in Euros. As of December 31, 2017, no milestones or royalties were due under these agreements, and we do not anticipate incurring milestone or royalty costs under these agreements until we advance our development of certain product pipeline candidates. We do not believe foreign currency exchange rate risk is a material risk at this time; however, these agreements could, in the future, give rise to foreign currency transaction gains or losses. As a result, our results of operations and financial position could be exposed to changing currency exchange rates. In the future, we may periodically use forward contracts to hedge certain transactions or to neutralize exposures.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of December 31, 2017. We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, and not absolute, assurance that the objectives of the control system will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. However, our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of December 31, 2017, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Annual Report on Internal Control Over Financial Reporting

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

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

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

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control – Integrated Framework (2013). These criteria are in the areas of control environment, risk assessment, control activities, information and communication, and monitoring. Management's assessment included extensive documentation, evaluating and testing the design and operating effectiveness of its internal controls over financial reporting.

Based on the Management's processes and assessment, as described above, management has concluded that, as of December 31, 2017, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

On March 2, 2018, we entered into the Purchase Agreement with Aspire Capital, pursuant to which we have the right to sell to Aspire Capital from time to time in our sole discretion up to $20.0 million in shares of our common stock over the next 30 months, subject to certain limitations and conditions set forth in the Purchase Agreement. In consideration for entering into the Purchase Agreement, we have agreed to issue to Aspire Capital 33,040 shares of our common stock, or the Commitment Shares, on March 2, 2018.

Concurrently with entering into the Purchase Agreement, we also entered into a registration rights agreement, or the Registration Rights Agreement, with Aspire Capital, pursuant to which we agreed to file with the SEC a prospectus supplement to our effective shelf registration statement on Form S-3 (File No. 333-218487), registering all of the shares of common stock that may be offered to Aspire Capital from time to time, including the Commitment Shares.

Under the Purchase Agreement, on any trading day we select, following the filing of the prospectus supplement and the satisfaction of other closing conditions, we have the right, in our sole discretion, to present Aspire Capital with a purchase notice, or a Purchase Notice, directing Aspire Capital (as principal) to purchase up to 75,000 shares of common stock per trading day, up to an aggregate of $20.0 million of common stock, at a per share price, or the Purchase Price, equal to the lesser of:

- the lowest sale price of the common stock on the purchase date; or
- the arithmetic average of the three lowest closing sale prices for our common stock during the 10 consecutive trading days ending on the trading day immediately preceding the purchase date.

The aggregate purchase price payable by Aspire Capital on any one purchase date may not exceed $500,000, unless otherwise mutually agreed, and upon mutual agreement we may issue up to 2,000,000 shares of common stock under a purchase notice.

In addition, on any date on which we submit a purchase notice to Aspire Capital, we also have the right, in our sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice, or a VWAP Purchase Notice, directing Aspire Capital to purchase an amount of common stock equal to up to 30% of the aggregate shares of common stock traded on our principal market on the next trading day, or the VWAP Purchase Date, as we determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the common stock traded on our principal market on the VWAP Purchase Date.

We may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

The Purchase Agreement provides that we and Aspire Capital will not effect any sales under the Purchase Agreement on any purchase date where the closing sale price of our common stock is less than $0.50. There are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of sales of common stock to Aspire Capital.

The Purchase Agreement provides that the number of shares that may be sold pursuant to the Purchase Agreement will be limited to 3,829,455, or the Exchange Cap, which represents 19.99% of the our outstanding shares of common stock as of March 2, 2018, unless stockholder approval or an exception pursuant to the rules of the NASDAQ Capital Market is obtained to issue more than 19.99%. This limitation will not apply if, at any time the Exchange Cap is reached and at all times thereafter, the average price paid for all shares issued under the Purchase Agreement is equal to or greater than $9.99, which was the consolidated closing bid price of our common stock on March 1, 2018. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the NASDAQ Capital Market.

The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost to us. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the our common stock during any time prior to the termination of the Purchase Agreement. Aspire Capital has no right to require any sales by us, but is obligated to make purchases from us as directed by us in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement.

Any proceeds we receive under the Purchase Agreement are expected to be used for or preparatory commercial and phase IIIb program activities for IV meloxicam, pipeline development activities, and general corporate purposes.

The foregoing descriptions of the Purchase Agreement and the Registration Rights Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the Purchase Agreement and the Registration Rights Agreement, which are attached hereto as Exhibits 10.38 and 4.8, respectively, and incorporated by reference herein.

Pepper Hamilton LLP, counsel to the Company, has issued an opinion to the Company, dated March 2, 2018, regarding the validity of the shares of common stock to be issued and sold pursuant to the Purchase Agreement. A copy of the opinion is filed as Exhibit 5.1 to this Annual Report on Form 10-K.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information with respect to this item will be set forth in the Proxy Statement for the 2018 Annual Meeting of Shareholders or “the Proxy Statement” under the headings Board Directors,” “Executive Officers,” “Section 16(a) Beneficial Ownership Reporting Compliance,” and “ Corporate Governance and Risk Management” and is incorporated herein by reference. The Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report.

Item 11. Executive Compensation

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

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

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options and other rights		Weighted-average exercise price of outstanding options and other rights(1)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))	
Equity compensation plans approved by security holders	3,024,156	(2)	$ 6.89	1,282,550	
Equity compensation plans not approved by security holders	841,312	(3)	$ 8.15	—	(4)
Total	3,865,468		$ 7.17	1,282,550	

(1) Represents the weighted-average exercise price of outstanding stock options and does not include restricted stock units.

(2) Consists of outstanding (i) options to purchase 2,795,563 shares of common stock and (ii) restricted stock units covering an aggregate of 270,593 shares of common stock. Shares in settlement of vested restricted stock units are deliverable within 30 days of the vesting date.

(3) Reflects grants of stock options and restricted stock units that were “inducement grants” as defined under NASDAQ Listing Rule 5635(c)(4). The terms and conditions of each inducement grant are subject to the terms and conditions of the Form of Award Agreement filed in the Company’s registration statement on Form S-8 with the SEC on December 23, 2015.

(4) Our board of directors has not established any specific number of shares that could be issued without shareholder approval. Inducement grants to new key employees are determined on a case-by-case basis. Other than possible inducement grants, we expect that all equity awards will be made under shareholder-approved plans.

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

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

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

Item 14. Principal Accounting Fees and Services

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

PART IV

Item 15. Exhibits, Consolidated Financial Statement Schedules

(a)(1) Consolidated Financial Statements.

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

Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2017 and 2016

Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2017, 2016 and 2015

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2017, 2016 and 2015

Consolidated Statements of Cash Flows for the years ended December 31, 2017, 2016 and 2015

(a)(2) Consolidated Financial Statement Schedules.

Not applicable.

(a)(3) Exhibits:

A list of exhibits to this Annual Report on Form 10-K is set forth on the Exhibit Index immediately preceding such exhibits and is incorporated herein by reference.

(b) Exhibits

See Exhibit Index.

(c) Not applicable

Item 16. Form 10-K Summary

None.

RECRO PHARMA, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the shareholders and board of directors
Recro Pharma, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Recro Pharma, Inc. and subsidiaries (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive income (loss), shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2017, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ KPMG LLP

We have served as the Company's auditor since 2009.

Philadelphia, Pennsylvania
March 2, 2018

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 60,984	$ 64,483
Short-term investments	3,498	—
Accounts receivable	9,686	10,411
Inventory	9,839	8,746
Prepaid expenses and other current assets	3,276	1,118
Total current assets	87,283	84,758
Property, plant and equipment, net	39,074	37,300
Deferred income taxes	18,573	17,060
Intangible assets, net	34,850	37,433
Goodwill	6,446	6,446
Total assets	$ 186,226	$ 182,997
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 7,954	$ 4,132
Accrued expenses and other current liabilities	9,897	9,893
Current portion of contingent consideration	32,053	—
Current portion of long-term debt, net	—	2,236
Total current liabilities	49,904	16,261
Long-term debt, net	53,598	22,152
Warrants and other long-term liabilities	3,516	3,397
Long-term portion of contingent consideration	50,360	69,574
Total liabilities	157,378	111,384
Commitments and contingencies (Note 13)		
Shareholders' equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding	—	—
Common stock, $0.01 par value. Authorized, 50,000,000 shares; issued and outstanding, 19,127,435 shares at December 31, 2017 and 19,043,216 shares at December 31, 2016	191	190
Additional paid-in capital	140,006	132,691
Accumulated deficit	(111,348)	(61,268)
Accumulated other comprehensive loss	(1)	—
Total shareholders' equity	28,848	71,613
Total liabilities and shareholders' equity	$ 186,226	$ 182,997

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Income (Loss)

	For the Year ended December 31,		
(amounts in thousands, except share and per share data)	**2017**	**2016**	**2015**
Revenue	$ 71,834	$ 69,337	$ 51,952
Operating expenses:			
Cost of sales (excluding amortization of intangible assets)	38,193	37,152	28,054
Research and development	33,095	33,278	12,281
General and administrative	25,426	12,742	13,017
Amortization of intangible assets	2,583	2,583	1,884
Change in warrant valuation	9	(373)	(1,560)
Change in contingent consideration valuation	12,839	9,728	5,246
Total operating expenses	112,145	95,110	58,922
Operating loss	(40,311)	(25,773)	(6,970)
Other income (expense):			
Interest income	385	49	12
Interest expense	(12,034)	(5,588)	(5,560)
Net loss before income taxes	(51,960)	(31,312)	(12,518)
Income tax benefit	1,880	1,107	15,551
Net income (loss)	$ (50,080)	$ (30,205)	$ 3,033
Per share information:			
Net loss per share of common stock, basic	$ (2.63)	$ (2.82)	$ 0.36
Net loss per share of common stock, diluted	$ (2.63)	$ (2.82)	$ 0.21
Weighted average common shares outstanding, basic	19,070,983	10,721,928	8,491,025
Weighted average common shares outstanding, diluted	19,070,983	10,721,928	8,749,234
Net Income (Loss)	$ (50,080)	$ (30,205)	$ 3,033
Other comprehensive loss:			
Unrealized gain (loss) on available-for-sale securities	(1)	—	—
Comprehensive income (loss)	$ (50,081)	$ (30,205)	$ 3,033

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Shareholders' Equity

For the Years Ended December 31, 2017, 2016 and 2015

(amounts in thousands, except share data)	Common Stock Shares	Common Stock Amount	Additional paid-in capital	Accumulated Deficit	Accumulated other comprehensive loss	Total
Balance, December 31, 2014	7,707,600	$ 77	$ 52,947	$ (34,096)	$ —	$ 18,928
Shares issued in equity financing facility	96,463	1	284	—	—	285
Stock option exercise	38,000	—	228	—	—	228
Stock-based compensation expense	—	—	3,064	—	—	3,064
Sales of common stock in, net of offering costs	1,379,311	14	14,798	—	—	14,812
Cashless warrant exercise	2,941	—	—	—	—	—
Net income	—	—	—	3,033	—	3,033
Balance, December 31, 2015	9,224,315	92	71,321	(31,063)	—	40,350
Sale of common stock under Aspire equity facility, net of transaction costs	1,143,940	11	7,364	—	—	7,375
Sales of common stock in public offerings, net of offering costs	8,656,666	87	50,168	—	—	50,255
Issuance of restricted stock units, net of shares withheld for income taxes	18,295	—	(51)	—	—	(51)
Stock-based compensation expense	—	—	3,889	—	—	3,889
Net loss	—	—	—	(30,205)	—	(30,205)
Balance, December 31, 2016	19,043,216	190	132,691	(61,268)	—	71,613
Stock-based compensation expense	—	—	5,546	—	—	5,546
Stock option exercise	7,756	—	53	—	—	53
Issuance of restricted stock units, net of shares withheld for income taxes	76,463	1	(250)	—	—	(249)
Warrants issued in financing facility, net of related tax effect	—	—	1,966	—	—	1,966
Other comprehensive loss	—	—	—	—	(1)	(1)
Net loss	—	—		(50,080)	—	(50,080)
Balance, December 31, 2017	19,127,435	$ 191	$ 140,006	$ (111,348)	$ (1)	$ 28,848

See accompanying notes to consolidated financial statements.

RECRO PHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(amounts in thousands)	For the Year ended December 31, 2017	2016	2015
Cash flows from operating activities:			
Net loss	$ (50,080)	$ (30,205)	$ 3,033
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	5,546	3,889	3,064
Non-cash interest expense	912	1,071	668
Depreciation expense	4,864	4,993	4,120
Loss on early extinguishment of debt	6,772	—	—
Amortization	2,583	2,583	1,884
Acquired in-process research and development charges	766	—	—
Change in warrant valuation	9	(373)	(1,560)
Change in contingent consideration valuation	12,839	9,728	5,246
Deferred income taxes	(1,690)	(1,423)	(15,637)
Changes in operating assets and liabilities, net of effect of acquisition:			
Inventory	(1,093)	237	1,271
Prepaid expenses and other current assets	(2,158)	(325)	225
Accounts receivable	725	(1,831)	3,992
Accounts payable, accrued expenses and other liabilities	2,963	8,454	2,152
Net cash provided by/(used) in operating activities	(17,042)	(3,202)	8,458
Cash flows from investing activities:			
Acquisition of Gainesville, net of cash acquired	—	—	(52,690)
Purchase of property and equipment	(6,172)	(3,770)	(2,411)
Purchase of short-term investments	(57,124)	—	—
Proceeds from maturity of investments	53,500	—	—
Acquisition of license agreement	(519)	—	—
Net cash used in investing activities	(10,315)	(3,770)	(55,101)
Cash flows from financing activities:			
Proceeds from issuance of long-term debt	60,000	—	50,000
Payments on long-term debt	(27,347)	(6,324)	(16,329)
Fees related to early extinguishment of debt	(4,420)	—	—
Payment of deferred financing costs	(4,178)	—	(1,718)
Proceeds from sale of common stock, net of transaction costs	—	58,051	14,812
Payments of withholdings on shares withheld for income taxes	(250)	(51)	—
Payment of deferred equity costs	—	—	(253)
Proceeds from option exercise	53	—	228
Net cash provided by financing activities	23,858	51,676	46,740
Net (decrease) increase in cash and cash equivalents	(3,499)	44,704	97
Cash and cash equivalents, beginning of year	64,483	19,779	19,682
Cash and cash equivalents, end of year	$ 60,984	$ 64,483	$ 19,779
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 5,341	$ 4,517	$ 4,892
Cash paid for taxes	$ 467	$ —	$ —
Purchase of property, plant and equipment included in accrued expenses and accounts payable	$ 1,274	$ 808	$ 208
Common stock issued in connection with equity facility	$ —	$ —	$ 285
Amortization of deferred equity costs	$ —	$ 421	$ —
Fair value recognized for warrants	$ 2,143	$ —	$ —
Withholdings on shares withheld for income taxes included in accrued expenses	$ 233	$ —	$ —
Retirement of fully depreciated property, plant and equipment	$ 161	$ —	$ —

See accompanying notes to consolidated financial statements.

(1) Background

Recro Pharma, Inc., or the Company, was incorporated in Pennsylvania on November 15, 2007. The Company is a specialty pharmaceutical company that operates through two business divisions: an Acute Care division and a revenue-generating contract development and manufacturing, or CDMO division. Each of these divisions are deemed to be reportable segments (see Note 3(m) and Note 17). The Acute Care division is primarily focused on developing innovative products for hospital and other acute care settings, and the CDMO division leverages the Company's formulation expertise to develop and manufacture pharmaceutical products using the Company's proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. On April 10, 2015, the Company acquired from Alkermes plc, or Alkermes, worldwide rights to intravenous and intramuscular, or injectable, meloxicam, a proprietary long-acting preferential COX-2 inhibitor being developed for the management of moderate to severe pain, as well as a contract manufacturing facility, royalty and formulation business in Gainesville, Georgia. The acquisition is referred to herein as the Gainesville Transaction. In July 2017, the Company submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or the FDA, for its lead investigational product candidate intravenous, or IV, meloxicam 30 mg for the management of moderate to severe pain. The FDA has accepted the NDA for review and has set a Prescription Drug User Fee Act, or PDUFA, date of May 26, 2018.

(2) Development-Stage Risks and Liquidity

The Company has incurred losses from operations since inception and has an accumulated deficit of $111,348 as of December 31, 2017. Though its CDMO segment has been profitable, the Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates, including the payment of the Gainesville Transaction contingent payments, which may become due upon achievement of certain development and commercialization milestones for meloxicam (see Note 4). Insufficient funds may cause the Company to delay, reduce the scope of or eliminate one or more of its development, commercialization or expansion activities. The Company may raise such funds through debt refinancing, 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 the 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's future operations are highly dependent on a combination of factors, including (i) the continued profitability of the CDMO segment; (ii) the timely and successful completion of additional financing and/or alternative sources of capital, debt, partnering or out-licensing transactions; (iii) the success of its research and development, including the results and timing of its clinical trials; (iv) the development of competitive therapies by other biotechnology and pharmaceutical companies; and, ultimately, (v) regulatory approval and market acceptance of the Company's proposed future products. Management believes that the Company's existing cash, cash equivalents and short-term investments as of December 31, 2017 and other expected financing sources will be sufficient to fund its operations over the next twelve months.

(3) Summary of Significant Accounting Principles

(a) Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements of the Company and its subsidiaries have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The Company's consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated.

In the opinion of management, the accompanying consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals, estimates and assumptions that impact the financial statements) considered necessary to present fairly the Company's financial position as of December 31, 2017and 2016 and its results of operations for the twelve months ended December 31, 2017, 2016 and 2015 and cash flows for the twelve months ended December 31, 2017, 2016 and 2015.

(b) Use of Estimates

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

(c) Cash and Cash Equivalents

Cash and cash equivalents represents cash in banks and highly liquid short-term investments that have maturities of three months or less when acquired to be cash equivalents. These highly liquid short-term investments are both readily convertible to known amounts of cash and so near their maturity that they present insignificant risk of changes in value because of the changes in interest rates.

(d) Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets, which are as follows: three to ten years for furniture and office equipment; six to ten years for manufacturing equipment; two to five years for vehicles; 35 to 40 years for buildings; and the shorter of the lease term or useful life for leasehold improvements. Repairs and maintenance cost are expensed as incurred.

(e) 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. 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 Consolidated Statements of Operations and Comprehensive Income (Loss) on the acquisition date

(f) Goodwill and Intangible Assets

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

The first step compares a reporting unit’s fair value to its carrying amount to identify potential goodwill impairment. If the carrying amount of a reporting unit exceeds the reporting unit’s fair value, the second step of the impairment test must be completed to measure the amount of the reporting unit’s goodwill impairment loss, if any. Step two requires an assignment of the reporting unit’s fair value to the reporting unit’s assets and liabilities to determine the implied fair value of the reporting unit’s goodwill. The implied fair value of the reporting unit’s goodwill is then compared with the carrying amount of the reporting unit’s goodwill to determine the goodwill impairment loss to be recognized, if any.

Intangible assets include the Company’s royalties and contract manufacturing relationships intangible asset as well as an IPR&D asset. The royalties and contract manufacturing relationships intangible asset is considered a definite-lived intangible asset and is amortized on a straight-line basis over a useful life of six years.

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

Consolidated Statements of Operations and Comprehensive Income (Loss). 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. 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. 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 assessed qualitative factors such as overall financial performance of its reporting units, anticipated changes in industry and market conditions, including recent tax reform, and competitive environments. As a result of the impairment tests, the Company determined that there was no impairment to goodwill or indefinite-lived intangible assets for the year ended December 31, 2017.

(g) Revenue Recognition

The Company generates revenues from research and development, manufacturing, packaging and related services for multiple pharmaceutical companies through its CDMO segment. The agreements that the Company has with its commercial partners provide for manufacturing revenues, royalties and/or profit sharing components.

Manufacturing and other related services revenue is recognized when persuasive evidence of an arrangement exists, shipment has occurred and the title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured.

In addition to manufacturing and packaging revenue, the customer agreements have royalties and/or profit sharing payments, computed on the net product sales of the commercial partner. Royalty and profit sharing revenues are generally recognized under the terms of the applicable license, development and/or supply agreement in the period the products are sold and when collectability is reasonably assured.

Revenues related to research and development are generally recognized as the related services or activities are performed, in accordance with the contract terms. To the extent that the agreements specify services are to be performed on a fixed basis, revenues are recognized consistent with the pattern of the work performed. In agreements which specify milestones, the Company recognizes revenue from non-refundable milestone payments when the earnings process is complete and the payment is reasonably assured. Non-refundable milestone payments related to arrangements under which the Company has continuing performance obligations would be deferred and recognized over the period of performance.

(h) Concentration of Credit Risk

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

The Company's accounts receivable balances are concentrated amongst approximately five customers and if any of these customers' receivable balances should be deemed uncollectible, it could have a material adverse effect on the Company's results of operations and financial condition.

The Company's CDMO division is dependent on its relationships with a small number of commercial partners, with its four largest customers having generated 98% of its revenues for the year ending December 31, 2017. A portion of the Company's revenues are dependent on U.S. based customers selling to end-users outside the U.S.

(i) Research and Development

Research and development costs for the Company's proprietary products/product candidates are charged to expense as incurred. Research and development expenses consist 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.

(j) Stock-Based Awards

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.

Non-employee stock-based awards are revalued until an award vests and the Company recognizes compensation expense on a straight-line basis over the vesting period of each separated vesting tranche of the award, which is known as the accelerated attribution method. The estimation of the number of stock awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, such amounts are recognized as an adjustment in the period in which estimates are revised.

(k) Income Taxes

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

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

(l) Net Income (Loss) Per Common Share

Basic net income (loss) per common share is determined by dividing net income (loss) applicable to common shareholders by the weighted average common shares outstanding during the period. For the years ending December 31, 2017 and 2016, the outstanding common stock options, warrants and unvested restricted stock units have been excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. As a result of the Company being in a net income position for the year ending December 31, 2015, there were 258,209 warrants that were included in the calculation of diluted net income per share because their effect was dilutive.

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

For purposes of calculating diluted income (loss) per common share, the denominator includes both the weighted average common shares outstanding and the number of common stock equivalents if the inclusion of such common stock equivalents would be dilutive.

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

	Year ended December 31,		
	2017	2016	2015
Basic Earnings Per Share			
Net income (loss)	$ (50,080)	$ (30,205)	$ 3,033
Weighted average common shares outstanding, basic	19,070,983	10,721,928	8,491,025
Net income (loss) per share of common stock, basic	$ (2.63)	$ (2.82)	$ 0.36
Diluted Earnings Per Share			
Net income (loss)	$ (50,080)	$ (30,205)	$ 3,033
Add change in warrant valuation	—	—	(1,174)
Diluted net income (loss)	$ (50,080)	$ (30,205)	$ 1,859
Weighted average common shares outstanding, diluted	19,070,983	10,721,928	8,491,025
Add shares from outstanding warrants	—	—	258,209
Weighted average common shares outstanding, diluted	19,070,983	10,721,928	8,749,234
Net income (loss) per share of common stock, diluted	$ (2.63)	$ (2.82)	$ 0.21

The following potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding as of December 31, 2017, 2016 and 2015 as they would be anti-dilutive:

	December 31,		
	2017	2016	2015
Options and restricted stock units outstanding	3,865,468	2,619,679	1,153,950
Warrants	1,133,592	784,928	490,000

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

(m) Segment Information

The Company determined its reportable segments based on its strategic business units, the commonalities among the products and services within each segment and the manner in which the Company reviews and evaluates operating performance. The Company has identified CDMO and Acute Care as reportable segments. Segment disclosures are included in Note 17. Segment operating profit (loss) is defined as segment revenue less segment operating expenses (segment operating expenses consist of general and administrative expenses, research and development expenses, and the change in valuation of contingent consideration and warrants). The following items are excluded from segment operating profit (loss): interest income and expense, and income tax benefit (expense). Segment assets are those assets and liabilities that are recorded and reported by segment operations. Segment operating capital employed represents segment assets less segment liabilities.

(n) Recent Accounting Pronouncements

In July 2017, the FASB issued Accounting Standards Update, or ASU, No. 2017-11 *“Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): Accounting for Certain Financial Instruments with Down Round Features,”* or ASU 2017-11. ASU 2017-11 simplifies the accounting for certain financial instruments with down round features, as equity-linked instruments or embedded equity-linked features will not be accounted for as a liability solely because there is a down-round feature. The amendments are effective for public companies for annual and interim periods beginning after December 15, 2018. The Company early adopted ASU 2017-11 for the year ending December 31, 2017 using the cumulative effect adjustment method. Recro's cumulative adjustment is $0 for the year ending December 31, 2017 as there was no impact to the two existing warrants outstanding as of the adoption date. Warrants issued after the adoption date are recorded using the guidance under ASU 2017-11.

In May 2017, the FASB issued ASU No. 2017-09, *Stock Compensation - Scope of Modification Accounting*. 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 is effective for fiscal years beginning after December 15, 2017. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

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 is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15 *"Classification of Certain Cash Receipts and Cash Payments,"* or ASU 2016-15. ASU 2016-15 provides guidance in the classification of certain cash receipts and payments in the statement of cash flows where diversity in practice exists. This new guidance is effective for annual periods beginning after December 15, 2017 using a retrospective transition method to each period presented, with early adoption permitted. The Company early adopted ASU 2016-15 for its quarter ending December 31, 2017. For the twelve months ended December 31, 2017, the Company recognized $31,767 as a cash outflow from financing activities on the Consolidated Statements of Cash Flows related to its prepayment of debt and debt extinguishment costs.

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. The new guidance is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the effect that this guidance may have on its consolidated financial statements.

In September 2015, the FASB issued ASU No. 2015-16, "*Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments,"* or ASU 2015-16. ASU 2015-16 addresses the accounting for and disclosure of measurement-period adjustments that occur in periods after a business combination is consummated. This update requires that the acquirer recognize measurement-period adjustments in the reporting period in which they are determined. Prior period information should not be revised. This update also requires an entity to present separately on the face of the income statement or disclose in the notes the amount recorded in the current-period income statement that would have been recorded in previous reporting periods if the adjustments had been recognized as of the acquisition date. The updated guidance is effective for annual and interim periods beginning after December 15, 2016. The Company adopted the guidance effective January 1, 2017. The guidance did not have a material impact to the consolidated financial statements upon adoption.

In July 2015, the FASB issued ASU No. 2015-11, "*Simplifying the Measurement of Inventory,"* or ASU 2015-11. ASU 2015-11 addresses changes in the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. The amendments in this guidance do not apply to inventory that is measured using last-in, first-out, or LIFO, or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out or average cost methods. Within the scope of this new guidance, an entity should measure inventory at the lower of cost and net realizable value; where net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The new guidance is effective for annual periods beginning after December 15, 2016, with early adoption permitted. The new guidance must be applied on a prospective basis. The Company adopted the guidance effective January 1, 2017. The guidance did not have a material impact to the consolidated financial statements upon adoption.

In May 2014, the FASB issued ASU No. 2014-09, *"Revenue from Contracts with Customers"* (ASU 2014-09). ASU 2014-09 represents a comprehensive new revenue recognition model that requires a company to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which a company expects to be entitled to receive in exchange for those goods or services. This ASU sets forth a new five-step revenue recognition model which replaces the prior revenue recognition guidance in its entirety and is intended to eliminate numerous industry-specific pieces of revenue recognition guidance that have historically existed. In August 2015, the FASB issued ASU No. 2015-14, "*Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date,"* which defers the effective date of ASU 2014-09 by one year, but permits companies to adopt one year earlier if they choose (i.e., the original effective date). As such, ASU 2014-09 will be effective for annual and interim reporting periods beginning after December 15, 2017. In March and April 2016, the FASB issued ASU No. 2016-08 *"Revenue from Contracts with Customers (Topic 606): Principal versus Agent Consideration (Reporting Revenue Gross versus Net)"* and ASU No. 2016-10 *"Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing,"* respectively, which clarifies the guidance on reporting revenue as a principal versus agent, identifying performance obligations and accounting for intellectual property licenses. In addition, in May 2016, the FASB issued ASU No. 2016-12 *"Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients,"* which amends certain narrow aspects of Topic 606, and in December 2016, the FASB issued ASU No. 2016-20 *"Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers,"* which amends certain narrow aspects of Topic 606 . The new standard permits two methods of adoption: the full retrospective method, which requires the standard to be applied to each prior period presented, or the modified retrospective method, which requires the cumulative effect of adoption to be recognized as an adjustment to opening retained earnings in the period of adoption. The Company will adopt the standard using the modified retrospective method. The Company is currently finalizing its analysis of the impact of ASU 2014-09 on its consolidated results of operations and financial position. The new standard will result in additional revenue-related disclosures in the footnotes to the consolidated financial statements. Adoption of this standard may require changes to business processes, systems and controls to support the additional required disclosures. The Company is in the process of implementing such changes.

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

Based on the analysis performed to date, we believe the new standard could require the acceleration of certain of our manufacturing revenue and/or royalty and profit share revenue and while we have not completed our analysis, we do not believe the net income impact will be material. We will be finalizing our assessment in advance of the filing of our first quarter 2018 Form 10-Q.

(4) Acquisition of Gainesville Facility and Meloxicam

On April 10, 2015, the Company completed the Gainesville Transaction. The consideration paid in connection with the Gainesville Transaction consisted of $50.0 million cash at closing, a $4.0 million working capital adjustment and a seven-year warrant to purchase 350,000 shares of the Company's common stock at an exercise price of $19.46 per share. In addition, the Company may be required to pay up to an additional $125.0 million in milestone payments including $45.0 million 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 following was the purchase price allocation for the Gainesville Transaction:

Purchase price agreement	$	50,000
Fair value of warrants		2,470
Fair value of contingent consideration		54,600
Working capital adjustment		4,010
	$	111,080

The contingent consideration consists of three separate components. The first component will be payable upon regulatory approval. The second 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 third 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.

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

The fair value of the first contingent consideration component recognized on the acquisition date was estimated by applying a risk-adjusted discount rate to the probability-adjusted contingent payments and the expected approval dates. The fair value of the second contingent consideration component recognized on the acquisition date was 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 third contingent consideration component recognized on the acquisition date was 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.

The results of operations of the acquired business, which has become the CDMO division, have been included in the consolidated statement of operations and comprehensive loss beginning April 10, 2015.

The IPR&D asset and customer relationships were valued using the multi-period excess earnings method, which is an income approach in which excess earnings are the earnings remaining after deducting the market rates of return on the estimated values of contributory assets, including debt-free net working capital, tangible and intangible assets. The excess earnings are thereby calculated for each quarter of a multi-quarter projection period discounted to a present value utilizing an appropriate discount rate for the subject asset.

The unaudited pro forma combined results of operations for the year ended December 31, 2015 (assuming the closing of the Gainesville Transaction had occurred on January 1, 2015) are as follows:

	For the year ended December 31, 2015
Revenue	$ 71,684
Net income	6,016

(5) NMB Related License Agreement

In June 2017, the Company acquired the exclusive global rights to two novel neuromuscular blocking agents, or NMBs, and a proprietary chemical reversal agent from Cornell University, or Cornell. The NMBs and reversal agent are referred to herein as the NMB Related Compounds. The NMB Related Compounds include one novel intermediate-acting NMB that has initiated Phase I clinical trials and two other agents, a novel short-acting NMB, and a rapid-acting reversal agent proprietary to these NMB Related Compounds.

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, of which $247 is reported as a component of Accrued expenses and other current liabilities and Other non-current liabilities on the Consolidated Balance Sheet as of December 31, 2017.

In addition, the Company is obligated to make: (i) an annual license maintenance fee payment until the first commercial sale of the NMB Related Compounds; and (ii) milestone payments upon the achievement of certain milestones, up to a maximum, for each NMB, of $5 million for U.S. regulatory approval and commercialization milestones and $3 million for European regulatory approval and commercialization milestones. The Company is also obligated to pay Cornell royalties on net sales of the NMB Related Compounds at a rate ranging from low to mid-single digits, depending on the applicable NMB Related Compounds and whether there is a valid patent claim in the applicable country, subject to an annual minimum royalty amount. Further, the Company will reimburse Cornell ongoing patent costs related to prosecution and maintenance of the patents related to the Cornell patents for the NMB Related Compounds.

The Company accounted for the transaction as an asset acquisition based on an evaluation of the accounting guidance (ASC Topic 805) and considered the early clinical stage of the novel and unproven NMB 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 NMB 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 Consolidated Statements of Operations and Comprehensive Income (Loss) on the acquisition date. The acquired IPR&D charge is expected to be deductible over a 15-year period for income tax purposes.

(6) Fair Value of Financial Instruments

The Company follows the provisions of FASB ASC Topic 820, "Fair Value Measurements and Disclosures," for fair value measurement recognition and disclosure purposes for its financial assets and financial liabilities that are remeasured and reported at fair value each reporting period. The Company measures certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents, short-term investments, warrants and the contingent consideration. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of financial assets and financial liabilities and their placement within the fair value hierarchy. Categorization is based on a three-tier valuation hierarchy, which prioritizes the inputs used in measuring fair value, as follows:

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

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

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

	Fair value measurements at reporting date using		
	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
At December 31, 2016:			
Assets:			
Money market mutual funds (See Note 7)	$ 37,079	$ —	$ —
U.S. Treasury obligations (See Note 7)	20,517	—	—
Cash equivalents	$ 57,596	$ —	$ —
Liabilities:			
Warrants (See Note 14(d))	—	—	$ 3,397
Contingent consideration (See Note 4)	—	—	69,574
	$ —	$ —	$ 72,971
At December 31, 2017:			
Assets:			
Cash equivalents			
Money market mutual funds (See Note 7)	$ 38,959	$ —	$ —
Total cash equivalents	$ 38,959	$ —	$ —
Short-term investments			
U.S. Treasury obligations (See Note 7)	$ 3,498	$ —	$ —
Total financial assets	$ 42,457	$ —	$ —
Liabilities:			
Warrants (See Note 14(d))	—	—	$ 3,406
Contingent consideration (See Note 4)	—	—	82,413
	$ —	$ —	$ 85,819

The Company developed its own assumptions to determine the value of the warrants that do not have observable inputs or available market data to support the fair value. This method of valuation involves using inputs such as the fair value of the Company's common stock, stock price volatility, the contractual term of the warrants, risk free interest rates and dividend yield. Due to the nature of these inputs, the valuation of the warrants is considered a Level 3 measurement.

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

	Warrants	Contingent Consideration
Balance at December 31, 2015	$ 3,770	$ 59,846
Additions	—	—
Remeasurement	(373)	9,728
Balance at December 31, 2016	$ 3,397	$ 69,574
Additions	—	—
Remeasurement	9	12,839
Total at December 31, 2017	$ 3,406	$ 82,413
Current portion as of December 31, 2017	—	32,053
Long-term portion as of December 31, 2017	3,406	50,360

The current portion of the contingent consideration represents the estimated probability adjusted fair value that is expected to become payable within one year as of December 31, 2017 (see Note 4 for additional information).

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

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, 2017, the financial assets and liabilities recorded on the Consolidated Balance Sheets that are not measured at fair value on a recurring basis include accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term nature of these instruments. The fair value of long-term debt, where a quoted market price is not available, is evaluated based on, among other factors, interest rates currently available to the Company for debt with similar terms, remaining payments and considerations of the Company's creditworthiness. The Company determined that the recorded book value of long-term debt approximated fair value at December 31, 2017 due to the comparison of the terms of the debt, including borrowing rates available to the Company through its recent completed debt refinancing process, availability of additional term loan tranches, and maturity.

(7) Short-term Investments

Short-term investments as of December 31, 2017 consist of government money market funds and U.S. Treasury obligations. In accordance with FASB ASC Topic 320, "Investments – Debt and Equity Securities," or ASC 320, the Company has classified its entire investment portfolio as available-for-sale securities with secondary or resale markets, and, as such, its portfolio is reported at fair value with unrealized gains and losses included in Comprehensive Income in stockholders' equity and realized gains and losses included in other income. The following is a summary of available-for-sale securities as of December 31, 2017.

	December 31, 2017			
	Amortized	Gross Unrealized		Estimated
Description	Cost	Gain	Loss	Fair Value
Money market mutual funds	$ 38,959	$ —	$ —	$ 38,959
U.S. Treasury obligations	3,499	—	(1)	3,498
Total investments	$ 42,458	$ —	$ (1)	$ 42,457

As of December 31, 2017, the Company's investments had maturities ranging from one to two months. As of December 31, 2016, all of the Company's investments in US. Treasury obligations had original maturities of less than three months. There were no unrealized gains or losses as of December 31, 2016 and 2015. The fair value of the Company's U.S. Treasury obligations is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads, benchmark securities, and other observable inputs.

Certain investment securities as of December 31, 2017 had fair values less than their amortized costs and, therefore, contained unrealized losses. The Company has evaluated these investments and has determined that the decline in value was not related to any Company or industry specific event. As of December 31, 2017, there were two U.S. Treasury investments with unrealized losses. The gross unrealized losses related to these investments were due to changes in interest rates. Given that the Company has no intent to sell any of these investments until a recovery of its fair value, which may be at maturity, and there are no current requirements to sell any of these investments, the Company did not consider these investments to be other-than-temporarily impaired as of December 31, 2017. The Company anticipates full recovery of amortized costs with respect to these investments at maturity or sooner in the event of a more favorable market interest rate environment. The duration of time the investments had been in a continuous unrealized loss position as of December 31, 2017 was less than 6 months.

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

(8) Inventory

Inventory is stated at the lower of cost and net realizable value. Included in inventory are raw materials and work-in-process used in the production of commercial products. Cost is determined using the first-in, first-out method. The Company expenses costs related to inventory until such time as it receives approval from the FDA to market a product, at which time the Company commences capitalization of costs relating to that product.

Inventory was as follows as of December 31, 2017 and 2016:

	December 31, 2017	December 31, 2016
Raw materials	$ 2,130	$ 2,618
Work in process	3,931	5,219
Finished goods	4,488	1,793
	10,549	9,630
Provision for inventory obsolescence	(710)	(884)
	$ 9,839	$ 8,746

The provision for inventory obsolescence decreased approximately $174 during the twelve months ended December 31, 2017, primarily due to the disposal of the fully reserved inventory during the year ended December 31, 2017. Adjustments to inventory are determined at the raw materials, work-in-process, and finished good levels to reflect obsolescence or impaired balances. Inventory is ordered to meet specific customer orders and largely reflects demand. Factors influencing inventory obsolescence include changes in demand, product life cycle, product pricing, physical deterioration and quality concerns

(9) Property, Plant and Equipment

Property, plant and equipment consists of the following:

	December 31, 2017	December 31, 2016
Land	$ 3,263	$ 3,263
Building and improvements	15,751	15,613
Furniture, office and computer equipment	4,376	3,811
Vehicles	30	30
Manufacturing equipment	24,153	21,508
Construction in progress	5,326	2,198
	52,899	46,423
Less: accumulated depreciation and amortization	13,825	9,123
Property, plant and equipment, net	$ 39,074	$ 37,300

Depreciation expense for the years ended December 2017, 2016 and 2015 was $4,864, $4,993 and $4,120, respectively.

(10) Intangible Assets

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

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships	$ 15,500	$ 7,050	$ 8,450
In-process research and development	26,400	—	26,400
Total	$ 41,900	$ 7,050	$ 34,850

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

The following represents the balance of intangible assets at December 31, 2016:

	Cost	Accumulated Amortization	Net Intangible Assets
Royalties and contract manufacturing relationships	$ 15,500	$ 4,467	$ 11,033
In-process research and development	26,400	—	26,400
Total	$ 41,900	$ 4,467	$ 37,433

Amortization expense for the years ended December 31, 2017, 2016 and 2015 was $2,583 $2,583, $1,884 and respectively. The amortization expense for the next three years will be $2,583 per year and $701 in the final year.

(11) Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2017	December 31, 2016
Clinical trial and related costs	$ 383	$ 2,564
Professional and consulting fees	1,010	360
Payroll and related costs	6,387	4,547
Property plant and equipment	216	720
Deferred revenue	546	418
Income tax payable	—	311
Interest payable	802	—
Other	553	973
	$ 9,897	$ 9,893

(12) Long-Term Debt

On November 17, 2017, the Company entered into a $100 million Credit Agreement, or the Credit Agreement, with Athyrium Opportunities III Acquisition LP, or Athyrium. The Credit Agreement provides for a term loan in the original principal amount of $60 million funded at closing. Pursuant to the terms of the Credit Agreement, there are two additional tranches of term loans, each in an aggregate original principal amount of $20 million. The second tranche term loan may be drawn upon on or before December 31, 2018 provided that the Company receives regulatory approval of the Company's IV meloxicam product candidate and will have at least $20 million in unrestricted cash after payment of the milestone payment due to Alkermes. The third tranche term loan may be drawn upon at any time on or prior to March 31, 2020 provided that the second term loan has been drawn upon and net sales of IV Meloxicam achieve $20 million for the most recent trailing twelve-month period. The maturity date of the Credit Agreement is November 17, 2022, the five-year anniversary of the closing.

The Term Loans will bear interest at a rate equal to the three-month LIBOR rate, with a 1% floor plus 9.75% per annum, with quarterly, interest-only payments until the maturity date. The unpaid principal amount of the Term Loans is due and payable on the maturity date. In addition, in accordance with the Credit Agreement the Company will have to pay a 1% exit fee of $600, which will be accreted to the carrying amount of the debt using the effective interest method over the term of the loan. In addition, if there is an early repayment, there is a sliding scale of prepayment penalties.

The Credit Agreement contains certain usual and customary affirmative and negative covenants, as well as financial covenants that the Company will need to satisfy on a monthly and quarterly basis. As of December 31, 2017, the Company was in compliance with the covenants.

As of December 31, 2017, the remaining payments due under the Credit agreement include a principal payment of $60,000 and an exit fee of $600 due at the maturity date.

In connection with the Credit Agreement, the Company issued warrants to each of Athyrium and its affiliate, Athyrium Opportunities II Acquisition LP, or Athyrium II, to purchase an aggregate of 348,664 shares of the Company's common stock, with an exercise price of $8.6043 per share. See Note 14(d) for additional information. The warrants are exercisable through November 17, 2024. The initial fair value of the warrant of $2,143 was recorded as a debt issuance costs.

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

In addition, the Company recorded debt issuance costs for the Credit Agreement of $4,439, which, along with the fair value of warrants, are being amortized using the effective interest method over the term of the Credit Agreement. Debit issuance cost amortization is included in interest expense within the Consolidated Statements of Operations and Comprehensive Income (Loss). As of December 31, 2017, the effective interest rate was 14.46%, which takes into consideration the non-cash accretion of the exit fee and the amortization of the debt issuance costs.

The components of the carrying value of the debt as of December 31, 2017, are detailed below:

Principal balance outstanding	$	60,000
Unamortized deferred issuance costs		(6,417)
Exit fee accretion		15
Total	$	53,598

The Company used proceeds from the initial term loan to (i) repay in full all outstanding indebtedness under its existing credit facility governed by the Credit Agreement, dated April 10, 2015, between the Company's subsidiary, Recro Gainesville LLC and OrbiMed Royalty Opportunities II, LP, or the OrbiMed Credit Agreement of $31,767, which included the remaining debt principal balance of $27,347 and early termination charges of $4,420 and (ii) pay transaction fees associated with the Athyrium Credit Agreement of $4,178. The remaining transaction fees of $261 will be paid in the following year.

Associated with the refinancing of the OrbiMed Credit Agreement and in accordance with ASC 405-20 "Extinguishments of Liabilities", the Company booked one-time loss on extinguishment of $6,772, which is reflected in the interest expense line within the Consolidated Statement of Operations and Comprehensive Loss.

The Company recorded debt issuance cost amortization for both credit agreements of $771, $907 and $713, for the years ended of December 31, 2017, 2016 and 2015, respectively.

(13) Commitments and Contingencies

(a) License and Supply Agreements

The Company is party to an exclusive license with Orion for the development and commercialization of Dexmedetomidine, 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. The Company is required to pay Orion lump sum payments of up to €20,500 ($24,557 as of December 31, 2017) 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, 2017, no such milestones have been achieved.

The Company is also party to an exclusive license agreement with Orion for the development and commercialization of Fadolmidine, or Fado, for use as a human therapeutic, in any dosage form in the Territory. The Company is required to pay Orion lump sum payments of up to €12,200 ($14,614 as of December 31, 2017) 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, 2017, no such milestones have been achieved.

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

(b) Contingent Consideration for the Gainesville Transaction

Pursuant to the purchase and sale agreement governing the Gainesville Transaction, the Company agreed to pay to Alkermes up to an additional $125.0 million in milestone payments including $45.0 million upon regulatory approval, 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).

The Company is party to a Development, Manufacturing and Supply Agreement, or Supply Agreement, with Alkermes (through a subsidiary of Alkermes), 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.

As part of the Gainesville Transaction, the Company acquired the rights to Zohydro ER®, which the Company licenses to its commercial partner Pernix, in the United States, and which is subject to ongoing intellectual property litigation and proceedings.

Zohydro ER® has been subject to four paragraph IV certifications with Actavis plc, or Actavis, one of which was filed in 2014 regarding the filing of Abbreviated NDAs, or ANDAs, with the FDA for a generic version of Zohydro ER®, one of which was filed in April 2015 regarding the filing of a supplemental ANDA, or sANDA, and another two of which were filed in November 2015 and October 2016 regarding one of the Company's recently issued patents relating to a formulation of Zohydro ER®. These certification notices allege that the three U.S. patents listed in the FDA's Orange Book for Zohydro ER®, with an expiration date in November 2019 or September 2034, will not be infringed by Actavis' proposed products, are invalid and/or are unenforceable. In 2014, Daravita Limited (a subsidiary of Alkermes and the Company's predecessor in interest) filed suit against Actavis in the U.S. District Court for the District of Delaware based on the ANDAs, and, in 2015, the Company filed suit against Actavis in the U.S. District Court for the District of Delaware based on the sANDA. In February 2017, the District Court in the Actavis case ruled in the Company's favor and enjoined Actavis from selling the proposed generic version of Zohydro ER®. Actavis has appealed this decision to the U.S. Court of Appeals for the Federal Circuit. In October 2017, the Company filed suit against Actavis in the U.S. District Court for the District of Delaware based upon another recently issued patent relating to a formulation of Zohydro ER®. Under the Company's license agreement with Pernix, it has the right to control the enforcement of its patents and related proceedings involving Zohydro ER® and any prospective generic entrant, and Pernix has the obligation to reimburse the Company for all reasonable costs of such actions. The litigations with Actavis settled in January 2018 via a multi-party settlement agreement with Pernix and Actavis, in which Actavis was granted a license to begin selling a generic version of Zohydro® ER on March 1, 2029, or earlier under certain circumstances.

(d) Leases

On January 1, 2017, the Company entered into a six-year lease for its Malvern, Pennsylvania facility that expires on December 31, 2022. In February 2017, the Company also entered into a three-year lease for office space in Dublin, Ireland that expires April 2020. The Company is also a party to operating leases for office equipment and storage. Rent expense includes rent as well as additional operating and tenant improvement expenses.

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

As of December 31, 2017, future minimum lease payments excluding operating expenses and tenant improvements for the leases, are as follows:

	Lease payments
2018	568
2019	504
2020	406
2021	362
2022	373
Total	$ 2,213

(e) Purchase Commitments

As of December 31, 2017, the Company had outstanding non-cancelable and cancelable purchase commitments in the amount of $25,298 related to inventory, capital expenditures and other goods and services, including pre-commercial/manufacturing scale-up and clinical activities.

(f) Certain Compensation and Employment Agreements

The Company has entered into employment agreements with certain of its named executive officers. As of December 31, 2017, these employment agreements provided for, among other things, annual base salaries in an aggregate amount of not less than $858 from that date through calendar year 2018.

(14) Capital Structure

(a) Common Stock

The Company is authorized to issue 50,000,000 shares of common stock, with a par value of $0.01 per share.

Reflected below are the Company's capital raises since its initial public offering, or IPO:

On March 12, 2014, the Company completed an IPO, in which the Company sold 4,312,500 shares of common stock at $8.00 per share, resulting in gross proceeds of $34,500. In connection with the IPO, the Company paid $4,244 in underwriting discounts, commissions and offering costs, resulting in net proceeds of $30,256. Also in connection with the IPO, all of the outstanding shares of the Company's Series A Redeemable Convertible Preferred Stock, including accreted dividends, and Bridge Notes, including accrued interest, were converted into common stock.

On July 7, 2015, the Company closed a private placement with certain accredited investors in which the Company sold 1,379,311 shares of common stock at a price of $11.60 per share, for net proceeds of $14,812. The Company paid the placement agents a fee equal to 6.0% of the aggregate gross proceeds from the private placement, plus reimbursement of certain expenses.

On August 19, 2016, the Company closed an underwritten public offering in which the company sold 1,986,666 shares of common stock at a price per share of $7.50, for net proceeds of $13,367 after deducting underwriting commissions and offering expenses.

On December 16, 2016, the Company closed an underwritten public offering in which the company sold 6,670,000 shares of common stock at a price per share of $6.00, for net proceeds of $36,888 after deducting underwriting commissions and offering expenses.

On December 29, 2017, the Company entered into a sales agreement, or the Sales Agreement, with Cowen and Company, LLC, or Cowen, pursuant to which the Company may sell from time to time, at its option, shares of its common stock, $0.01 par value per share, having an aggregate offering price of up to $40,000,000 through Cowen, as the placement agent. As of December 31, 2017, the Company did not have any sales of common stock under the Sales Agreement.

(b) Common Stock Purchase Agreement

On February 2, 2015, the Company entered into a Common Stock Purchase Agreement, or the 2015 Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, pursuant to which Aspire Capital was committed to purchase, at the

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

Company's election, up to an aggregate of $10,000 of shares of the Company's common stock over the 24-month term of the 2015 Purchase Agreement. On the execution of the 2015 Purchase Agreement, the Company issued 96,463 shares of common stock to Aspire Capital with a fair value of $285, as consideration for entering in the 2015 Purchase Agreement. In addition, the Company incurred $253 of costs in connection with the 2015 Purchase Agreement, which, along with the fair value of the common stock, has been recorded as deferred equity costs. During 2016, the Company sold 1,143,940 shares of common stock under the 2015 Purchase Agreement for $7,796. The agreement expired in February 2017.

On March 2, 2018, The Company entered into a common stock purchase agreement, or the Purchase Agreement, with Aspire Capital Fund, LLC, or Aspire Capital, which provides that, upon the terms and subject to the conditions and limitations set forth in the Purchase Agreement, Aspire Capital is committed to purchase, at the Company's sole election, up to an aggregate of $20.0 million of its shares of common stock over the approximately 30-month term of the Purchase Agreement. On the execution of the Purchase Agreement, the Company agreed to issue 33,040 shares of common stock to Aspire Capital as consideration for entering into the Purchase Agreement.

(c) Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, with a par value of $0.01 per share. As of December 31, 2017, no preferred stock was issued or outstanding.

(d) Warrants

As of December 31, 2017, the Company had the following warrants outstanding to purchase shares of the Company's common stock:

Number of Shares	Exercise Price per Share		Expiration Date
140,000	$	12.00	March 2019
350,000	$	19.46	April 2022
294,928	$	3.28	April 2022
348,664	$	8.60	November 2024

The warrants to purchase 140,000 and 348,664 shares related to Aegis Capital Corporation and Athyrium, respectively, are equity classified. During the year ended December 31, 2017, the Company recorded Athyrium equity classified warrants of $1,966, which is the fair value of $2,143 net of the related tax effect of $177.

The warrants to purchase 350,000 and 294,928 shares related to Alkermes and OrbiMed, respectively, are liability classified since they contain a contingent net cash settlement feature. The fair value of both warrants will be remeasured through settlement or expiration with changes in fair value recognized as a period charge within the statement of operations.

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

	December 31, 2017		December 31, 2016	
Fair value	$	3,406	$	3,397
Expected dividend yield		— %		— %
Expected volatility		75 %		85 %
Risk-free interest rates		2.09 %		1.93 %
Remaining contractual term		4.25 years		5.25 years

Each of the warrant agreements include usual and customary standard antidilution provisions and the OrbiMed, Athyrium and Aegis agreements contains additional antidilution provisions as well.

(15) Comprehensive Income/Loss

The Company's comprehensive loss is shown on the Consolidated Statements of Operations and Comprehensive Income (Loss) as of December 31, 2017, 2016 and 2015 and is comprised of net unrealized losses on the Company's available-for-sale securities. The total of comprehensive loss for the twelve months ended December 31, 2017 and 2016 was $50,081 and $30,205, respectively. The total of comprehensive income for the twelve months ended December 31, 2015 was $3,033. There was no tax effect for the twelve months ended December 31, 2017, 2016 or 2015 of other comprehensive loss.

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

(16) Stock-Based Compensation

The Company established the 2008 Stock Option Plan, or the 2008 Plan, which allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company's common stock to designated employees, non-employee directors, and consultants and advisors. As of December 31, 2017, no stock appreciation rights have been issued. Subsequent to adoption, the 2008 Plan was amended to increase the authorized number of shares available for grant to 444,000 shares of common stock. In October 2013, the Company 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, the Company'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 board of directors by an amount equal to 5% of the outstanding common stock on December 1st of that year. In December 2017, 2016 and 2015, the number of shares available for issuance under the A&R Plan was increased by 956,341, 619,181, and 461,215, respectively. The total number of shares authorized for issuance under the A&R plan as of December 31, 2017 is 4,036,737.

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, 2017, 1,282,376 shares and 174 shares are available for future grants under the 2013 Plan and 2008 Plan, respectively.

The weighted average grant-date fair value of the options awarded to employees during the years ended December 31, 2017, 2016 and 2015 was $5.44, $5.08 and 8.10, 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, 2017	December 31, 2016
Range of expected option life	6 years	6 years
Expected volatility	75.1%-84.71%	82.47%
Risk-free interest rate	1.87-2.27%	1.07-2.09%
Expected dividend yield	—	—

The following table summarizes stock option activity during the year ended December 31, 2017:

	Number of shares	Weighted average exercise price	Weighted average remaining contractual life
Balance, December 31, 2015	2,042,194	$ 7.00	
Granted	596,106	7.21	
Exercised	—	0.00	
Expired/forfeited/cancelled	(26,371)	10.86	
Balance, December 31, 2016	2,611,929	$ 7.01	7.4 years
Granted	1,105,170	7.62	
Exercised	(7,756)	6.86	
Expired/forfeited/cancelled	(114,468)	7.89	
Balance, December 31, 2017	3,594,875	$ 7.17	7.1 years
Vested	2,042,132	$ 6.73	5.8 years
Vested and expected to vest	3,594,875	$ 7.17	7.1 years

Included in the table above are 817,750 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).

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

During the year ending December 31, 2016, the Company adopted ASU 2016-09 and elected to account for forfeitures as they occur.

The following table summarizes restricted stock units activity during the year ended December 31, 2017.

	Number of shares
Balance, December 31, 2016	7,750
Granted	369,043
Vested and settled	(104,450)
Expired/forfeited/cancelled	(1,750)
Balance, December 31, 2017	270,593
Expected to vest	270,593

During 2017, the Company granted 91,150 performance-based restricted stock units, or RSUs, which vested based on attaining clinical and operational goals during 2017, as well as 277,893 time-based RSUs, which vest over four years.

In September 2017, the performance condition associated with the Company's outstanding performance-based RSUs was achieved, which resulted in stock-based compensation expense of $656. Included in the 104,450 units of restricted stock vested during the twelve months ended December 31, 2017 are 27,987 shares with a weighted average fair value of $8.92 per share that were withheld for withholding tax purposes upon vesting of such awards from stockholders who elected to net share settle such tax withholding obligation.

Stock-based compensation expense for the twelve months ended December 31, 2017, 2016 and 2015 was $5,546, $3,889 and $3,064, respectively.

As of December 31, 2017, there was $10,078 of unrecognized compensation expense related to unvested options and RSUs that are expected to vest and will be expensed over a weighted average period of 2.7 years.

The aggregate intrinsic value represents the total amount by which the fair value of the common stock subject to options exceeds the exercise price of the related options. As of December 31, 2017, the aggregate intrinsic value of the vested and unvested options was $5,696 and $2,643, respectively

In January 2018, the Company granted 496,286 options at a price of $9.04 per share, as well as 242,396 time-based restricted stock units, which are not included in the above table.

(17) Segment Reporting

The Company operates through two business segments: an Acute Care segment and a revenue-generating CDMO segment. The Acute Care segment is primarily focused on developing innovative products for hospital and related settings, and the CDMO segment leverages the Company's formulation expertise to develop and manufacture pharmaceutical products using the Company's proprietary delivery technologies for commercial partners who commercialize or plan to commercialize these products. Acute Care has no revenue, and its costs consist primarily of expenses incurred in conducting the Company's clinical and preclinical studies, acquiring clinical trial materials, regulatory activities, personnel costs and pre-commercialization of meloxicam. CDMO revenue streams are derived from manufacturing, royalty and profit-sharing revenues, as well as CDMO's research and development services performed for commercial partners.

The accounting policies of the segments are the same as those described in the summary of significant accounting policies (see Note 3). The Company evaluates performance of its reportable segments based on revenue and operating income (loss). The Company does not allocate interest income, interest expense or income taxes to its operating segments.

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

The following table summarizes segment information as of and for the years ended December 31, 2017, 2016 and 2015:

	For the Year ended December 31, 2017	2016	2015
Revenues:			
CDMO	$ 71,834	$ 69,337	$ 51,952
Acute Care	—	—	—
Total	$ 71,834	$ 69,337	$ 51,952
Operating income (loss):			
CDMO	$ 25,409	$ 24,232	$ 17,558
Acute Care	(65,720)	(50,005)	(24,528)
Total	$ (40,311)	$ (25,773)	$ (6,970)
Depreciation and amortization:			
CDMO	$ 7,376	$ 7,572	$ 6,004
Acute Care	72	4	—
Total	$ 7,447	$ 7,576	$ 6,004
Capital expenditures:			
CDMO	$ 5,405	$ 3,735	$ 2,411
Acute Care	767	35	—
Total	$ 6,172	$ 3,770	$ 2,411

	December 31, 2017	December 31, 2016
Total assets:		
CDMO	$ 78,136	$ 77,828
Acute Care	108,090	105,169
Total	$ 186,226	$ 182,997

(18) Income Taxes

The components of loss before income tax are as follows:

	December 31, 2017	2016	2015
Domestic	$ (24,353)	$ 1,207	$ (10,002)
Foreign	(27,607)	(32,519)	(2,516)
Loss before income taxes	$ (51,960)	$ (31,312)	$ (12,518)

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

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

	December 31, 2017	December 31, 2016	December 31, 2015
Current:			
Federal	$ (190)	$ 298	$ 83
State and local	—	18	3
Foreign	—	—	—
	(190)	316	86
Deferred:			
Federal	$ (705)	$ (1,607)	$ (13,418)
State and local	(985)	184	(2,219)
Foreign	3,450	4,065	315
	1,760	2,642	(15,322)
Change in valuation allowance	(3,450)	(4,065)	(315)
	$ (1,880)	$ (1,107)	$ (15,551)

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, 2017	2016	2015
U.S. federal statutory income tax rate	34.0 %	34.0 %	34.0 %
Foreign tax rate differential	(11.4)%	(22.3)%	(4.3)%
State taxes, net of federal benefit	1.9 %	(0.1)%	2.6 %
Nondeductible expenses	0.2 %	0.5 %	4.2 %
Research and development credits	0.9 %	4.5 %	1.7 %
Change in federal tax rate	(15.2)%	0.0 %	0.0 %
Change in valuation allowance	(6.6)%	(13.1)%	86.1 %
Other	(0.2)%	—	—
Effective income tax rate	3.6 %	3.5 %	124.3 %

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

	December 31, 2017	December 31, 2016
Net operating loss carryforwards	$ 10,704	$ 6,742
Research and development credits	3,389	3,108
Capitalized start-up costs	1,431	2,343
Intangibles	2,236	2,181
Contingent consideration	6,588	5,364
Stock-based compensation	2,873	2,718
Other temporary differences	430	517
Gross deferred tax asset	27,651	22,973
Valuation allowance	(7,830)	(4,379)
Net deferred tax asset	19,821	18,594
Deferred tax liability	(1,248)	(1,534)
Net deferred taxes	$ 18,573	$ 17,060

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. During 2015, in connection with an international corporate restructuring, it was determined that the Company would more likely than not to realize its deferred tax assets associated with its U.S. operations. Accordingly, the Company recorded a benefit associated with the release of its prior year valuation allowance in the amount of $11,087. The Company believes that it is more likely than not that the Company's deferred income tax asset associated with its foreign net operating losses will not be realized in the immediate future. As such, there is a full valuation allowance against the net deferred tax assets associated with foreign operations as of December 31, 2017 and 2016.

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

The following table summarizes carryforwards of Federal net operating losses and tax credits as of December 31, 2017:

	Amount	Expiration
Federal net operating losses	$ 9,010	2028 – 2034
State net operating losses	12,380	2028 – 2034
Foreign net operating losses	62,646	No expiration
Federal and state research and development credits	3,389	2028 – 2034

A portion of the Company's deferred tax asset is offset by a valuation allowance relating to foreign net operating losses (NOL). The valuation allowance reduces deferred tax assets to an amount that represents management's best estimate of the amount of such deferred tax assets that more than likely will be realized. At December 31, 2017, the Company had foreign NOL carryforwards of $62,646 and recorded a full valuation allowance against the amount.

Under the Tax Reform Act of 1986 (the Act), the utilization of a corporation's net operating loss and research and development tax credit carryforwards is limited following a greater than 50% change in ownership during a three-year period. Any unused annual limitation may be carried forward to future years for the balance of the carryforward period. The Company has done an analysis to determine whether or not ownership changes, as defined by the Act, have occurred since inception. The Company determined that it experienced ownership changes, as defined by the Act, during the 2008, 2014 and 2016 tax years as a result of past financings; accordingly, the Company's ability to utilize the aforementioned carryforwards will be limited. Although the carryforwards will be limited, the Company has determined that none of the net operating losses will expire prior to being utilized as a result of the changes. In addition, state net operating loss carryforwards may be further limited, including in Pennsylvania, which has a limitation of 30%, 35% or 40% of taxable income after modifications and apportionment on state net operating losses utilized in any one year during tax years beginning during 2017, 2018 or 2019 going forward, respectively.

The Company will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2017, 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. Due to net operating loss and tax credit carry forwards that remain unutilized, income tax returns for tax years from inception through 2016 remain subject to examination by the taxing jurisdictions.

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%. The Company recognized a one-time net expense from the deferred tax remeasurement of approximately $7.9 million.

- 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, we are 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.

- The Company's ability to deduct certain amounts of executive compensation could be limited given the expanded limitations

While the Company has not yet completed its full assessment of the effects of the Tax Act, it is able to determine reasonable estimates for the impacts of the key items specified above, thus it reported provisional amounts for these items. In accordance with Staff Accounting Bulletin No. 118 ("SAB 118"), the Company has provided additional disclosures related to these provisional amounts.

The Company was unable to determine a reasonable estimate of the decrease to its stock compensation deferred tax asset, if any, under the Tax Act due to expanded limitations on the deductibility of executive compensation. Additionally, to the extent that any of the Company's deferred tax estimates are different than actual, there will be a permanent adjustment to the effective tax rate in 2018. The Company will continue to apply its existing accounting under ASC 740 for this matter. The aforementioned provisional amounts related to the deferred tax balances are based on information available at this time and may change due to a variety of factors, including, among others, (i) anticipated guidance from the U.S. Department of Treasury about implementing the Tax Act, (ii) potential additional guidance from the Securities and Exchange Commission or the Financial Accounting Standards Board related to the Tax Act, (iii) any impact resulting from our 2018 financial closing and reporting processes, and (iv) management's further assessment of the Tax Act and related regulatory guidance. The Company will continue its assessment of the impact of the Tax Act on its business and consolidated financial statements throughout the one-year measurement period as provided by SAB 118.

(19) Related Party Transactions

The Company's President and Chief Executive Officer, or CEO, owns a majority of the stock of Malvern Consulting Group, or MCG, a pharmaceutical incubator and consulting firm. The CEO's husband, who is also a shareholder of the Company, is a consultant and a shareholder of MCG. In addition, the CEO's son is the President and a shareholder of MCG. During 2016, certain immediate family members of the CEO were employees of MCG, including the CEO's brother and sister-in-law. Since formation, the Company entered into various transactions with MCG, as detailed below. However, since becoming a public company, the Company sought to decrease its involvement with MCG, and, as of December 31, 2016, the Company no longer has any involvement or transactions with MCG.

During 2016, certain of the Company's executive officers, its CEO, its Senior Vice President, Development and its Senior Vice President, Regulatory Affairs and Quality Assurance, who is also the CEO's sister, provided minimal consulting services from time to time to MCG. Until December 31, 2016, the Company was a party to a Master Consulting Services Agreement with MCG. Pursuant to the agreement, MCG provided the Company with certain consulting services for a fee based upon hourly rates previously approved by the Company's Board of Directors. In consideration for such services, the Company recorded $363 and $465 for the twelve months ended December 31, 2016 and 2015, respectively. A portion of these amounts were used during 2016 and 2015 to pay a portion of the respective salaries of MCG employees that, as described above, included immediate family members of the Company's CEO.

Until December 31, 2016, the Company was party to an Office Services Agreement with MCG for the lease of an aggregate of 8,458 square feet of office and lab space located at its Malvern, Pennsylvania facility and the provision of IT services and general office support. Pursuant to the Office Services Agreement, the Company paid MCG $206 and $114 in the twelve months ended December 31, 2016 and 2015, respectively. The Company terminated this agreement on December 31, 2016 and is now a party to a six-year lease directly with the landlord of the Company's Malvern, Pennsylvania facility (see Note 13).

As of December 31, 2016, the Company terminated the Master Consulting Agreement and the Office Services Agreement and MCG no longer provides any services or has any contracts with the Company.

The Company's Senior Vice President, Regulatory and Quality, who is the CEO's sister, has held that position since 2014. Effective January 1, 2017, the CEO's sister-in-law and brother, respectively, terminated their employment with MCG and were hired as the Company's Director of Human Resources and the Company's Vice President, Manufacturing. The Company's board of directors approved these hires consistent with the Company's related person transaction policy

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 regulatory project support and consultancy. In consideration for such services, the Company recorded $151 for the twelve months ended December 31, 2017. A portion of the amount relates to consultancy services provided by the Non-Executive Director.

(20) Retirement Plan

The Company has a voluntary 401(k) Savings Plan (the 401(k) Plan) in which all employees are eligible to participate. The Company's policy is to match 100% of the employee contributions up to a maximum of 5% of employee compensation. Total Company contributions to the 401(k) plan for the year ended December 31, 2017, 2016 and 2015 were $1,160, $711 and $492, respectively.

EXHIBIT INDEX

Exhibit No.	Description	Method of Filing
2.1†	Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc.	Incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on March 11, 2015 (File No. 001-36329).
2.2	First Amendment, dated December 8, 2016 to Purchase and Sale Agreement, dated March 7, 2015, by and among Recro Pharma, Inc., Recro Pharma LLC, Daravita Limited, Alkermes Pharma Ireland Limited and Eagle Holdings USA, Inc.	Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on December 8, 2016 (File No. 001-36329).
3.1	Second Amended and Restated Articles of Incorporation of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
3.2	Third Amended and Restated Bylaws of Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
4.1	Specimen certificate evidencing shares of common stock.	Incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A filed on December 20, 2013 (File No. 333-191879).
4.2	Investor Rights Agreement, dated September 4, 2008, by and among Recro Pharma, Inc., and the investors party thereto.	Incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
4.3	Form of Alkermes Warrant.	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on March 11, 2015 (File No. 001-36329).
4.4	Form of OrbiMed Warrant.	Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on March 11, 2015 (File No. 001-36329).
4.5	Form of IPO Warrant.	Incorporated herein by reference to Exhibit A of Exhibit 1.1 to the Company's Registration Statement on Form S-1/A filed on February 11, 2014 (File No. 333-191879).
4.6†	Common Stock Purchase Warrant, dated November 17, 2017, in favor of Athyrium Opportunities III Acquisition LP*	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
4.7†	Common Stock Purchase Warrant, dated November 17, 2017, in favor of Athyrium Opportunities II Acquisition LP*	Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
4.8	Registration Rights Agreement, dated March 2, 2018, by and between Recro Pharma, Inc. and Aspire Capital Fund, LLC.	Filed herewith.
5.1	Opinion of Pepper Hamilton LLP.	Filed herewith.
10.1†	Dexmedetomidine License Agreement, dated August 22, 2008, by and among Recro Pharma, Inc. and Orion Corporation.	Incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.2†	First Amendment to Dexmedetomidine License Agreement, dated January 17, 2009, by and between Recro Pharma, Inc., and Orion Corporation.	Incorporated herein by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).

Exhibit No.	Description	Method of Filing
10.3†	Dexmedetomidine API Supply Agreement, dated August 22, 2008, by and among Recro Pharma, Inc., and Orion Corporation.	Incorporated herein by reference to Exhibit 10.3 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.4•	Employment Agreement, dated October 8, 2013, between Recro Pharma, Inc. and Gerri Henwood.	Incorporated herein by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.5•	Employment Agreement, dated July 1, 2016, between Recro Pharma, Inc. and Michael Celano.	Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 5, 2016 (File No. 001-36329).
10.6•	Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Randall Mack.	Incorporated herein by reference to Exhibit 10.7 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.7•	Employment Agreement, dated October 9, 2013, between Recro Pharma, Inc. and Diane Myers.	Incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.8•	Employment Agreement, dated December 1, 2015, between Recro Pharma, Inc. and Stewart McCallum, M.D.	Incorporated herein by reference to Exhibit 10.33 to the Company's Post-Effective Amendment on Form S-1 filed on December 23, 2015 (File No. 333-201841).
10.9•	Employment Agreement, dated February 16, 2016, between Recro Pharma, Inc. and Fred Graff.	Incorporated herein by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K filed on March 24, 2016 (File No. 001-36329).
10.10•	Employment Agreement, dated June 5, 2017, between Recro Pharma, Inc. and Ryan D. Lake.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 9, 2017 (File No. 001-36329).
10.11•	Employment Agreement, dated August 21, 2017, between Recro Pharma, Inc. and Jyrki Mattila, MD, PhD, MBA	Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on November 9, 2017 (File No. 001-36329).
10.12•	Form of Amendment to the Employment Agreement of each of Gerri Henwood, Randall Mack, Diane Myers and Donna Nichols.	Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on December 19, 2014 (File No. 001-36329).
10.13•	2013 Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on March 13, 2014 (File No. 001-36329).
10.14•	2008 Stock Option Plan.	Incorporated herein by reference to Exhibit 10.10 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.15•	Form of 2008 Stock Option Plan Award Agreement.	Incorporated herein by reference to Exhibit 10.11 to the Company's Registration Statement on Form S-1/A filed on November 29, 2013 (File No. 333-191879).
10.16•	Form of 2013 Equity Incentive Plan Award Agreement.	Incorporated herein by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed on March 25, 2015 (File No. 001-36329).
10.17•	Form of Recro Pharma, Inc. Amended and Restated Equity Incentive Plan Award Agreement for Restricted Stock Units.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K on December 22, 2015 (File No. 001-36329).

Exhibit No.	Description	Method of Filing
10.18•	Recro Pharma, Inc. Amended and Restated Equity Incentive Plan.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 26, 2015 (File No. 001-36329).
10.19•	Form of Award Agreement for Option Inducement Awards	Incorporated herein by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-8 filed on December 23, 2015 (File No. 333-208750).
10.20•	Form of Award Agreement for Restricted Stock Unit Inducement Awards	Filed herewith.
10.21†	Asset Transfer and License Agreement, dated as of April 10, 2015, between Alkermes Pharma Ireland Limited and DV Technology LLC.	Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015 (File No. 001-36329).
10.22	Amendment to Asset Transfer and License Agreement, dated December 23, 2015, between Alkermes Pharma Ireland Limited and Recro Gainesville LLC	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 23, 2015 (File No. 001-36329).
10.23†	Transition Services Agreement, dated as of April 10, 2015, by and among Alkermes Pharma Ireland Limited, Recro Pharma, Inc., DV Technology LLC, and Alkermes Gainesville LLC.	Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on May 12, 2015 (File No. 001-36329).
10.24†	Development, Manufacturing and Supply Agreement, dated July 10, 2015, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.25†	First Amendment to the Development, Manufacturing and Supply Agreement, dated October 19, 2016, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K filed on March 9, 2017 (File No. 001-36329).
10.26†	Second Amendment to the Development, Manufacturing and Supply Agreement, dated February 1, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K filed on March 9, 2017 (File No. 001-36329).
10.27†	Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.28	Supplemental Agreement, dated December 8, 2004, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.29	Supplemental Agreement No. 2, dated January 17, 2014, to Amended and Restated License and Supply Agreement, dated June 26, 2003, by and among Elan Corporation, plc (predecessor-in-interest to Recro Gainesville LLC) and Watson Laboratories, Inc.	Incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on August 14, 2015 (File No. 001-36329).
10.30	Form of Securities Purchase Agreement, dated July 1,2015, by and among Recro Pharma, Inc. and the purchasers party thereto.	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 8, 2015 (File No. 001-36329).
10.31†	Third Amendment to the Development, Manufacturing and Supply Agreement, dated June 15, 2017, by and between Alkermes Pharma Ireland Limited and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36329).
10.32†	Licensing Agreement, dated June 30, 2017, by and between Cornell University and Recro Pharma, Inc.	Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36329).

Exhibit No.	Description	Method of Filing
10.33†	Master Manufacturing Services Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36329).
10.34†	Product Agreement, dated July 14, 2017, by and between Patheon UK Limited and Recro Ireland Limited	Incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on August 11, 2017 (File No. 001-36329).
10.35†	Credit Agreement, dated as of November 17, 2017, by and between Recro Pharma, Inc. and Athyrium Opportunities III Acquisition LP. *	Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
10.36†	Security Agreement, dated as of November 17, 2017, by Recro Pharma, Inc. in favor of Athyrium Opportunities III Acquisition LP.	Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on November 20, 2017 (File No. 001-36329).
10.37	Sales Agreement, dated as of December 29, 2017, by and between Recro Pharma, Inc. and Cowen and Company, LLC.	Incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on December 29, 2017 (File No. 001-36329).
10.38	Common Stock Purchase Agreement, dated March 2, 2018, by and between Recro Pharma, Inc. and Aspire Capital Fund, LLC.	Filed herewith.
21.1	Subsidiaries of Recro Pharma, Inc.	Filed herewith.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.	Filed herewith.
23.2	Consent of Pepper Hamilton LLP.	Included in Exhibit 5.1.
31.1	Rule 13a-14(a)/15d-14(a) certification of Principal Executive Officer	Filed herewith.
31.2	Rule 13a-14(a)/15d-14(a) certification of Chief Operating Officer	Filed herewith.
31.3	Rule 13a-14(a)/15d-14(a) certification of Principal Financial Officer	Filed herewith.
32.1	Section 1350 certification, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101 INS	XBRL Instance Document	Filed herewith.
101 SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101 CAL	XBRL Taxonomy Extension Calculation Linkbase	Filed herewith.
101 DEF	XBRL Taxonomy Extension Definition Linkbase	Filed herewith.
101 LAB	XBRL Taxonomy Extension Label Linkbase	Filed herewith.

• Management contract or compensatory plan or arrangement.

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

SIGNATURES

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

Date:

RECRO PHARMA, INC.

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

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

Signature	Title	Date
/s/ Gerri A. Henwood Gerri A. Henwood	President, Chief Executive Officer and Director (Principal Executive Officer)	March 2, 2018
/s/ Michael Celano Michael Celano	Chief Operating Officer	March 2, 2018
/s/ Ryan D. Lake Ryan D. Lake	Chief Financial Officer (Principal Financial Officer)	March 2, 2018
/s/ Alfred Altomari Alfred Altomari	Director	March 2, 2018
/s/ William L. Ashton William L. Ashton	Director	March 2, 2018
/s/ Michael Berelowitz Michael Berelowitz	Director	March 2, 2018
/s/ Winston J. Churchill Winston J. Churchill	Director	March 2, 2018
/s/ Karen Flynn Karen Flynn	Director	March 2, 2018
/s/ Bryan M. Reasons Bryan M. Reasons	Director	March 2, 2018
/s/ Wayne B. Weisman Wayne B. Weisman	Director	March 2, 2018

Exhibit 4.8

REGISTRATION RIGHTS AGREEMENT

REGISTRATION RIGHTS AGREEMENT (this "**Agreement**"), dated as of March 2, 2018, by and between **RECRO PHARMA, INC.,** a Pennsylvania corporation (the "**Company**"), and **ASPIRE CAPITAL FUND, LLC,** an Illinois limited liability company (together with its permitted assigns, the "**Buyer**"). Capitalized terms used herein and not otherwise defined herein shall have the respective meanings set forth in the Common Stock Purchase Agreement by and between the parties hereto, dated as of the date hereof (as amended, restated, supplemented or otherwise modified from time to time, the "**Purchase Agreement**").

WHEREAS:

A. Upon the terms and subject to the conditions of the Purchase Agreement, (i) the Company has agreed to issue to the Buyer, and the Buyer has agreed to purchase, up to Twenty Million Dollars ($20,000,000) of the Company's common stock, par value $0.01 per share (the "**Common Stock**"), pursuant to Section 1 of the Purchase Agreement (such shares, the "**Purchase Shares**"), and (ii) the Company has agreed to issue to the Buyer such number of shares of Common Stock as is required pursuant to Section 4(e) of the Purchase Agreement (the **"Commitment Shares"**); and

B. To induce the Buyer to enter into the Purchase Agreement, the Company has agreed to provide certain registration rights under the Securities Act of 1933, as amended, and the rules and regulations thereunder, or any similar successor statute (collectively, the "**1933 Act**"), and applicable state securities laws.

NOW, THEREFORE, in consideration of the promises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Buyer hereby agree as follows:

1. DEFINITIONS.

As used in this Agreement, the following terms shall have the following meanings:

a. "**Person**" means any person or entity including any corporation, a limited liability company, an association, a partnership, an organization, a business, an individual, a governmental or political subdivision thereof or a governmental agency.

b. "**Prospectus**" means the base prospectus, including all documents incorporated therein by reference, included in any Registration Statement (as hereinafter defined), as it may be supplemented by a prospectus or prospectus supplement (including the Prospectus Supplement (as hereinafter defined)), in the form in which such prospectus and/or Prospectus Supplement have most recently been filed by the Company with the U.S. Securities and Exchange Commission (the "**SEC**") pursuant to Rule 424(b) under the 1933 Act, together with any then issued "issuer free writing prospectus(es)," as defined in Rule 433 of the 1933 Act, relating to the Registrable Securities.

c. "**Register**," "**registered**," and "**registration**" refer to a registration effected by preparing and filing one or more registration statements of the Company in compliance with the 1933 Act and pursuant to Rule 415 under the 1933 Act or any successor rule providing for offering securities on a continuous basis ("**Rule 415**"), and the declaration or ordering of effectiveness of such registration statement(s) by the SEC.

d. "**Registrable Securities**" means the Purchase Shares that may from time to time be issued or issuable to the Buyer upon purchases of the Available Amount under the Purchase Agreement (without regard to any limitation or restriction on purchases), the Commitment Shares issued or issuable to the Buyer, and any shares of capital stock issued or issuable with respect to the Purchase Shares, the Commitment Sharesor the Purchase Agreement as a result of any stock split, stock dividend, recapitalization, exchange or similar event, without regard to any limitation on purchases under the Purchase Agreement.

e. "**Registration Statement**" means the Shelf Registration Statement and any other registration statement of the Company, as amended when it became effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus subsequently filed with the SEC pursuant to Rule 424(b) under the 1933 Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the 1933 Act, covering the sale of the Registrable Securities.

f. "**Shelf Registration Statement**" means the Company's existing registration statement on Form S-3 (File No. 333-218487).

2. REGISTRATION.

a. Mandatory Registration. The Company shall within two (2) Business Days from the Commencement Date file with the SEC a prospectus supplement to the prospectus dated June 12, 2017 forming a part of the Shelf Registration Statement specifically relating to the Registrable Securities (the "**Prospectus Supplement**"). The Buyer and its counsel shall have had a reasonable opportunity to review and comment upon such Prospectus Supplement prior to its filing with the SEC. The Buyer shall furnish all information reasonably requested by the Company for inclusion therein. The Company shall use its commercially reasonable efforts to keep the Shelf Registration Statement effective pursuant to Rule 415 promulgated under the 1933 Act and available for sales of all of the Registrable Securities at all times until the earlier of (i) the Company no longer qualifies to make sales under the Shelf Registration Statement (which shall be understood to include the inability of the Company to immediately register sales of Registrable Securities to the Buyer under the Shelf Registration Statement or any New Registration Statement (as defined below) pursuant to General Instruction I.B.6 of Form S-3), (ii) the date on which the Company shall have sold all the Registrable Securities and no Available Amount remains under the Purchase Agreement, or (iii) the date on which the Purchase Agreement is terminated (the "**Registration Period**"). The Shelf Registration Statement (including any amendments or supplements thereto and prospectuses contained therein) shall not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

b. Rule 424 Prospectus. The Company shall, as required by applicable securities regulations,from time to time file with the SEC, pursuant to Rule 424 promulgated under the 1933 Act,a prospectus, including any amendments or prospectus supplements thereto, to be used in connection with sales of the Registrable Securities under the Registration Statement. The Buyer and its counsel shall have two (2) Business Days to review and comment upon such prospectus prior to its filing with the

SEC. The Buyer shall use its commercially reasonable efforts to comment upon such prospectus within two (2) Business Days from the date the Buyer receives the final version of such prospectus.

c. Sufficient Number of Shares Registered In the event the number of shares available under the Shelf Registration Statement is insufficient to cover the Registrable Securities, the Company shall, to the extent necessary and permissible, amend the Shelf Registration Statement or file a new registration statement (a "**New Registration Statement**"), so as to cover all of such Registrable Securities as soon as reasonably practicable, but in any event not later than ten (10) Business Days after the necessity therefor arises. The Company shall use its reasonable best efforts to have such amendment and/or New Registration Statement become effective as soon as reasonably practicable following the filing thereof.

3. RELATED OBLIGATIONS.

With respect to the Registration Statement and whenever any Registrable Securities are to be registered pursuant to Sections 2(a) and (c), including on the Shelf Registration Statement or on any New Registration Statement, the Company shall use its commercially reasonable efforts to effect the registration of the Registrable Securities in accordance with the intended method of disposition thereof and, pursuant thereto, the Company shall have the following obligations:

a. The Company shall prepare and file with the SEC such amendments (including post-effective amendments) and supplements to any Registration Statement and any New Registration Statement and any Prospectus used in connection with such Registration Statement, as may be necessary to keep the Registration Statement or any New Registration Statement effective at all times during the Registration Period, subject to Permitted Delays and Section 3(e) hereof and, during such period, comply with the provisions of the 1933 Act with respect to the disposition of all Registrable Securities of the Company covered by the Registration Statement or any New Registration Statement until such time as all of such Registrable Securities shall have been disposed of in accordance with the intended methods of disposition by the seller or sellers thereof as set forth in such Registration Statement. Should the Company file a post-effective amendment to the Registration Statement or a New Registration Statement, the Company will use its commercially reasonable efforts to have such filing declared effective by the SEC within thirty (30) consecutive Business Days following the date offiling, which such period shall be extended for an additional thirty (30) Business Days if the Company receives a comment letter from the SEC in connection therewith. If (i) there is material non-public information regarding the Company which the Company's Board of Directors reasonably determines not to be in the Company's best interest to disclose and which the Company is not otherwise required to disclose or (ii) there is a significant business opportunity (including, but not limited to, the acquisition or disposition of assets (other than in the ordinary course of business) or any merger, consolidation, tender offer or other similar transaction) available to the Company which the Company's Board of Directors reasonably determines not to be in the Company's best interest to disclose and which the Company would be required to disclose under a Registration Statement or a New Registration Statement, then the Company may postpone or suspend filing or effectiveness of such Registration Statement or New Registration Statement or use of the prospectus under the Registration Statement or New Registration Statement for a period not to exceed thirty (30) consecutive days, provided that the Company may not postpone or suspend its obligation under this Section 3(a) for more than sixty (60) days in the aggregate during any twelve (12) month period (each, a "**Permitted Delay**").

b. The Company shall submit to the Buyer for review and comment any disclosure in the Registration Statement, and all amendments and supplements thereto (other than prospectus supplements that consist only of a copy of a filed Form 10-K, Form 10-Q or Current Report on Form 8-K or any amendment as a result of the Company's filing of a document that is incorporated by reference into the Registration Statement), containing information provided by the Buyer for inclusion in such document and any descriptions or disclosure regarding the Buyer, the Purchase Agreement, including the transaction contemplated thereby, or this Agreement at least two (2) Business Days prior to their filing with the SEC, and not file any document in a form to which Buyer reasonably and timely objects. Upon request of the Buyer, the Company shall provide to the Buyer all disclosure in the Registration Statement and all amendments and supplements thereto (other than prospectus supplements that consist only of a copy of a filed Form 10-K, Form 10-Q or Current Report on Form 8-K or any amendment as a result of the Company's filing of a document that is incorporated by reference into a Registration Statement) at least two (2) Business Days prior to their filing with the SEC, and not file any document in a form to which Buyer reasonably and timely objects. The Buyer shall use its reasonable best efforts to comment upon the Registration Statement or any New Registration Statement and any amendments or supplements thereto within two (2) Business Days from the date the Buyer receives the final version thereof. The Company shall furnish to the Buyer, without charge, any correspondence from the SEC or the staff of the SEC to the Company or its representatives relating to the Registration Statement or any New Registration Statement.

c. Upon request of the Buyer, the Company shall furnish to the Buyer, (i) promptly after the same is prepared and filed with the SEC, at least one copy of the Registration Statement and any amendment(s) thereto, including all financial statements and schedules, all documents incorporated therein by reference and all exhibits, (ii) upon the effectiveness of any amendment(s) to a Registration Statement, a copy of the prospectus included in such Registration Statement and all amendments and supplements thereto (or such other number of copies as the Buyer may reasonably request) and (iii) such other documents, including copies of any preliminary or final prospectus, as the Buyer may reasonably request from time to time in order to facilitate the disposition of the Registrable Securities owned by the Buyer.

d. The Company shall use commercially reasonable efforts to (i) register and qualify, unless an exemption from registration and qualification is available, the Registrable Securities covered by a Registration Statement under such other securities or "blue sky" laws of such jurisdictions in the United States as the Buyer reasonably requests, (ii) subject to Permitted Delays, prepare and file in those jurisdictions, such amendments (including post-effective amendments) and supplements to such registrations and qualifications as may be necessary to maintain the effectiveness thereof during the Registration Period, (iii) take such other actions as may be necessary to maintain such registrations and qualifications in effect at all times during the Registration Period, and (iv) take all other actions reasonably necessary or advisable to qualify the Registrable Securities for sale in such jurisdictions; provided, however, that the Company shall not be required in connection therewith or as a condition thereto to (x) qualify to do business in any jurisdiction where it would not otherwise be required to qualify but for this Section 3(d), (y) subject itself to general taxation in any such jurisdiction, or (z) file a general consent to service of process in any such jurisdiction. The Company shall promptly notify the Buyer who holds Registrable Securities of the receipt by the Company of any notification with respect to the suspension of the registration or qualification of any of the Registrable Securities for sale under the securities or "blue sky" laws of any jurisdiction in the United States or its receipt of actual notice of the initiation or threat of any proceeding for such purpose.

e. Subject to Permitted Delays, as promptly as reasonably practicable after becoming aware of such event or facts, the Company shall notify the Buyer in writing if the Company has determined that the Prospectus included in any Registration Statement, as then in effect, includes an untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, and as promptly as reasonably practical (taking into account the Company's good faith assessment of any adverse consequences to the Company and its shareholders of premature disclosure of such event or facts) prepare a prospectus supplement or amendment to such Registration Statement to correct such untrue statement or omission, and, upon the Buyer's request, deliver a copy of such prospectus supplement or amendment to the Buyer. In providing this notice to the Buyer, the Company shall not include any other information about the facts underlying the Company's determination and shall not in any way communicate any material nonpublic information about the Company or the Common Stock to the Buyer. The Company shall also promptly notify the Buyer in writing (i) when a prospectus or any prospectus supplement or post-effective amendment has been filed, and when a Registration Statement or any post-effective amendment has become effective (notification of such effectiveness shall be delivered to the Buyer by facsimile or e-mail on the same day of such effectiveness), (ii) of any request by the SEC for amendments or supplements to any Registration Statement or related prospectus or related information, and (iii) of the Company's reasonable determination that a post-effective amendment to a Registration Statement would be appropriate. In no event shall the delivery of a notice under this Section 3(e), or the resulting unavailability of a Registration Statement, without regard to its duration, for disposition of securities by Buyer be considered a breach by the Company of its obligations under this Agreement. The preceding sentence in this Section 3(e) does not limit whether an event of default has occurred as set forth in Section 9(a) of the Purchase Agreement.

f. The Company shall use its commercially reasonable efforts to prevent the issuance of any stop order or other suspension of effectiveness of any Registration Statement, or the suspension of the qualification of any Registrable Securities for sale in any jurisdiction and, if such an order or suspension is issued, to obtain the withdrawal of such order or suspension at the earliest practical time and to notify the Buyer of the issuance of such order and the resolution thereof or its receipt of actual notice of the initiation or threat of any proceeding for such purpose.

g. The Company shall (i) cause all the Registrable Securities to be listed on each securities exchange on which securities of the same class or series issued by the Company are then listed, if any, if the listing of such Registrable Securities is then permitted under the rules of such exchange, or (ii) secure designation and quotation of all the Registrable Securities if the Principal Market (as such term is defined in the Purchase Agreement) is an automated quotation system. The Company shall pay all fees and expenses in connection with satisfying its obligation under this Section.

h. The Company shall cooperate with the Buyer to facilitate the timely preparation and delivery of certificates (not bearing any restrictive legend) representing the Registrable Securities to be offered pursuant to any Registration Statement and enable such certificates to be in such denominations or amounts as the Buyer may reasonably request and registered in such names as the Buyer may request.

i. The Company shall at all times provide a transfer agent and registrar with respect to its Common Stock.

j. If reasonably requested by the Buyer, the Company shall (i) promptly incorporate in a prospectus supplement or post-effective amendment to the Registration Statement such information as the Buyer believes should be included therein relating to the sale and distribution of Registrable Securities, including, without limitation, information with respect to the number of Registrable Securities being sold, the purchase price being paid therefor and any other terms of the offering of the Registrable Securities; (ii) make all required filings of such prospectus supplement or post-effective amendment as promptly as practicable once notified of the matters to be incorporated in such prospectus supplement or post-effective amendment; and (iii) supplement or make amendments to any Registration Statement (including by means of any document incorporated therein by reference).

k. The Company shall use itscommercially reasonable efforts to cause the Registrable Securities covered by any Registration Statement to be registered with or approved by such other governmental agencies or authorities in the United States as may be necessary to consummate the disposition of such Registrable Securities.

l. If reasonably requested by the Buyer at any time, the Company shall deliver to the Buyer a written confirmation of whether or not the effectiveness of such Registration Statement has lapsed at any time for any reason (including, without limitation, the issuance of a stop order) and whether or not the Registration Statement is currently effective and available to the Company for sale of all of the Registrable Securities.

m. The Company agrees to take all other reasonable actions as necessary and reasonably requested by the Buyer to expedite and facilitate disposition by the Buyer of Registrable Securities pursuant to any Registration Statement.

4. OBLIGATIONS OF THE BUYER.

a. The Buyer has furnished to the Company in Exhibit A hereto such information regarding itself, the Registrable Securities held by it and the intended method of disposition of the Registrable Securities held by it as required to effect the registration of such Registrable Securities and shall execute such documents in connection with such registration as the Company may reasonably request. The Company shall notify the Buyer in writing of any other information the Company reasonably requires from the Buyer in connection with any Registration Statement hereunder. The Buyer will as promptly as practicable notify the Company of any material change in the information set forth in Exhibit A, other than changes in its ownership of the Common Stock.

b. The Buyer agrees to cooperate with the Company as reasonably requested by the Company in connection with the preparation and filing of any amendments and supplements to any Registration Statement hereunder.

5. EXPENSES OF REGISTRATION.

All reasonable expenses of the Company, other than sales or brokerage commissions and fees and disbursements of counsel for the Buyer, incurred in connection with registrations, filings or qualifications pursuant to Sections 2 and 3, including, without limitation, all registration, listing and qualifications fees, printers and accounting fees, and fees and disbursements of counsel for the Company, shall be paid by the Company.

6. INDEMNIFICATION.

a. To the fullest extent permitted by law, the Company will, and hereby does, indemnify, hold harmless and defend the Buyer, each Person, if any, who controls the Buyer, the members, the directors, officers, partners, employees, agents, representatives of the Buyer and each Person, if any, who controls the Buyer within the meaning of the 1933 Act or the Securities Exchange Act of 1934, as amended (the "**1934 Act**") (each, an "**Indemnified Person**"), against any third party losses, claims, damages, liabilities, judgments, fines, penalties, charges, costs, reasonable attorneys' fees, amounts paid in settlement (with the prior consent of the Company, such consent not to be unreasonably withheld) or reasonable expenses, (collectively, "**Claims**") reasonably incurred in investigating, preparing or defending any action, claim, suit, inquiry, proceeding, investigation or appeal taken from the foregoing by or before any court or governmental, administrative or other regulatory agency or body or the SEC, whether pending or threatened, whether or not an indemnified party is or may be a party thereto ("**Indemnified Damages**"), to which any of them may become subject insofar as such Claims (or actions or proceedings, whether commenced or threatened, in respect thereof) arise out of or are based upon: (i) any untrue statement or alleged untrue statement of a material fact in the Registration Statement, any New Registration Statement or any post-effective amendment thereto or in any filing made in connection with the qualification of the offering under the securities or other "blue sky" laws of any jurisdiction in which Registrable Securities are offered ("**Blue Sky Filing**"), or the omission or alleged omission to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) any untrue statement or alleged untrue statement of a material fact contained in the final Prospectus or the omission or alleged omission to state therein any material fact necessary to make the statements made therein, in light of the circumstances under which the statements therein were made, not misleading, or (iii) any violation or alleged violation by the Company of the 1933 Act, the 1934 Act, any other law, including, without limitation, any state securities law, or any rule or regulation thereunder relating to the offer or sale of the Registrable Securities pursuant to the Registration Statement or any New Registration Statement(the matters in the foregoing clauses (i) through (iii) being, collectively, "**Violations**"). The Company shall reimburse each Indemnified Person promptly as such expenses are incurred and are due and payable, for any reasonable legal fees or other reasonable expenses incurred by them in connection with investigating or defending any such Claim. Notwithstanding anything to the contrary contained herein, the indemnification agreement contained in this Section 6(a): (A) shall not apply to a Claim by an Indemnified Person arising out of or based upon a Violation which occurs in reliance upon and in conformity with information furnished in writing to the Company by the Buyer orsuch Indemnified Person expressly for use in connection with the preparation of the Registration Statement, any New Registration Statement, the Prospectus or any such amendment thereof or supplement thereto, if such prospectus was timely made available by the Company; (B) with respect to any superseded prospectus, shall not inure to the benefit of any such person from whom the person asserting any such Claim purchased the Registrable Securities that are the subject thereof (or to the benefit of any other Indemnified Person) if the untrue statement or omission of material fact contained in the superseded prospectus was corrected in the revised prospectus, as then amended or supplemented, if such revised prospectus was timely made available by the Company pursuant to Section 3(c) or Section 3(e), and the Indemnified Person was promptly advised in writing not to use the incorrect prospectus prior to the use giving rise to a violation; (C) shall not be available to the extent such Claim is based on a failure of the Buyer to deliver, or to cause to be delivered, the prospectus made available by the Company, if such prospectus was theretofore made available by the Company pursuant to Section 3(c) or Section 3(e); and (D) shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the prior written consent of the Company, which consent shall not be unreasonably withheld. Such indemnity shall remain in full force and effect regardless of any investigation made by or on behalf of the Indemnified Person and shall survive the transfer of the Registrable Securities by the Buyer pursuant to Section 8.

b. In connection with the Registration Statement any New Registration Statement or Prospectus, the Buyer agrees to indemnify, hold harmless and defend, to the same extent and in the same manner as is set forth in Section 6(a), the Company, each of its directors, each of its officers who signed the Registration Statement or signs any New Registration Statement, each Person, if any, who controls the Company within the meaning of the 1933 Act or the 1934 Act (collectively and together with an Indemnified Person, an "**Indemnified Party**"), against any Claim or Indemnified Damages to which any of them may become subject, under the 1933 Act, the 1934 Act or otherwise, insofar as such Claim or Indemnified Damages arise out of or are based upon any Violation, in each case to the extent, and only to the extent, that such Violation occurs in reliance upon and in conformity with written information about the Buyer set forth on Exhibit A attached hereto or updated from time to time in writing by the Buyer and furnished to the Company by the Buyer expressly for inclusion in the Shelf Registration Statement or Prospectus or any New Registration Statement or from the failure of the Buyer to deliver or to cause to be delivered the prospectus made available by the Company, if such prospectus was timely made available by the Company pursuant to Section 3(c) or Section 3(e); and, subject to Section 6(d), the Buyer will reimburse any legal or other expenses reasonably incurred by them in connection with investigating or defending any such Claim; provided, however, that the indemnity agreement contained in this Section 6(b) and the agreement with respect to contribution contained in Section 7 shall not apply to amounts paid in settlement of any Claim if such settlement is effected without the prior written consent of the Buyer, which consent shall not be unreasonably withheld. Such indemnity shall remain in full force and effect and shall survive the transfer of the Registrable Securities by the Buyer pursuant to Section 8.

c. Promptly after receipt by an Indemnified Person or Indemnified Party under this Section 6 of notice of the commencement of any action or proceeding (including any governmental action or proceeding) involving a Claim, such Indemnified Person or Indemnified Party shall, if a Claim in respect thereof is to be made against any indemnifying party under this Section 6, deliver to the indemnifying party a written notice of the commencement thereof, and the indemnifying party shall have the right to participate in, and, to the extent the indemnifying party so desires, jointly with any other indemnifying party similarly noticed, to assume control of the defense thereof with counsel mutually satisfactory to the indemnifying party and the Indemnified Person or the Indemnified Party, as the case may be, and upon such notice, the indemnifying party shall not be liable to the Indemnified Person or Indemnified Party for any legal or other expenses subsequently incurred by the Indemnified Person or Indemnified Party in connection with the defense thereof; provided, however, that an Indemnified Person or Indemnified Party (together with all other Indemnified Persons and Indemnified Parties that may be represented without conflict by one counsel) shall have the right to retain its own counsel with the fees and expenses to be paid by the indemnifying party, if, in the reasonable opinion of counsel retained by the indemnifying party, the representation by such counsel of the Indemnified Person or Indemnified Party and the indemnifying party would be inappropriate due to actual or potential differing interests between such Indemnified Person or Indemnified Party and any other party represented by such counsel in such proceeding. The Indemnified Party or Indemnified Person shall cooperate with the indemnifying party in connection with any negotiation or defense of any such action or claim by the indemnifying party and shall furnish to the indemnifying party all information reasonably available to the Indemnified Party or Indemnified Person which relates to such action or claim. The indemnifying party shall keep the Indemnified Party or Indemnified Person fully apprised as to the status of the defense or any settlement negotiations with respect thereto. No indemnifying party shall be liable for any settlement of any action, claim or proceeding effected without its written consent, provided, however, that the indemnifying party shall not unreasonably withhold, delay or condition its consent. No indemnifying party shall, without the consent of the Indemnified Party or Indemnified Person, consent to entry of any judgment or enter into any settlement or other compromise which does not include as an unconditional term thereof the giving by the claimant or plaintiff to such Indemnified Party or Indemnified Person of a release from all liability in respect to such claim or litigation. Following indemnification as provided for hereunder, the indemnifying party shall be subrogated to all rights of the Indemnified Party or Indemnified Person with respect to all third parties, firms or corporations relating to the matter for which indemnification has been made. The failure to deliver written notice to the indemnifying party within a reasonable time of the commencement of any such action shall not relieve such indemnifying party of any liability to the Indemnified Person or Indemnified Party under this Section 6, except to the extent that the indemnifying party is prejudiced in its ability to defend such action.

d. The indemnification required by this Section 6 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or Indemnified Damages are incurred. Any person receiving a payment pursuant to this Section 6 which person is later determined to not be entitled to such payment shall return such payment (including reimbursement of expenses) to the person making it.

e. The indemnity agreements contained herein shall be in addition to (i) any cause of action or similar right of the Indemnified Party or Indemnified Person against the indemnifying party or others, and (ii) any liabilities the indemnifying party may be subject to pursuant to the law.

7. CONTRIBUTION.

To the extent any indemnification by an indemnifying party is prohibited or limited by law, the indemnifying party agrees to make the maximum contribution with respect to any amounts for which it would otherwise be liable under Section 6 to the fullest extent permitted by law; provided, however, that: (i) no seller of Registrable Securities guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any party who was not guilty of fraudulent misrepresentation; and (ii) contribution by any seller of Registrable Securities shall be limited in amount to the net amount of proceeds received by such seller from the sale of such Registrable Securities.

8. ASSIGNMENT OF REGISTRATION RIGHTS.

The Company shall not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Buyer; provided, however, that any transaction, whether by merger, reorganization, restructuring, consolidation, financing or otherwise, whereby the Company remains the surviving entity immediately after such transaction shall not be deemed an assignment. The Buyer may not assign its rights under this Agreement without the prior written consent of the Company.

9. AMENDMENT OF REGISTRATION RIGHTS.

Provisions of this Agreement may be amended and the observance thereof may be waived (either generally or in a particular instance and either retroactively or prospectively) only with the written consent of the Company and the Buyer.

10. MISCELLANEOUS.

a. Any notices, consents, waivers or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered: (i) upon receipt, when delivered personally; (ii) upon receipt, when sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); (iii) upon receipt, when sent by electronic message (provided the recipient responds to the message and confirmation of both electronic messages are kept on file by the sending party); or (iv) one (1) Business Day after timely deposit with a nationally recognized overnight delivery service, in each case properly addressed to the party to receive the same. The addresses and facsimile numbers for such communications shall be:

If to the Company:

Recro Pharma, Inc.
490 Lapp Road
Malvern, PA 19355
Telephone: 484-395-2470
Facsimile: 484-395-2471
Attention: Michael Celano
Email: mcelano@recropharma.com

With a copy (which shall not constitute notice) to:

Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103
Telephone: 215-981-4331
Facsimile: 215-981-4750
Attention: Rachael M. Bushey
Email: busheyr@pepperlaw.com

If to the Buyer:

Aspire Capital Fund, LLC
155 North Wacker Drive, Suite 1600
Chicago, IL 60606
Telephone: 312-658-0400
Facsimile: 312-658-4005
Attention: Steven G. Martin
Email: smartin@aspirecapital.com

With a copy (which shall not constitute notice) to:

Morrison & Foerster LLP

2000 Pennsylvania Avenue, NW, Suite 6000
Washington, DC 20006
Telephone: 202-778-1611
Facsimile: 202-887-0763
Attention: Martin P. Dunn, Esq.
Email: mdunn@mofo.com

or at such other address and/or facsimile number and/or to the attention of such other person as the recipient party has specified by written notice given to each other party at least one (1) Business Day prior to the effectiveness of such change. Written confirmation of receipt (A) given by the recipient of such notice, consent, waiver or other communication, (B) mechanically or electronically generated by the sender's facsimile machine containing the time, date, and recipient facsimile number, (C) electronically generated by the sender's electronic mail containing the time, date and recipient email address or (D) provided by a nationally recognized overnight delivery service, shall be rebuttable evidence of receipt in accordance with clause (i), (ii), (iii) or (iv) above, respectively. Any party to this Agreement may give any notice or other communication hereunder using any other means (including messenger service, ordinary mail or electronic mail), but no such notice or other communication shall be deemed to have been duly given unless it actually is received by the party for whom it is intended.

b. No failure or delay in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other right, power or privilege.

c. The corporate laws of the Commonwealth of Pennsylvania shall govern all issues concerning the relative rights of the Company and its shareholders. All other questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by the internal laws of the State of Illinois, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Illinois or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Illinois. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of Chicago for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of any provision of this Agreement in any other jurisdiction. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUE JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OU AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

d. This Agreement, the Purchase Agreement and the other Transaction Documents constitute the entire understanding among the parties hereto with respect to the subject matter hereof and thereof. There are no restrictions, promises, warranties or undertakings, other than those set forth or referred to herein and therein. This Agreement, the Purchase Agreement and the other Transaction Documents supersede all other prior oral or written agreements between the Buyer, the Company, their affiliates and persons acting on their behalf with respect to the subject matter hereof and thereof.

e. Subject to the requirements of Section 8, this Agreement shall inure to the benefit of and be binding upon the permitted successors and assigns of each of the parties hereto.

f. The headings in this Agreement are for convenience of reference and shall not form part of, or affect the interpretation of, this Agreement.

g. This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party; provided that a facsimile or pdf (or other electronic reproduction of a) signature shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original, not a facsimile or pdf (or other electronic reproduction of a) signature.

h. Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

i. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent and no rules of strict construction will be applied against any party.

j. This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

* * * * * *

IN WITNESS WHEREOF, the parties have caused this Registration Rights Agreement to be duly executed as of day and year first above written.

THE COMPANY:

RECRO PHARMA, INC.

By: /s/ Geraldine A. Henwood
Name: Geraldine A. Henwood
Title: Chief Executive Officer

BUYER:

ASPIRE CAPITAL FUND, LLC

BY: ASPIRE CAPITAL PARTNERS, LLC
BY: CHRISKO INVESTORS INC.

By: /s/ Christos Komissopoulos
Name: Christos Komissopoulos
Title: President

EXHIBIT A

Information About The Buyer Furnished To The Company By The Buyer Expressly For Use In Connection With The Registration Statement and Prospectus

Aspire Capital Partners LLC (“Aspire Partners”) is the Managing Member of Aspire Capital Fund LLC (“Aspire Fund”). SGM Holdings Corp (“SGM”) is the Managing Member of Aspire Partners. Mr. Steven G. Martin (“Mr. Martin”) is the president and sole shareholder of SGM, as well as a principal of Aspire Partners. Mr. Erik J. Brown (“Mr. Brown”) is the president and sole shareholder of Red Cedar Capital Corp (“Red Cedar”), which is a principal of Aspire Partners. Mr. Christos Komissopoulos (“Mr. Komissopoulos”) is president and sole shareholder of Chrisko Investors Inc. (“Chrisko”), which is a principal of Aspire Partners. Mr. William F. Blank, III (“Mr. Blank”) is president and sole shareholder of WML Ventures Corp. (“WML Ventures”), which is a principal of Aspire Partners. Each of Aspire Partners, SGM, Red Cedar, Chrisko, WML Ventures, Mr. Martin, Mr. Brown, Mr. Komissopoulos and Mr. Blank may be deemed to be a beneficial owner of common stock held by Aspire Fund. Each of Aspire Partners, SGM, Red Cedar, Chrisko, WML Ventures, Mr. Martin, Mr. Brown, Mr. Komissopoulos and Mr. Blank disclaims beneficial ownership of the common stock held by Aspire Fund.

Exhibit 5.1

Pepper Hamilton LLP
Attorneys at Law

3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799
215.981.4000
Fax 215.981.4750

March 2, 2018

Board of Directors of Recro Pharma, Inc.
490 Lapp Road
Malvern, Pennsylvania 19355

Ladies and Gentlemen:

We are acting as counsel to Recro Pharma, Inc., a Pennsylvania corporation (the "**Company**"), in connection with the Company's issuance of up to $20,000,000 of shares (the "**Purchase Shares**") of the Company's common stock, par value $0.01 per share (the "**Common Stock**"), and an addition 33,040 shares of Common Stock (the "**Commitment Shares**", and together with the Purchase Shares, the "**Shares**"), pursuant to that certain Common Stock Purchase Agreement, dated March 2, 2018 (the "**Agreement**"), by and between the Company and Aspire Capital Fund, LLC ("**Aspire**"). The Shares will be sold by the Company pursuant to the Company's registration statement on Form S-3 under the Securities Act of 1933, as amended (the "**Act**"), filed with the Securities and Exchange Commission (the "**Commission**") on June 2, 2017 and declared effective by the Commission on June 12, 2017 (the "**Registration Statement**"), a base prospectus dated June 12, 2017 (the "**Base Prospectus**") and a final prospectus supplement dated March 2, 2018 (together with the Base Prospectus, the "**Prospectus**"). This opinion letter is furnished to you at your request to enable you to fulfill the requirements of Item 601(b)(5) of Regulation S-K, 17 C.F.R. § 229.601(b)(5), in connection with the issuance of the Shares.

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

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

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

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

We hereby consent to the filing of this opinion letter as Exhibit 5.1 to the above-described Form10-K and to the reference to this firm under the caption “Legal Matters” in the Prospectus. In giving this consent, we do not thereby admit that we are an “expert” within the meaning of the Act.

Very truly yours,

/S/ PEPPER HAMILTON LLP

PEPPER HAMILTON LLP

Exhibit 10.20

Recro Pharma, Inc.
Award Agreement for
[ ]

We are pleased to advise you that Recro Pharma, Inc. (the "Company") hereby awards to you Restricted Stock Units, subject to your signing this Award Agreement (this " Agreement"). The date of award of the Restricted Stock Units shall for all purposes be [__________], 201[__] (the "Grant Date").

The Company maintains the Recro Pharma, Inc. Amended and Restated Equity Incentive Plan (the "Plan"), which provides the general terms and restrictions for certain equity incentive awards to the Company's employees, consultants and directors. These Restricted Stock Units are not awarded pursuant to the Plan, but rather are intended to constitute a non-plan based "inducement grant," as described in Nasdaq Listing Rule 5635(c)(4). Nonetheless, the terms and provisions of the Plan are hereby incorporated into this Agreement by this reference, as though fully set forth herein, as if this award was granted pursuant to the Plan.

All capitalized terms used but not defined herein will have the meanings ascribed to them in the Plan. In addition to the terms, conditions and restrictions set forth in the Plan, all terms, conditions and restrictions set forth in this Agreement are applicable to the award of Restricted Stock Units as evidenced hereby:

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

2. Grant of Restricted Stock Units . As of the Grant Date, the Company hereby awards to you the number of Restricted Stock Units set forth on the Grant Schedule (the "Award"), subject to the restrictions and on the terms and conditions set forth in this Agreement

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

4. Performance Target. To the extent that the Grant Schedule includes a performance-based target, the Grant Schedule will specify the extent to which the Restricted Stock Units will be forfeited for failure to achieve the performance-based target.

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

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

7. Termination of Employment. In the event of your termination of service with the Company and its Affiliates that is a "separation from service" within the meaning of section 409A of the Code and applicable Treasury Regulations issued under section 409A, all unvested Restricted Stock Units will vest or be forfeited according to the terms and conditions of the Grant Schedule, unless your employment agreement provides for a result that is more favorable to you. To the extent compliance with the requirements of Treasury Regulation § 1.409A-3(i)(2) is necessary to avoid the application of an additional tax under section 409A of the Code to the issuance of Shares to you, then any issuance of Shares to you that would otherwise be made during the six-month period beginning on the date of such termination will be deferred and delivered to you immediately following the lapse of such six-month period.

8. Issuance of Shares.

a. Unless otherwise set forth on the Grant Schedule, within thirty (30) days following each Vesting Date (including any accelerated vesting date provided in the Grant Schedule or pursuant to the your employment agreement), the Company shall issue to the you, either by book-entry registration or issuance of a stock certificate or certificates, a number of Shares equal to the number of Restricted Stock Units granted hereunder that have vested as of such date. Any Shares issued to you hereunder shall be fully paid and non-assessable.

b. The Company may require as a condition of the issuance of Shares, pursuant to Section 8(a) hereof, that you remit to the Company an amount sufficient in the opinion of the Company to satisfy any federal, state and other governmental tax withholding requirements related to the issuance of such shares. The Committee, in its sole discretion, may permit you to satisfy such obligation by delivering shares of Common Stock or by directing the Company to withhold from delivery shares of Common Stock, in either case valued at their Fair Market Value on the applicable issuance date, with fractional shares being settled in cash .

c. You will not be deemed for any purpose to be, or have rights as, a stockholder of the Company by virtue of the grant of Restricted Stock Units, until shares of Common Stock are issued in settlement of such Restricted Stock Units pursuant to Section 8(a) hereof. Upon the issuance of a stock certificate or the making of an appropriate book entry on the books of the transfer agent, you will have all of the rights of a stockholder.

d. With respect to any grant of Restricted Stock Units that vests in whole or in part based on the Company's achievement of financial or operating results, if it is determined by the Committee that gross negligence, intentional misconduct or fraud you caused or partially caused the Company to restate all or a portion of its financial statements, the Committee shall, to the extent permitted by law, require repayment of Shares delivered pursuant to the vesting of the Restricted Stock Units, and/or effect the cancellation of unvested Restricted Stock Units, if (i) the vesting of the Award was calculated based upon, or contingent on, the achievement of financial or operating results that were the subject of or affected by the restatement, and (ii) the extent of vesting of the Award would have been less had the financial statements been correct. The required repayment or cancellation shall be such as will put you in the same position relative to vesting of the Award as you would have been in had the financial statements been correct.

9. Securities Matters. The Company shall be under no obligation to effect the registration pursuant to the Securities Act of 1933, as amended (the "1933 Act") of any interests in the Plan or any Shares to be issued thereunder or to effect similar compliance under any state laws. The Company shall not be obligated to cause to be issued any Shares, whether by means of stock certificates or appropriate book entries, unless and until the Company is advised by its counsel that the issuance of such Shares is in compliance with all applicable laws, regulations of governmental authority and the requirements of any securities exchange on which Shares are traded. The Committee may require, as a condition of the issuance of Shares pursuant to the terms hereof, that the recipient of such Shares make such covenants, agreements and representations, and that any certificates bear such legends and any book entries be subject to such electronic coding or stop order, as the Committee, in its sole discretion, deems necessary or desirable. You specifically understand and agree that the Shares, if and when issued, may be "restricted securities," as that term is defined in Rule 144 under the 1933 Act and, accordingly, you may be required to hold the shares indefinitely unless they are registered under the 1933 Act or an exemption from such registration is available.

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

11. Withholding. The Company reserves the right to withhold, in accordance with any applicable laws, from any consideration payable or property transferable you any taxes required to be withheld by federal, state or local law as a result of the grant or vesting of this Award or other disposition of the Shares.

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

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

14. Governing Law. This Agreement and all claims or causes of action (whether in contract or tort) that may be based upon, arise out of or relate to this Agreement or

the negotiation, execution or performance of this Agreement (including any claim or cause of action based upon, arising out of or related to any representation or warranty made in or in connection with this Agreement or as an inducement to enter this Agreement) shall be governed by, and enforced in accordance with, the laws of the Commonwealth of Pennsylvania, without regard to the application of the principles of conflicts of laws.

15. No Right of Continued Employment. Nothing contained in the Plan or this Agreement shall restrict the right of the Company and/or its affiliates to terminate your employment or service. Any termination of your employment or service, regardless of the reason therefor, shall have the consequences provided for in the Plan and this Agreement with respect to your rights under the Plan.

16. Amendment. This Agreement may be amended, in whole or in part and in any manner not inconsistent with the provisions of the Plan, at any time and from time to time, by written agreement between the Company and you.

17. Notice. Any notice to be given to the Company shall be in writing and either hand delivered or mailed to the office of the President of the Company. If mailed, it shall be addressed to the Company at 490 Lapp Road, Malvern, PA 19355. Any notice given to you shall be addressed to you at your address as reflected in the personnel records of the Company, or at such other address as either party hereto may hereafter designate by like notice to the other. Notice shall be deemed to have been duly delivered when hand delivered or, if mailed, on the fifth day after such notice is postmarked.

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

RECRO PHARMA, INC.

By: ______________________________________
Gerri Henwood, President / Chief Executive Officer

In order to indicate your acceptance of the award of Restricted Stock Units granted by this Agreement subject to the restrictions and upon the terms and conditions set forth above and in the Plan, please execute and immediately return to the Company the enclosed duplicate original of this Agreement.

ACCEPTED AND AGREED,
Intending to be legally bound:

[NAME OF GRANTEE]

Date

Grant Schedule

Grantee's name:

Grant Date:

1. Number of Restricted Stock Units granted:

2. Target Number of Restricted Stock Units granted:

3. Vesting Date:

If a Change of Control occurs, any outstanding Restricted Stock Units that are then still subject to vesting conditions shall become vested as of the date of such Change of Control, provided the Grantee remains an employee of the Company through such date. If the Grantee terminates employment with the Company by reason of the Grantee's death or Disability, the Restricted Stock Units will remain outstanding during the applicable performance period and will vest in full based on satisfaction of the applicable performance goal.

Unless otherwise provided for above, if the Grantee's employment with the Company and its Affiliates terminates or is terminated for any other reason, any Restricted Stock Units that are then still subject to vesting conditions as of such date shall be immediately forfeited with no other compensation due to the Grantee.

A number of Shares equal to the number of vested Restricted Stock Units shall be issued to the Grantee, either by book-entry registration or issuance of a stock certificate or certificates, as soon as administratively practicable following the Vesting Date, but in no event later than 2½ months following the end of the calendar year containing the applicable Vesting Date. Notwithstanding the foregoing, to the extent the Restricted Stock Units become vested as a result of Change of Control, a number of Stock Award Shares equal to such units will be issued to the Grantee not later than thirty (30) days following the date of such Change of Control.

Notwithstanding the foregoing, no Restricted Stock Units subject to this Agreement shall vest unless the Grantee has complied with all applicable provisions of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended (the "HSR Act"). If the Restricted Stock Units subject to this Agreement would have vested pursuant to this Agreement but did not vest solely because the Grantee was not in compliance with all applicable provisions of the HSR Act, the Vesting Date and the Share issuance date for such Restricted Stock Units shall occur on the first date following the date on which such Restricted Stock Units would otherwise have vested pursuant to this Agreement on which the Grantee has complied with all applicable provisions of the HSR Act.

COMMON STOCK PURCHASE AGREEMENT

COMMON STOCK PURCHASE AGREEMENT (the "**Agreement**"), dated as of March 2, 2018, by and between **RECRO PHARMA, INC.**, a Pennsylvania corporation (the "**Company**"), and **ASPIRE CAPITAL FUND, LLC**, an Illinois limited liability company (the "**Buyer**"). Capitalized terms used herein and not otherwise defined herein are defined in Section 10 hereof.

WHEREAS:

Subject to the terms and conditions set forth in this Agreement, the Company wishes to sell to the Buyer, and the Buyer wishes to buy from the Company, up to Twenty Million Dollars ($20,000,000) of the Company's common stock, par value $0.01 per share (the "**Common Stock**"). The shares of Common Stock to be purchased hereunder are referred to herein as the "**Purchase Shares**."

NOW THEREFORE, the Company and the Buyer hereby agree as follows:

1. PURCHASE OF COMMON STOCK.

Subject to the terms and conditions set forth in this Agreement, the Company has the right to sell to the Buyer, and the Buyer has the obligation to purchase from the Company, Purchase Shares as follows:

(a) Commencement of Purchases of Common Stock. Immediately upon Commencement (as defined below), the purchase and sale of Purchase Shares hereunder shall occur from time to time upon written notices by the Company to the Buyer on the terms and conditions as set forth herein following the satisfaction of the conditions (the "**Commencement**") as set forth in Sections 6 and 7 below (the date of satisfaction of such conditions, the "**Commencement Date**").

(b) The Company's Right to Require Regular Purchases. Subject to the terms and conditions of this Agreement, on any given Business Day after the Commencement Date, the Company shall have the right but not the obligation to direct the Buyer by its delivery to the Buyer of a Purchase Notice from time to time, and the Buyer thereupon shall have the obligation, to buy the number of Purchase Shares specified in such notice, up to a maximum of 75,000 Purchase Shares, on such Business Day (as long as such notice is delivered on or before 5:00 p.m. Eastern time on such Business Day) (each such purchase, a "**Regular Purchase**") at the Purchase Price on the Purchase Date; however, in no event shall the Purchase Amount of a Regular Purchase exceed Five Hundred Thousand Dollars ($500,000) per Business Day, unless the Buyer and the Company mutually agree. The Company and the Buyer may mutually agree to increase the number of Purchase Shares that may be sold per a Regular Purchase to as much as an additional 2,000,000 Purchase Shares per Business Day. The Company may deliver additional Purchase Notices to the Buyer from time to time so long as the most recent purchase has been completed. The share amounts in the first sentence of this Section 1(b) shall be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split, or other similar transaction.

(c) VWAP Purchases. Subject to the terms and conditions of this Agreement, in addition to purchases of Purchase Shares as described in Section 1(b) above, with one Business Day's prior written notice (as long as such notice is delivered on or before 5:00 p.m. Eastern time on the Business Day immediately preceding the VWAP Purchase Date), the Company shall also have the right but not the obligation to direct the Buyer by the Company's delivery to the Buyer of a VWAP Purchase Notice from time to time, and the Buyer thereupon shall have the obligation, to buy the VWAP Purchase Share Percentage of the trading volume of the Common Stock on the VWAP Purchase Date up to the VWAP Purchase Share Volume Maximum on the VWAP Purchase Date (each such purchase, a "**VWAP Purchase**") at the VWAP Purchase Price. The Company may deliver a VWAP Purchase Notice to the Buyer on or before 5:00 p.m. Eastern time on a date on which the Company also submitted a Purchase Notice for a Regular Purchase of at least 75,000 Purchase Shares to the Buyer. The share amount in the prior sentence shall be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split, or other similar transaction. A VWAP Purchase shall automatically be deemed completed at such time on the VWAP Purchase Date that the Sale Price falls below the VWAP Minimum Price Threshold; in such circumstance, the VWAP Purchase Amount shall be calculated using (i) the VWAP Purchase Share Percentage of the aggregate shares traded on the Principal Market for such portion of the VWAP Purchase Date prior to the time that the Sale Price fell below the VWAP Minimum Price Threshold and (ii) a VWAP Purchase Price calculated using the volume weighted average price of Common Stock sold during such portion of the VWAP Purchase Date prior to the time that the Sale Price fell below the VWAP Minimum Price Threshold. Each VWAP Purchase Notice must be accompanied by instructions to the Company's Transfer Agent to immediately issue to the Buyer an amount of Common Stock equal to the VWAP Purchase Share Estimate, a good faith estimate by the Company of the number of Purchase Shares that the Buyer shall have the obligation to buy pursuant to the VWAP Purchase Notice. In no event shall the

Buyer, pursuant to any VWAP Purchase, purchase a number of Purchase Shares that exceeds the VWAP Purchase Share Estimate issued on the VWAP Purchase Date in connection with such VWAP Purchase Notice; however, the Buyer will immediately return to the Company any amount of Common Stock issued pursuant to the VWAP Purchase Share Estimate that exceeds the number of Purchase Shares the Buyer actually purchases in connection with such VWAP Purchase. Upon completion of each VWAP Purchase Date, the Buyer shall submit to the Company a confirmation of the VWAP Purchase in form and substance reasonably acceptable to the Company. The Company may deliver additional VWAP Purchase Notices to the Buyer from time to time so long as the most recent purchase has been completed. The Company may, by written notice to the Buyer, in its sole discretion at any time after the date of this Agreement, irrevocably terminate this Section 1(c) and its right to direct the Buyer to make VWAP Purchases.

(d) Payment for Purchase Shares. For each Regular Purchase, the Buyer shall pay to the Company an amount equal to the Purchase Amount as full payment for such Purchase Shares via wire transfer of immediately available funds on the same Business Day that the Buyer receives such Purchase Shares. For each VWAP Purchase, the Buyer shall pay to the Company an amount equal to the VWAP Purchase Amount as full payment for such Purchase Shares via wire transfer of immediately available funds on the second Business Day following the VWAP Purchase Date. All payments made under this Agreement shall be made in lawful money of the United States of America via wire transfer of immediately available funds to such account as the Company may from time to time designate by written notice in accordance with the provisions of this Agreement. Whenever any amount expressed to be due by the terms of this Agreement is due on any day that is not a Business Day, the same shall instead be due on the next succeeding day that is a Business Day.

(e) Purchase Price Floor. The Company and the Buyer shall not effect any sales under this Agreement on any Purchase Date where the Closing Sale Price is less than the Floor Price. "**Floor Price**" means $0.50 per share of Common Stock, which shall be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar transaction.

(f) Records of Purchases. The Buyer and the Company shall each maintain records showing the remaining Available Amount at any given time and the dates and Purchase Amounts for each purchase, or shall use such other method reasonably satisfactory to the Buyer and the Company to reconcile the remaining Available Amount.

(g) Taxes. The Company shall pay any and all transfer, stamp or similar taxes that may be payable with respect to the issuance and delivery of any shares of Common Stock to the Buyer made under this Agreement.

(h) Compliance with Principal Market Rules. Notwithstanding anything in this Agreement to the contrary, and in addition to the limitations set forth in Section 1(e), the total number of shares of Common Stock that may be issued under this Agreement, including the Commitment Shares (as defined in Section 4(e) hereof), shall be limited to 3,829,455 shares of Common Stock (the "**Exchange Cap**"), which equals 19.99% of the Company's outstanding shares of Common Stock as of the date hereof, unless shareholder approval is obtained to issue more than such 19.99%. The Exchange Cap shall be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split or similar transaction. The foregoing limitation shall not apply if shareholder approval has not been obtained and at any time the Exchange Cap is reached and at all times thereafter the average price paid for all shares of Common Stock issued under this Agreement is equal to or greater than $9.98 (the "**Minimum Price**"), a price equal to the consolidated closing bid price on the Business Day prior to the date hereof (in such circumstance, for purposes of the Principal Market, the transaction contemplated hereby would not be "below market" and the Exchange Cap would not apply). The Minimum Price shall be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar transaction. Notwithstanding anything to the contrary in this Agreement or otherwise, the Company shall not be required or permitted to issue, and the Buyer shall not be required to purchase, any shares of Common Stock under this Agreement if such issuance would breach the Company's obligations under the rules or regulations of the Principal Market. The Company may, in its sole discretion, determine whether to obtain shareholder approval to issue more than 19.99% of its outstanding shares of Common Stock hereunder if such issuance would require shareholder approval under the rules or regulations of the Principal Market.

(i) Beneficial Ownership Limitation. The Company shall not issue and the Buyer shall not purchase any shares of Common Stock under this Agreement if such shares proposed to be issued and sold, when aggregated with all other shares of Common Stock then owned beneficially (as calculated pursuant to Section 13(d) of the Securities Exchange Act of 1934, as amended (the "**1934 Act**") and Rule 13d-3 promulgated thereunder) by the Buyer and its affiliates would result in the beneficial ownership by the Buyer and its affiliates of more than 19.99% of the then issued and outstanding shares of Common Stock of the Company.

2. BUYER'S REPRESENTATIONS AND WARRANTIES.

The Buyer represents and warrants to the Company that as of the date hereof and as of the Commencement Date:

(a) Investment Purpose. The Buyer is entering into this Agreement and acquiring the Commitment Shares and the Purchase Shares (the Purchase Shares and the Commitment Shares are collectively referred to herein as the "**Securities**"), for its own account for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof; provided however, by making the representations herein, the Buyer does not agree to hold any of the Securities for any minimum or other specific term.

(b) Accredited Investor Status. The Buyer is an "accredited investor" as that term is defined in Rule 501(a)(3) of Regulation D under the 1933 Act.

(c) [Intentionally Omitted.]

(d) Information. The Buyer has been furnished with all materials relating to the business, finances and operations of the Company and materials relating to the offer and sale of the Securities that have been reasonably requested by the Buyer, including, without limitation, the SEC Documents (as defined in Section 3(f) hereof). The Buyer understands that its investment in the Securities involves a high degree of risk. The Buyer (i) is able to bear the economic risk of an investment in the Securities including a total loss, (ii) has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of the proposed investment in the Securities and (iii) has had an opportunity to ask questions of and receive answers from the officers of the Company concerning the financial condition and business of the Company and other matters related to an investment in the Securities. Neither such inquiries nor any other due diligence investigations conducted by the Buyer or its representatives shall modify, amend or affect the Buyer's right to rely on the Company's representations and warranties contained in Section 3 below. The Buyer has sought such accounting, legal and tax advice as it has considered necessary to make an informed investment decision with respect to its acquisition of the Securities.

(e) No Governmental Review. The Buyer understands that no United States federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Securities or the fairness or suitability of the investment in the Securities nor have such authorities passed upon or endorsed the merits of the offering of the Securities.

(f) [Intentionally Omitted.]

(g) Organization. The Buyer is a limited liability company duly organized and validly existing in good standing under the laws of the jurisdiction in which it is organized, and has the requisite organizational power and authority to own its properties and to carry on its business as now being conducted.

(h) Validity; Enforcement. This Agreement has been duly and validly authorized, executed and delivered on behalf of the Buyer and is a valid and binding agreement of the Buyer enforceable against the Buyer in accordance with its terms, subject as to enforceability to (i) general principles of equity and to applicable bankruptcy, insolvency, reorganization, moratorium, liquidation and other similar laws relating to, or affecting generally, the enforcement of applicable creditors' rights and remedies and (ii) public policy underlying any law, rule or regulation (including any federal or state securities law, rule or regulation) with regards to indemnification, contribution or exculpation. The execution and delivery of the Transaction Documents (as defined in Section 3(b) hereof) by the Buyer and the consummation by it of the transactions contemplated hereby and thereby do not conflict with the Buyer's certificate of organization or operating agreement or similar documents, and do not require further consent or authorization by the Buyer, its managers or its members.

(i) Residency. The Buyer is a resident of the State of Illinois.

(j) No Prior Short Selling. The Buyer represents and warrants to the Company that at no time prior to the date of this Agreement has any of the Buyer, its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any (i) "short sale" (as such term is defined in Section 242.200 of Regulation SHO of the 1934 Act) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.

3. REPRESENTATIONS AND WARRANTIES OF THE COMPANY.

The Company represents and warrants to the Buyer that as of the date hereof and as of the Commencement Date:

(a) Organization and Qualification. The Company and its "Subsidiaries" (which for purposes of this Agreement means any entity in which the Company, directly or indirectly, owns more than 50% of the voting stock or capital stock or other similar equity interests) are corporations or limited liability companies duly organized and validly existing in good standing under the laws of the jurisdiction in which they are incorporated or organized, and have the requisite corporate or organizational power and authority to own their properties and to carry on their business as now being conducted. Each of the Company and its Subsidiaries is duly qualified as a foreign corporation or limited liability company to do business and is in good standing in every jurisdiction in which its ownership of property or the nature of the business conducted by it makes such qualification necessary, except to the extent that the failure to be so qualified or be in good standing could not reasonably be expected to have a Material Adverse Effect. As used in this Agreement, "**Material Adverse Effect**" means any material adverse effect on any of: (i) the business, properties, assets, operations, results of operations or financial condition of the Company and its Subsidiaries, if any, taken as a whole, or (ii) the authority or ability of the Company to perform its obligations under the Transaction Documents (as defined in Section 3(b) hereof). The Company has no material Subsidiaries except as set forth on Section 3(a) of the disclosure letter delivered by the Company to Buyer pursuant to this Agreement (the "**Disclosure Letter**").

(b) Authorization; Enforcement; Validity. (i) The Company has the requisite corporate power and authority to enter into and perform its obligations under this Agreement, the Registration Rights Agreement (as defined in Section 4(a) hereof) and each of the other agreements entered into by the parties on the Commencement Date and attached hereto as exhibits to this Agreement (collectively, the "**Transaction Documents**"), and to issue the Securities in accordance with the terms hereof and thereof, (ii) the execution and delivery of the Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby, including without limitation, the issuance of the Commitment Shares and the reservation for issuance and the issuance of the Purchase Shares issuable under this Agreement, have been duly authorized by the Company's Board of Directors or duly authorized committee thereof, do not conflict with the Company's Articles of Incorporation or Bylaws (as defined below), and do not require further consent or authorization by the Company, its Board of Directors, except as set forth in this Agreement, or its shareholders (other than as contemplated by Section 1(h) hereof), (iii) this Agreement has been, and each other Transaction Document shall be on the Commencement Date, duly executed and delivered by the Company and (iv) this Agreement constitutes, and each other Transaction Document upon its execution on behalf of the Company, shall constitute, the valid and binding obligations of the Company enforceable against the Company in accordance with their terms, except as such enforceability may be limited by (y) general principles of equity or applicable bankruptcy, insolvency, reorganization, moratorium, liquidation or similar laws relating to, or affecting generally, the enforcement of creditors' rights and remedies and (z) public policy underlying any law, rule or regulation (including any federal or state securities law, rule or regulation) with regards to indemnification, contribution or exculpation. The Board of Directors of the Company or duly authorized committee thereof has approved the resolutions (the "**Signing Resolutions**") substantially in the form as set forth as **Exhibit B** attached hereto to authorize this Agreement and the transactions contemplated hereby. The Signing Resolutions are valid, in full force and effect and have not been modified or supplemented in any material respect. The Company has delivered to the Buyer a true and correct copy of the Signing Resolutions as approved by the Board of Directors of the Company.

(c) Capitalization. As of the date hereof, the authorized capital stock of the Company consists of (i) 50,000,000 shares of Common Stock, par value $0.01, of which as of the date hereof, 19,156,851 shares are issued and outstanding, zero shares are held as treasury shares, 4,184,358 shares are issuable upon the exercise of stock options outstanding, 486,598 shares are issuable upon the vesting and settlement of restricted stock units outstanding; 509,985 shares of Common Stock are reserved and available for future issuance under the Company's Amended and Restated Equity Incentive Plan and its 2008 Stock Option Plan; and 1,133,592 shares of Common Stock are issuable upon the exercise of outstanding warrants, and (ii) 10,000,000 shares of preferred stock, of which as of the date hereof zero shares are issued and outstanding. All of such outstanding shares have been, or upon issuance will be, validly issued and are fully paid and non-assessable. Except as disclosed in Section 3(c) of the Disclosure Letter, (i) no shares of the Company's capital stock are subject to preemptive rights or any other similar rights or any liens or encumbrances suffered or permitted by the Company, (ii) there are no outstanding debt securities of the Company or any of its Subsidiaries, (iii) there are no outstanding options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, or contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to issue additional shares of capital stock of the Company or any of its Subsidiaries or options, warrants, scrip, rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities or rights convertible into, any shares of capital stock of the Company or any of its Subsidiaries, (iv) there are no material agreements or arrangements under which the Company or any of its Subsidiaries is obligated to register the sale of any of their securities under the 1933 Act (except the Registration Rights Agreement), (v) there are no outstanding securities or instruments of the Company or any of its Subsidiaries which contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any of its Subsidiaries is or may become bound to redeem a security of the Company or any of its Subsidiaries, (vi) there are no securities or instruments containing anti-dilution or similar provisions that will be triggered by the issuance of the Securities as described in this Agreement and (vii) the Company does not have any stock appreciation rights or "phantom stock" plans or agreements or any similar plan or agreement. The Company has furnished or made available to the Buyer true and correct copies of the Company's Second Amended and Restated Articles of Incorporation, as in effect on the date hereof (the "**Articles of Incorporation**"), and the Company's Third Amended and Restated Bylaws, as in effect on the date hereof (the "**Bylaws**").

(d) Issuance of Securities. The Commitment Shares have been duly authorized and, upon issuance in accordance with the terms hereof, the Commitment Shares shall be (i) validly issued, fully paid and non-assessable and (ii) free from all taxes, liens and charges with respect to the issuance thereof. Upon issuance and payment therefore in accordance with the terms and conditions of this Agreement, the Purchase Shares shall be validly issued, fully paid and non-assessable and free from all taxes, liens and charges with respect to the issue thereof, with the holders being entitled to all rights accorded to a holder of Common Stock.

(e) No Conflicts. The execution, delivery and performance of the Transaction Documents by the Company and the consummation by the Company of the transactions contemplated hereby and thereby (including, without limitation, the reservation for issuance and issuance of the Purchase Shares) will not (i) result in a violation of the Articles of Incorporation, any Certificate of Designations, Preferences and Rights of any outstanding series of preferred stock of the Company, or the Bylaws or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default) under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Company or any of its Subsidiaries is a party, or result, to the Company's knowledge, in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities laws and regulations and the rules and regulations of the Principal Market applicable to the Company or any of its Subsidiaries) or by which any property or asset of the Company or any of its Subsidiaries is bound or affected, except in the case of conflicts, defaults, terminations, amendments, accelerations, cancellations and violations under clause (ii), which could not reasonably be expected to result in a Material Adverse Effect. Neither the Company nor its Subsidiaries is in violation of any term of or in default under its Articles of Incorporation, including any Certificate of Designation, Preferences and Rights of any outstanding series of preferred stock of the Company, or Bylaws or their organizational charter or bylaws, respectively. Neither the Company nor any of its Subsidiaries is in violation of any term of or is in default under any material contract, agreement, mortgage, indebtedness, indenture, instrument, judgment, decree or order or any statute, rule or regulation applicable to the Company or its Subsidiaries, except for possible violations, defaults, terminations or amendments that could not reasonably be expected to have a Material Adverse Effect. The business of the Company and its Subsidiaries is not being conducted, and shall not be conducted, in violation of any law, ordinance, or regulation of any governmental entity, except for possible violations, the sanctions for which either individually or in the aggregate could not reasonably be expected to have a Material Adverse Effect. Except as specifically contemplated by this Agreement, reporting obligations under the 1934 Act or as required under the 1933 Act or applicable state securities laws or the filing of a Listing of Additional Shares Notification Form with the Principal Market, the Company is not required to obtain any consent, authorization or order of, or make any filing or registration with, any court or governmental agency or any regulatory or self-regulatory agency in order for it to execute, deliver or perform any of its obligations under or contemplated by the Transaction Documents in accordance with the terms hereof or thereof. Except for reporting obligations under the 1934 Act, all consents, authorizations, orders, filings and registrations which the Company is required to obtain pursuant to the preceding sentence shall be obtained or effected on or prior to the Commencement Date. The Company is not subject to any notices or actions from or to the Principal Market, other than routine matters incident to listing on the Principal Market and not involving a violation of the rules of the Principal Market. To the Company's knowledge, the Principal Market has not commenced any delisting proceedings against the Company.

(f) SEC Documents; Financial Statements. Since September 30, 2016, the Company has filed all reports, schedules, forms, statements and other documents required to be filed by it with the SEC pursuant to the reporting requirements of the 1934 Act (all of the foregoing filed prior to the date hereof and all exhibits included therein and financial statements and schedules thereto and documents incorporated by reference therein being hereinafter referred to as the "**SEC Documents**"). As of their respective dates (except as they have been correctly amended), the SEC Documents complied in all material respects with the requirements of the 1934 Act and the rules and regulations of the SEC promulgated thereunder applicable to the SEC Documents, and none of the SEC Documents, at the time they were filed with the SEC (except as they may have been properly amended), contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading. As of their respective dates (except as they have been properly amended), the financial statements of the Company included in the SEC Documents complied as to form in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto. Such financial statements have been prepared in accordance with generally accepted accounting principles, consistently applied, during the periods involved (except (i) as may be otherwise indicated in such financial statements or the notes thereto or (ii) in the case of unaudited interim statements, to the extent they may exclude footnotes or may be condensed or summary statements) and fairly present in all material respects the financial position of the Company as of the dates thereof and the results of its operations and cash flows for the periods then ended (subject, in the case of unaudited statements, to normal year-end audit adjustments). Except for routine correspondence, such as comment letters and notices of effectiveness in connection with previously filed registration statements or periodic reports publicly available on EDGAR, to the Company's knowledge, the Company or any of its Subsidiaries are not presently the subject of any inquiry, investigation or action by the SEC.

(g) Absence of Certain Changes. Since September 30, 2017, there has been no material adverse change in the business, properties, operations, financial condition or results of operations of the Company or its Subsidiaries taken as a whole. For purposes of this Agreement, neither a decrease in cash or cash equivalents or in the market price of the Common Stock nor losses incurred in the ordinary course of the Company's business shall be deemed or considered a material adverse change. The Company has not taken any steps, and does not currently expect to take any steps, to seek protection pursuant to any Bankruptcy Law nor does the Company or any of its Subsidiaries have any knowledge or reason to believe that its creditors intend to initiate involuntary bankruptcy or insolvency proceedings. The Company is financially solvent and is generally able to pay its debts as they become due**.**

(h) Absence of Litigation. To the Company's knowledge, there is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of the Company or any of its Subsidiaries, threatened against the Company, the Common Stock or any of the Company's Subsidiaries or any of the Company's or the Company's Subsidiaries' officers or directors in their capacities as such, which could reasonably be expected to have a Material Adverse Effect (each, an "**Action**").

(i) Acknowledgment Regarding Buyer's Status. The Company acknowledges and agrees that the Buyer is acting solely in the capacity of arm's length purchaser with respect to the Transaction Documents and the transactions contemplated hereby and thereby. The Company further acknowledges that the Buyer is not acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated hereby and thereby and any advice given by the Buyer or any of its representatives or agents in connection with the Transaction Documents and the transactions contemplated hereby and thereby is merely incidental to the Buyer's purchase of the Securities. The Company further represents to the Buyer that the Company's decision to enter into the Transaction Documents has been based solely on the independent evaluation by the Company and its representatives and advisors.

(j) Intellectual Property Rights. To the Company's knowledge, the Company and its Subsidiaries own or possess adequate rights or licenses to use all material trademarks, trade names, service marks, service mark registrations, service names, patents, patent rights, copyrights, inventions, licenses, approvals, governmental authorizations, trade secrets and other intellectual property rights (collectively, "**Intellectual Property**") necessary to conduct their respective businesses as now conducted, except to the extent that the failure to own, possess, license or otherwise hold adequate rights to use Intellectual Property would not, individually or in the aggregate, have a Material Adverse Effect. To the Company's knowledge, none of the Company's active and registered Intellectual Property have expired or terminated, or, by the terms and conditions thereof, will expire or terminate within two years from the date of this Agreement, except as would not reasonably be expected to have a Material Adverse Effect. The Company and its Subsidiaries do not have any knowledge of any infringement by the Company or its Subsidiaries of any Intellectual Property of others, or of any such development of similar or identical trade secrets or technical information by others with respect to the Company's or its Subsidiaries' Intellectual Property and, there is no claim, action or proceeding being made or brought against, or to the Company's knowledge, being threatened against, the Company or its Subsidiaries regarding Intellectual Property, which could reasonably be expected to have a Material Adverse Effect.

(k) Environmental Laws. To the Company's knowledge, the Company and its Subsidiaries (i) are in material compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of the environment or human health and safety and with respect to hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) have received all material permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) are in material compliance with all terms and conditions of any such permit, license or approval, except where, in each of the three foregoing clauses, the failure to so comply or receive such approvals could not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

(l) Title. The Company and its Subsidiaries have good and marketable title to all personal property owned by them that is material to the business of the Company and its Subsidiaries, in each case free and clear of all liens, encumbrances and defects except such as are described in Section 3(l) of the Disclosure Letter or such as do not materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company and any of its

Subsidiaries or could not reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. Any real property and facilities held under lease by the Company and any of its Subsidiaries, to the Company's knowledge, are held by them under valid, subsisting and enforceable leases with such exceptions as are not material and do not interfere with the use made and proposed to be made of such property and buildings by the Company and its Subsidiaries.

(m) Insurance. The Company and each of its Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as management of the Company believes to be reasonable and customary in the businesses in which the Company and its Subsidiaries are engaged. To the Company's knowledge, since December 31, 2015, neither the Company nor any such Subsidiary has been refused any insurance coverage sought or applied for and neither the Company nor any such Subsidiary, to the Company's knowledge, will be unable to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not reasonably be expected to have a Material Adverse Effect.

(n) Regulatory Permits. The Company and its Subsidiaries possess all material certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct their respective businesses as currently conducted, and neither the Company nor any such Subsidiary has received any written notice of proceedings relating to the revocation or modification of any such material certificate, authorization or permit.

(o) Tax Status. The Company and each of its Subsidiaries has made or filed all federal and state income and all other material tax returns, reports and declarations required by any jurisdiction to which it is subject (unless and only to the extent that the Company and each of its Subsidiaries has set aside on its books reserves reasonably adequate for the payment of all unpaid and unreported taxes or filed valid extensions) and has paid all taxes and other governmental assessments and charges that are material in amount, shown or determined to be due on such returns, reports and declarations, except those being contested in good faith and has set aside on its books reserves reasonably adequate for the payment of all taxes for periods subsequent to the periods to which such returns, reports or declarations apply. To the Company's knowledge, there are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction.

(p) Transactions With Affiliates. Other than the grant or exercise of stock options or any other equity securities offered pursuant to duly adopted stock or incentive compensation plans identified in Section 3(c), none of the officers, directors or employees of the Company is presently a party to any transaction with the Company or any of its Subsidiaries (other than for services as employees, officers and directors and reimbursement for expenses incurred on behalf of the Company), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any corporation, partnership, trust or other entity in which any officer, director, or any such employee has a material interest or is an officer, director, trustee or general partner.

(q) Application of Takeover Protections. The Company and its Board of Directors have taken or will take prior to the Commencement Date all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Articles of Incorporation or the laws of the state of its incorporation which is or could become applicable to the Buyer as a result of the transactions contemplated by this Agreement, including, without limitation, the Company's issuance of the Securities and the Buyer's ownership of the Securities.

(r) Registration Statement. The Shelf Registration Statement (as defined in Section 4(a) hereof) has been declared effective by the SEC, and no stop order has been issued or is pending or, to the knowledge of the Company, threatened by the SEC with respect thereto. As of the date hereof, the Company has a dollar amount of securities registered and unsold under the Shelf Registration Statement, which is not less than the sum of (i) the Available Amount and (ii) the market value of the Commitment Shares on the date hereof.

4. COVENANTS.

(a) Filing of Form 8-K and Prospectus Supplement. The Company agrees that it shall, within the time required under the 1934 Act, file a Current Report on Form 8-K disclosing this Agreement and the transaction contemplated hereby or the Company may, in its discretion, disclose this Agreement and the transactions contemplated hereby in its Annual Report on Form 10-K if filed within four Business Days after the date of the execution of this Agreement. The Company shall file within two (2) Business Days from the date hereof a prospectus supplement to the prospectus dated June 12, 2017 forming a part of the Company's existing shelf registration statement on Form S-3 (File No. 333-218487, the "Shelf Registration Statement") covering the sale of the Commitment Shares and Purchase Shares (the "Prospectus Supplement") in accordance with the terms of the Registration Rights Agreement between the Company and the Buyer, dated as of the date hereof (the "Registration Rights

Agreement"). The Company shall use its reasonable best efforts to keep the Shelf Registration Statement and any New Registration Statement (as defined in the Registration Rights Agreement) effective pursuant to Rule 415 promulgated under the 1933 Act and available for sales of all Securities to the Buyer until such time as (i) it no longer qualifies to make sales under the Shelf Registration Statement (which shall be understood to include the inability of the Company to immediately register sales of Securities to the Buyer under the Shelf Registration Statement or any New Registration Statement pursuant to General Instruction I.B.6 of Form S-3), (ii) the date on which all the Securities have been sold under this Agreement and no Available Amount remains thereunder, or (iii) the Agreement has been terminated. The Shelf Registration Statement (including any amendments or supplements thereto and prospectuses or prospectus supplements, including the Prospectus Supplement, contained therein) shall not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein, or necessary to make the statements therein, in light of the circumstances in which they were made, not misleading.

(b) Blue Sky. The Company shall take such action, if any, as is reasonably necessary in order to obtain an exemption for or to qualify (i) the initial sale of the Securities to the Buyer under this Agreement and (ii) any subsequent sale of the Securities by the Buyer, in each case, under applicable securities or "Blue Sky" laws of the states of the United States in such states as is reasonably requested by the Buyer from time to time, and shall provide evidence of any such action so taken to the Buyer at its written request; *provided*, *however*, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

(c) Listing. The Company shall promptly secure the listing of all of the Securities upon each national securities exchange and automated quotation system that requires an application by the Company for listing, if any, upon which shares of Common Stock are then listed (subject to official notice of issuance) and shall maintain such listing, so long as any other shares of Common Stock shall be so listed. The Company shall use its commercially reasonable efforts to maintain the Common Stock's listing on the Principal Market. Neither the Company nor any of its Subsidiaries shall take any action that would be reasonably expected to result in the delisting or suspension of the Common Stock on the Principal Market, unless the Common Stock is immediately thereafter traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market, or the OTCQB or OTCQX market places of the OTC Markets. The Company shall pay all fees and expenses in connection with satisfying its obligations under this Section.

(d) Limitation on Short Sales and Hedging Transactions. The Buyer agrees that beginning on the date of this Agreement and ending on the date of termination of this Agreement as provided in Section 11(k), the Buyer and its agents, representatives and affiliates shall not in any manner whatsoever enter into or effect, directly or indirectly, any (i) "short sale" (as such term is defined in Section 242.200 of Regulation SHO of the 1934 Act) of the Common Stock or (ii) hedging transaction, which establishes a net short position with respect to the Common Stock.

(e) Issuance of Commitment Shares. In connection with the Commencement, the Company shall issue to the Buyer as consideration for the Buyer entering into this Agreement 33,040 shares of Common Stock (the "**Commitment Shares**"). The Commitment Shares shall be issued without any restrictive legend whatsoever or prior sale requirement.

(f) Due Diligence. The Buyer shall have the right, from time to time as the Buyer may reasonably deem appropriate, to perform reasonable due diligence on the Company during normal business hours and subject to reasonable prior notice to the Company. The Company and its officers and employees shall provide information and reasonably cooperate with the Buyer in connection with any reasonable request by the Buyer related to the Buyer's due diligence of the Company, including, but not limited to, any such request made by the Buyer in connection with (i) the filing of the prospectus supplement described in Section 4(a) hereof and (ii) the Commencement; provided, however, that at no time is the Company required to disclose material nonpublic information to the Buyer or breach any obligation of confidentiality or non-disclosure to a third party or make any disclosure that could cause a waiver of attorney-client privilege. Except as may be required by law, court order or governmental authority, each party hereto agrees not to disclose any Confidential Information of the other party to any third party and shall not use the Confidential Information of such other party for any purpose other than in connection with, or in furtherance of, the transactions contemplated hereby; provided, that to the extent such disclosure is required by law, court order or governmental authority, the receiving party shall provide the disclosing party with reasonable prior written notice of such disclosure and make a reasonable effort to assist the disclosing party in obtaining a protective order preventing or limiting the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law, court order or governmental authority requires. Each party hereto acknowledges that the Confidential Information shall remain the property of the disclosing party and agrees that it shall take all reasonable measures to protect the secrecy of any Confidential Information disclosed by the other party.

5. TRANSFER AGENT INSTRUCTIONS.

All of the Purchase Shares to be issued under this Agreement shall be issued without any restrictive legend unless the Buyer expressly consents otherwise. The Company shall issue irrevocable instructions to the Transfer Agent, and any subsequent transfer agent, to issue Common Stock in the name of the Buyer for the Purchase Shares (the "**Irrevocable Transfer Agent Instructions"**). The Company warrants to the Buyer that no instruction other than the Irrevocable Transfer Agent Instructions referred to in this Section 5, will be given by the Company to the Transfer Agent with respect to the Purchase Shares and that the Commitment Shares and the Purchase Shares shall otherwise be freely transferable on the books and records of the Company as and to the extent provided in this Agreement and the Registration Rights Agreement.

6. CONDITIONS TO THE COMPANY'S RIGHT TO COMMENCE SALES OF SHARES OF COMMON STOCK UNDER THIS AGREEMENT.

The right of the Company hereunder to commence sales of the Purchase Shares is subject to the satisfaction of each of the following conditions on or before the Commencement Date (the date that the Company may begin sales of Purchase Shares):

(a) The Buyer shall have executed each of the Transaction Documents and delivered the same to the Company;

(b) The representations and warranties of the Buyer shall be true and correct as of the Commencement Date as though made at that time (except for representations and warranties that speak as of a specific date, which shall be true and correct in all material respects as of such specific date) and the Buyer shall have performed, satisfied and complied in all material respects with the covenants and agreements required by this Agreement to be performed, satisfied or complied with by the Buyer at or prior to the Commencement Date; and

(c) The Prospectus Supplement shall have been delivered to the Buyer and no stop order with respect to the registration statement covering the sale of shares to the Buyer shall be pending or threatened by the SEC.

7. CONDITIONS TO THE BUYER'S OBLIGATION TO MAKE PURCHASES OF SHARES OF COMMON STOCK.

The obligation of the Buyer to buy Purchase Shares under this Agreement is subject to the satisfaction of each of the following conditions on or before the Commencement Date (the date that the Company may begin sales of Purchase Shares) and once such conditions have been initially satisfied, there shall not be any ongoing obligation to satisfy such conditions after the Commencement has occurred:

(a) The Company shall have executed each of the Transaction Documents and delivered the same to the Buyer;

(b) The Company shall have issued to the Buyer the Commitment Shares;

(c) The Common Stock shall be authorized for quotation on the Principal Market, trading in the Common Stock shall not have been within the last 365 days suspended by the SEC or the Principal Market, other than a general halt in trading in the Common Stock by the Principal Market under halt codes indicating pending or released material news, and the Securities shall be approved for listing upon the Principal Market;

(d) The Buyer shall have received the opinion of the Company's legal counsel dated as of the Commencement Date in customary form and substance;

(e) The representations and warranties of the Company shall be true and correct in all material respects (except to the extent that any of such representations and warranties is already qualified as to materiality in Section 3 above, in which case, such representations and warranties shall be true and correct without further qualification) as of the date of this Agreement and as of the Commencement Date as though made at that time (except for representations and warranties that speak as of a specific date, which shall be true and correct in all material respects as of such specific date) and the Company shall have performed, satisfied and complied in all material respects with the covenants, agreements and conditions required by the Transaction Documents to be performed, satisfied or complied with by the Company at or prior to the Commencement Date. The Buyer shall have received a certificate, executed by the CEO, President or CFO of the Company, dated as of the Commencement Date, to the foregoing effect in the form attached hereto as **Exhibit A**;

(f) The Board of Directors of the Company or a duly authorized committee thereof shall have adopted resolutions substantially in the form attached hereto as **Exhibit B**, which shall be in full force and effect without any amendment or supplement thereto as of the Commencement Date;

(g) As of the Commencement Date, the Company shall have reserved out of its authorized and unissued Common Stock, solely for the purpose of effecting future purchases of Purchase Shares hereunder, 4,000,000 shares of Common Stock;

(h) The Irrevocable Transfer Agent Instructions, in form acceptable to the Buyer shall have been delivered to and acknowledged in writing by the Company and the Buyer and have been delivered to the Transfer Agent;

(i) The Company shall have delivered to the Buyer a certificate evidencing the incorporation and good standing of the Company in the Commonwealth of Pennsylvania issued by the Secretary of Commonwealth of the Commonwealth of Pennsylvania as of a date within ten (10) Business Days of the Commencement Date;

(j) [Intentionally Omitted];

(k) The Company shall have delivered to the Buyer a secretary's certificate executed by the Secretary of the Company, dated as of the Commencement Date, in the form attached hereto as **Exhibit C**;

(l) No stop order with respect to the Shelf Registration Letter shall be pending or threatened by the SEC. The Company shall have prepared and delivered to the Buyer a final and complete form of prospectus supplement, dated and current as of the Commencement Date, to be used in connection with any issuances of any Commitment Shares or any Purchase Shares to the Buyer, and to be filed by the Company within two (2) Business Days after the Commencement Date pursuant to Rule 424(b). The Company shall have made all filings under all applicable federal and state securities laws necessary to consummate the issuance of the Commitment Shares and the Purchase Shares pursuant to this Agreement in compliance with such laws;

(m) No Event of Default has occurred and is continuing, or any event which, after notice and/or lapse of time, would become an Event of Default has occurred;

(n) On or prior to the Commencement Date, the Company shall take all necessary action, if any, and such actions as reasonably requested by the Buyer, in order to render inapplicable any control share acquisition, business combination, shareholder rights plan or poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Articles of Incorporation or the laws of the Commonwealth of Pennsylvania that is or could become applicable to the Buyer as a result of the transactions contemplated by this Agreement, including, without limitation, the Company's issuance of the Securities and the Buyer's ownership of the Securities; and

(o) The Company shall have provided the Buyer with the information reasonably requested by the Buyer in connection with its due diligence requests made prior to, or in connection with, the Commencement, in accordance with the terms of Section 4(f) hereof.

8. INDEMNIFICATION.

In consideration of the Buyer's execution and delivery of the Transaction Documents and acquiring the Securities hereunder and in addition to all of the Company's other obligations under the Transaction Documents, the Company shall defend, protect, indemnify and hold harmless the Buyer and all of its affiliates, members, officers, directors, and employees, and any of the foregoing person's agents or other representatives (including, without limitation, those retained in connection with the transactions contemplated by this Agreement) (collectively, the "**Indemnitees**") from and against any and all third party actions, causes of action, suits, claims, losses, costs, penalties, fees, liabilities and damages, and expenses in connection therewith (irrespective of whether any such Indemnitee is a party to the action for which indemnification hereunder is sought), and including reasonable attorneys' fees and disbursements (the "**Indemnified Liabilities**"), incurred by any Indemnitee as a result of, or arising out of, or relating to (a) any misrepresentation or breach of any representation or warranty made by the Company in the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, (b) any breach of any covenant, agreement or obligation of the Company contained in the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, or (c) any cause of action, suit or claim brought or made against such Indemnitee and arising out of or resulting from the execution, delivery, performance or enforcement of the Transaction Documents or any other certificate, instrument or document contemplated hereby or thereby, other than with respect to Indemnified Liabilities which directly and primarily result from (A) a breach of any of the Buyer's representations and warranties, covenants or agreements contained in this Agreement, or (B) the gross negligence, bad faith or willful misconduct of the Buyer or any other Indemnitee. To the extent that the foregoing undertaking by the Company may be unenforceable for any reason, the Company shall make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities which is permissible under applicable law.

9. EVENTS OF DEFAULT.

An "**Event of Default**" shall be deemed to have occurred at any time as any of the following events occurs:

(a) during any period in which the effectiveness of any registration statement is required to be maintained pursuant to the terms of the Registration Rights Agreement, the effectiveness of such registration statement lapses for any reason (including, without limitation, the issuance of a stop order) or is unavailable to the Company for sale of all of the Registrable Securities (as defined in the Registration Rights Agreement) to the Buyer in accordance with the terms of the Registration Rights Agreement, and such lapse or unavailability continues for a period of ten (10) consecutive Business Days or for more than an aggregate of thirty (30) Business Days in any 365-day period, which is not in connection with a post-effective amendment to any such registration statement or the filing of a new registration statement; provided, however, that in connection with any post-effective amendment to such registration statement or filing of a new registration statement that is required to be declared effective by the SEC, such lapse or unavailability may continue for a period of no more than thirty (30) consecutive Business Days, which such period shall be extended for an additional thirty (30) Business Days if the Company receives a comment letter from the SEC in connection therewith;

(b) the suspension from trading or failure of the Common Stock to be listed on a Principal Market for a period of three (3) consecutive Business Days;

(c) the delisting of the Common Stock from the Principal Market, and the Common Stock is not immediately thereafter trading on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market, the OTC Bulletin Board or the OTCQB marketplace or OTCQX marketplace of the OTC Markets Group, Inc.;

(d) the failure for any reason by the Transfer Agent to issue Purchase Shares to the Buyer within five (5) Business Days after the applicable Purchase Date that the Buyer is entitled to receive;

(e) the Company's breach of any representation or warranty (as of the dates made), covenant or other term or condition under any Transaction Document if such breach could reasonably be expected to have a Material Adverse Effect and except, in the case of a breach of a covenant which is reasonably curable, only if such breach continues uncured for a period of at least five (5) Business Days;

(f) if any Person commences a proceeding against the Company pursuant to or within the meaning of any Bankruptcy Law;

(g) if the Company pursuant to or within the meaning of any Bankruptcy Law; (A) commences a voluntary case, (B) consents to the entry of an order for relief against it in an involuntary case, (C) consents to the appointment of a Custodian of it or for all or substantially all of its property, (D) makes a general assignment for the benefit of its creditors or (E) becomes insolvent;

(h) a court of competent jurisdiction enters an order or decree under any Bankruptcy Law that (A) is for relief against the Company in an involuntary case, (B) appoints a Custodian of the Company or for all or substantially all of its property, or (C) orders the liquidation of the Company or any Subsidiary; or

(i) if at any time after the Commencement Date, the Exchange Cap is reached unless and until shareholder approval is obtained pursuant to Section 1(h) hereof. The Exchange Cap shall be deemed to be reached at such time if, upon submission of a Purchase Notice or VWAP Purchase Notice under this Agreement, the issuance of such shares of Common Stock would exceed the number of shares of Common Stock which the Company may issue under this Agreement without breaching the Company's obligations under the rules or regulations of the Principal Market.

In addition to any other rights and remedies under applicable law and this Agreement, including the Buyer termination rights under Section 11(k) hereof, so long as an Event of Default has occurred and is continuing, or if any event which, after notice and/or lapse of time, would become an Event of Default, has occurred and is continuing, or so long as the Closing Sale Price is below the Floor Price, the Company may not require and the Buyer shall not be obligated to purchase any shares of Common Stock under this Agreement. If pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company, a Custodian is appointed for the Company or for all or substantially all of its property, or the Company makes a general assignment for the benefit of its creditors, (any of which would be an Event of Default as described in Sections 9(f), 9(g) and 9(h) hereof) this Agreement shall automatically terminate without any liability or payment to the Company without further action or notice by any Person. No such termination of this Agreement under Section 11(k)(i) shall affect the Company's or the Buyer's obligations under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

10. CERTAIN DEFINED TERMS.

For purposes of this Agreement, the following terms shall have the following meanings:

(a) "**1933 Act**" means the Securities Act of 1933, as amended.

(b) "**Available Amount**" means initially Twenty Million Dollars ($20,000,000) in the aggregate which amount shall be reduced by the Purchase Amount each time the Buyer purchases shares of Common Stock pursuant to Section 1 hereof.

(c) "**Bankruptcy Law**" means Title 11, U.S. Code, or any similar federal or state law for the relief of debtors.

(d) "**Business Day**" means any day on which the Principal Market is open for trading during normal trading hours (i.e., 9:30 a.m. to 4:00 p.m. Eastern Time), including any day on which the Principal Market is open for trading for a period of time less than the customary time.

(e) "**Closing Sale Price**" means the last closing trade price for the Common Stock on the Principal Market as reported by the Principal Market.

(f) "**Confidential Information**" means any information disclosed by either party to the other party, either directly or indirectly, in writing, orally or by inspection of tangible objects (including, without limitation, documents, prototypes, samples, plant and equipment), which is designated as "Confidential," "Proprietary" or some similar designation. Information communicated orally shall be considered Confidential Information if such information is confirmed in writing as being Confidential Information within ten (10) Business Days after the initial disclosure. Confidential Information may also include information disclosed to a disclosing party by third parties. Confidential Information shall not, however, include any information which (i) was publicly known and made generally available in the public domain prior to the time of disclosure by the disclosing party; (ii) becomes publicly known and made generally available after disclosure by the disclosing party to the receiving party through no action or inaction of the receiving party; (iii) is already in the possession of the receiving party at the time of disclosure by the disclosing party as shown by the receiving party's files and records immediately prior to the time of disclosure; (iv) is obtained by the receiving party from a third party without a breach of such third party's obligations of confidentiality; (v) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as shown by documents and other competent evidence in the receiving party's possession; or (vi) is required by law to be disclosed by the receiving party, provided that the receiving party gives the disclosing party prompt written notice of such requirement prior to such disclosure and assistance in obtaining an order protecting the information from public disclosure.

(g) "**Custodian**" means any receiver, trustee, assignee, liquidator or similar official under any Bankruptcy Law.

(h) "**Maturity Date**" means the date that is thirty (30) months from the Commencement Date.

(i) "**Person**" means an individual or entity including any limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization and a government or any department or agency thereof.

(j) "**Principal Market**" means the Nasdaq Capital Market; provided however, that in the event the Company's Common Stock is ever listed or traded on the New York Stock Exchange, the NYSE MKT, the Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market, the OTC Bulletin Board or either of the OTCQB Marketplace or the OTCQX Marketplace of the OTC Markets Group, then the "Principal Market" shall mean such other market or exchange on which the Company's Common Stock is then listed or traded.

(k) "**Purchase Amount**" means, with respect to any particular purchase made hereunder, the portion of the Available Amount to be purchased by the Buyer pursuant to Section 1 hereof as set forth in a valid Purchase Notice or VWAP Purchase Notice which the Company delivers to the Buyer.

(l) "**Purchase Date**" means with respect to any Regular Purchase made hereunder, the Business Day of receipt by the Buyer of a valid Purchase Notice that the Buyer is to buy Purchase Shares pursuant to Section 1(b) hereof.

(m) “**Purchase Notice**” shall mean an irrevocable written notice from the Company to the Buyer directing the Buyer to buy Purchase Shares pursuant to Section 1(b) hereof as specified by the Company therein at the applicable Purchase Price on the Purchase Date.

(n) “**Purchase Price**” means the lesser of (i) the lowest Sale Price of the Common Stock on the Purchase Date or (ii) the arithmetic average of the three (3) lowest Closing Sale Prices for the Common Stock during the ten (10) consecutive Business Days ending on the Business Day immediately preceding such Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar transaction).

(o) “**Sale Price**” means any trade price for the shares of Common Stock on the Principal Market during normal trading hours, as reported by the Principal Market.

(p) “**SEC**” means the United States Securities and Exchange Commission.

(q) “**Transfer Agent**” means the transfer agent of the Company as set forth in Section 11(f) hereof or such other person who is then serving as the transfer agent for the Company in respect of the Common Stock.

(r) “**VWAP Minimum Price Threshold**” means, with respect to any particular VWAP Purchase Notice, the Sale Price on the VWAP Purchase Date equal to the greater of (i) 80% of the Closing Sale Price on the Business Day immediately preceding the VWAP Purchase Date or (ii) such higher price as set forth by the Company in the VWAP Purchase Notice.

(s) “**VWAP Purchase Amount**” means, with respect to any particular VWAP Purchase Notice, the portion of the Available Amount to be purchased by the Buyer pursuant to Section 1(c) hereof pursuant to a valid VWAP Purchase Notice which requires the Buyer to buy the VWAP Purchase Share Percentage of the aggregate shares traded on the Principal Market during normal trading hours on the VWAP Purchase Date up to the VWAP Purchase Share Volume Maximum, subject to the VWAP Minimum Price Threshold.

(t) “**VWAP Purchase Date**” means, with respect to any VWAP Purchase made hereunder, the Business Day following the receipt by the Buyer of a valid VWAP Purchase Notice that the Buyer is to buy Purchase Shares pursuant to Section 1(c) hereof.

(u) “**VWAP Purchase Notice**” shall mean an irrevocable written notice from the Company to the Buyer directing the Buyer to buy Purchase Shares on the VWAP Purchase Date pursuant to Section 1(c) hereof as specified by the Company therein at the applicable VWAP Purchase Price with the applicable VWAP Purchase Share Percentage specified therein.

(v) “**VWAP Purchase Share Percentage**” means, with respect to any particular VWAP Purchase Notice pursuant to Section 1(c) hereof, the percentage set forth in the VWAP Purchase Notice which the Buyer will be required to buy as a specified percentage of the aggregate shares traded on the Principal Market during normal trading hours up to the VWAP Purchase Share Volume Maximum on the VWAP Purchase Date subject to Section 1(c) hereof but in no event shall this percentage exceed thirty percent (30%) of such VWAP Purchase Date’s share trading volume of the Common Stock on the Principal Market during normal trading hours.

(w) “**VWAP Purchase Price**” means the lesser of (i) the Closing Sale Price on the VWAP Purchase Date; or (ii) ninety-seven percent (97%) of volume weighted average price for the Common Stock traded on the Principal Market during normal trading hours on (A) the VWAP Purchase Date if the aggregate shares traded on the Principal Market on the VWAP Purchase Date have not exceeded the VWAP Purchase Share Volume Maximum and the Sale Price of Common Stock has not fallen below the VWAP Minimum Price Threshold (to be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar transaction), or (B) the portion of the VWAP Purchase Date until such time as the sooner to occur of (1) the time at which the aggregate shares traded on the Principal Market has exceeded the VWAP Purchase Share Volume Maximum, or (2) the time at which the Sale Price of Common Stock falls below the VWAP Minimum Price Threshold (to be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar transaction).

(x) “**VWAP Purchase Share Estimate**” means the number of shares of Common Stock that the Company has in its sole discretion irrevocably instructed its Transfer Agent to issue to the Buyer via the Depository Trust Company (“**DTC**”) Fast Automated Securities Transfer Program in connection with a VWAP Purchase Notice pursuant to Section 1(c) hereof and issued to the Buyer’s or its designee’s balance account with DTC through its Deposit Withdrawal At Custodian (DWAC) system on the VWAP Purchase Date (to be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar transaction).

(y) “**VWAP Purchase Share Volume Maximum**” means a number of shares of Common Stock traded on the Principal Market during normal trading hours on the VWAP Purchase Date equal to: (i) the VWAP Purchase Share Estimate, divided by (ii) the VWAP Purchase Share Percentage (to be appropriately adjusted for any reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar transaction).

11. MISCELLANEOUS.

(a) Governing Law; Jurisdiction; Jury Trial. The corporate laws of the Commonwealth of Pennsylvania shall govern all issues concerning the relative rights of the Company and its shareholders. All other questions concerning the construction, validity, enforcement and interpretation of this Agreement and the other Transaction Documents shall be governed by the internal laws of the State of Illinois, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of Illinois or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of Illinois. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of Chicago, Illinois, for the adjudication of any dispute hereunder or under the other Transaction Documents or in connection herewith or therewith, or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION HEREWITH OR ARISING OUT OF THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY.**

(b) Counterparts. This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party; provided that a facsimile or pdf (or other electronic reproduction) signature shall be considered due execution and shall be binding upon the signatory thereto with the same force and effect as if the signature were an original, not a facsimile or PDF (or other electronic reproduction) signature.

(c) Headings. The headings of this Agreement are for convenience of reference and shall not form part of, or affect the interpretation of, this Agreement.

(d) Severability. If any provision of this Agreement shall be invalid or unenforceable in any jurisdiction, such invalidity or unenforceability shall not affect the validity or enforceability of the remainder of this Agreement in that jurisdiction or the validity or enforceability of any provision of this Agreement in any other jurisdiction.

(e) Entire Agreement. This Agreement and the Registration Rights Agreement supersede all other prior oral or written agreements between the Buyer, the Company, their affiliates and persons acting on their behalf with respect to the matters discussed herein, and this Agreement, the other Transaction Documents and the instruments referenced herein contain the entire understanding of the parties with respect to the matters covered herein and therein and, except as specifically set forth herein or therein, neither the Company nor the Buyer makes any representation, warranty, covenant or undertaking with respect to such matters. Each of the Company and the Buyer acknowledge and agree that it has not relied on, in any manner whatsoever, any representations or statements, written or oral, other than as expressly set forth in this Agreement.

(f) Notices. Any notices, consents or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered: (i) upon receipt when delivered personally; (ii) upon receipt when sent by facsimile (provided confirmation of transmission is mechanically or electronically generated and kept on file by the sending party); (iii) upon receipt, when sent by electronic message (provided the recipient responds to the message and confirmation of both electronic messages are kept on file by the sending party); or (iv) one (1) Business Day after timely deposit with a nationally recognized overnight delivery service, in each case properly addressed to the party to receive the same. The addresses and facsimile numbers for such communications shall be:

If to the Company:

Recro Pharma, Inc.
490 Lapp Road
Malvern, PA 19355
Telephone: 484-395-2470

Facsimile: 484-395-2471
Attention: Michael Celano
Email: mcelano@recropharma.com

With a copy (which shall not constitute notice) to:

Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103
Telephone: 215-981-4331
Facsimile: 215-981-4750
Attention: Rachael M. Bushey
Email: busheyr@pepperlaw.com

If to the Buyer:

Aspire Capital Fund, LLC
155 North Wacker Drive, Suite 1600
Chicago, IL 60606
Telephone: 312-658-0400
Facsimile: 312-658-4005
Attention: Steven G. Martin
Email: smartin@aspirecapital.com

With a copy to (which shall not constitute delivery to the Buyer):

Morrison & Foerster LLP
2000 Pennsylvania Avenue, NW, Suite 6000
Washington, DC 20006
Telephone: 202-778-1611
Facsimile: 202-887-0763
Attention: Martin P. Dunn, Esq.
Email: mdunn@mofo.com

If to the Transfer Agent:

Broadridge Corporate Issuer Solutions, Inc.
2 Journal Square, 7th Floor
Jersey City, NJ 07306
Telephone: 201-714-3800
Facsimile: 201-714-8862
Attention: Jennifer A. Whitney, Broadridge Relationship Manager
Email: Jennifer.Whitney@broadridge.com

or at such other address and/or facsimile number and/or to the attention of such other person as the recipient party has specified by written notice given to each other party at least one (1) Business Day prior to the effectiveness of such change. Written confirmation of receipt (A) given by the recipient of such notice, consent or other communication, (B) mechanically or electronically generated by the sender's facsimile machine containing the time, date, and recipient facsimile number, (C) electronically generated by the sender's electronic mail containing the time, date and recipient email address or (D) provided by a nationally recognized overnight delivery service, shall be rebuttable evidence of receipt in accordance with clause (i), (ii), (iii) or (iv) above, respectively.

(g) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns. The Company shall not assign this Agreement or any rights or obligations hereunder without the prior written consent of the Buyer, including by merger or consolidation; *provided*, *however*, that any transaction, whether by merger, reorganization, restructuring, consolidation, financing or otherwise, whereby the Company remains the surviving entity immediately after such transaction shall not be deemed a succession or assignment. The Buyer may not assign its rights or obligations under this Agreement.

(h) No Third Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other person.

(i) Publicity. The Buyer shall have the right to approve before issuance any press release, SEC filing or any other public disclosure made by or on behalf of the Company whatsoever with respect to, in any manner, the Buyer, its purchases hereunder or any aspect of this Agreement or the transactions contemplated hereby; provided, however, that the Company shall be entitled, without the prior approval of the Buyer, to make any press release or other public disclosure (including any filings with the SEC) with respect to such transactions as is required by applicable law and regulations so long as the Company and its counsel consult with the Buyer in connection with any such press release or other public disclosure at least one (1) Business Day prior to its release; provided, however, that the Company's obligations pursuant to this Section 11(i) shall not apply if the material provisions of such press release, SEC filing, or other public disclosure previously has been publicly disclosed by the Company in accordance with this Section 11(i). The Buyer must be provided with a copy thereof at least one (1) Business Day prior to any release or use by the Company thereof.

(j) Further Assurances. Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as the other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

(k) Termination. This Agreement may be terminated only as follows:

(i) By the Buyer any time an Event of Default exists without any liability or payment to the Company. However, if pursuant to or within the meaning of any Bankruptcy Law, the Company commences a voluntary case or any Person commences a proceeding against the Company, a Custodian is appointed for the Company or for all or substantially all of its property, or the Company makes a general assignment for the benefit of its creditors, (any of which would be an Event of Default as described in Sections 9(f), 9(g) and 9(h) hereof) this Agreement shall automatically terminate without any liability or payment to the Company without further action or notice by any Person. No such termination of this Agreement under this Section 11(k)(i) shall affect the Company's or the Buyer's obligations under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

(ii) In the event that the Commencement shall not have occurred, the Company shall have the option to terminate this Agreement for any reason or for no reason without any liability whatsoever of either party to the other party under this Agreement except as set forth in Section 11(k)(viii) hereof.

(iii) In the event that the Commencement shall not have occurred within ten (10) Business Days, due to the failure to satisfy any of the conditions set forth in Sections 6 and 7 above with respect to the Commencement, either party shall have the option to terminate this Agreement at the close of business on such date or thereafter without liability of either party to any other party; provided, however, that the right to terminate this Agreement under this Section 11(k)(iii) shall not be available to either party if such failure to satisfy any of the conditions set forth in Sections 6 and 7 is the result of a breach of this Agreement by such party or the failure of any representation or warranty of such party included in this Agreement to be true and correct in all material respects.

(iv) At any time after the Commencement Date, the Company shall have the option to terminate this Agreement for any reason or for no reason by delivering notice (a "**Company Termination Notice**") to the Buyer electing to terminate this Agreement without any liability whatsoever of either party to the other party under this Agreement except as set forth in Section 11(k)(viii) hereof. The Company Termination Notice shall not be effective until one (1) Business Day after it has been received by the Buyer.

(v) This Agreement shall automatically terminate on the date that the Company sells and the Buyer purchases the full Available Amount as provided herein, without any action or notice on the part of any party and without any liability whatsoever of any party to any other party under this Agreement except as set forth in Section 11(k)(viii) hereof.

(vi) If by the Maturity Date for any reason or for no reason the full Available Amount under this Agreement has not been purchased as provided for in Section 1 of this Agreement, this Agreement shall automatically terminate on the Maturity Date, without any action or notice on the part of any party and without any liability whatsoever of any party to any other party under this Agreement except as set forth in Section 11(k)(viii) hereof.

(vii) Except as set forth in Sections 11(k)(i) (in respect of an Event of Default under Sections 9(f), 9(g) and 9(h)), 11(k)(v) and 11(k)(vi), any termination of this Agreement pursuant to this Section 11(k) shall be effected by written notice from the Company to the Buyer, or the Buyer to the Company, as the case may be, setting forth the basis for the termination hereof.

(viii) The representations and warranties of the Company and the Buyer contained in Sections 2, 3 and 5 hereof, the indemnification provisions set forth in Section 8 hereof and the agreements and covenants set forth in Sections 4(e) and 11, shall survive the Commencement and any termination of this Agreement. No termination of this Agreement shall affect the Company's or the Buyer's rights or obligations (A) under the Registration Rights Agreement, which shall survive any such termination in accordance with its terms, or (B) under this Agreement with respect to pending purchases and the Company and the Buyer shall complete their respective obligations with respect to any pending purchases under this Agreement.

(l) No Financial Advisor, Placement Agent, Broker or Finder. The Company represents and warrants to the Buyer that it has not engaged any financial advisor, placement agent, broker or finder in connection with the transactions contemplated hereby. The Buyer represents and warrants to the Company that it has not engaged any financial advisor, placement agent, broker or finder in connection with the transactions contemplated hereby. Each party shall be responsible for the payment of any fees or commissions, if any, of any financial advisor, placement agent, broker or finder engaged by such party relating to or arising out of the transactions contemplated hereby. Each party shall pay, and hold the other party harmless against, any liability, loss or expense (including, without limitation, attorneys' fees and out of pocket expenses) arising in connection with any such claim.

(m) No Strict Construction. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party.

(n) Failure or Indulgence Not Waiver. No failure or delay in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other right, power or privilege.

* * * * *

IN WITNESS WHEREOF, the Buyer and the Company have caused this Common Stock Purchase Agreement to be duly executed as of the date first written above.

THE COMPANY:

RECRO PHARMA, INC.

By: /s/ Geraldine A. Henwood
Name: Geraldine A. Henwood
Title: Chief Executive Officer

BUYER:

ASPIRE CAPITAL FUND, LLC
BY: ASPIRE CAPITAL PARTNERS, LLC
BY: CHRISKO INVESTORS INC.

By: /s/ Christos Komissopoulos
Name: Christos Komissopoulos
Title: President

EXHIBITS

Exhibit A	Form of Officer's Certificate
Exhibit B	Form of Resolutions of Board of Directors of the Company
Exhibit C	Form of Secretary's Certificate

EXHIBIT A

FORM OF OFFICER'S CERTIFICATE

This Officer's Certificate ("**Certificate**") is being delivered pursuant to Section 7(e) of that certain Common Stock Purchase Agreement dated as of March 2, 2018 (the "**Common Stock Purchase Agreement**"), by and between **RECRO PHARMA**, a Pennsylvania corporation (the "**Company**"), and **ASPIRE CAPITAL FUND, LLC**, an Illinois limited liability company (the "**Buyer**"). Terms used herein and not otherwise defined shall have the meanings ascribed to them in the Common Stock Purchase Agreement.

The undersigned, _______________, __________of the Company, hereby certifies as follows:

1. I am the _ of the Company and make the statements contained in this Certificate in my capacity as such;

2. The representations and warranties of the Company are true and correct in all material respects (except to the extent that any of such representations and warranties is already qualified as to materiality in Section 3 of the Common Stock Purchase Agreement, in which case, such representations and warranties are true and correct without further qualification) as of the date when made and as of the Commencement Date as though made at that time (except for representations and warranties that speak as of a specific date);

3. The Company has performed, satisfied and complied in all material respects with covenants, agreements and conditions required by the Transaction Documents to be performed, satisfied or complied with by the Company at or prior to the Commencement Date.

4. The Company has not taken any steps, and does not currently expect to take any steps, to seek protection pursuant to any Bankruptcy Law nor does the Company or any of its Subsidiaries have any knowledge or reason to believe that its creditors intend to initiate involuntary bankruptcy or insolvency proceedings. The Company is financially solvent and is generally able to pay its debts as they become due.

IN WITNESS WHEREOF, I have hereunder signed my name on this _____day of March, 2018.

The undersigned as Secretary of **RECRO PHARMA, INC.**, a Pennsylvania corporation, hereby certifies that _ is the duly elected, appointed, qualified and acting _ of **RECRO PHARMA, INC.** and that the signature appearing above is his genuine signature.

, Secretary

EXHIBIT B

FORM OF COMPANY RESOLUTIONS
FOR SIGNING PURCHASE AGREEMENT

WHEREAS, management has reviewed with the Board of Directors the background, terms and conditions of the transactions subject to the Common Stock Purchase Agreement (the "**Purchase Agreement**") by and between the Company and Aspire Capital Fund, LLC ("**Aspire**"), including all materials terms and conditions of the transactions subject thereto, providing for the purchase by Aspire of up to Twenty Million Dollars ($20,000,000) of the Company's common stock, par value $0.01 per share (the "**Common Stock**"); and

WHEREAS, after careful consideration of the Purchase Agreement, the documents incident thereto and other factors deemed relevant by the Board of Directors, the Board of Directors has determined that it is advisable and in the best interests of the Company to engage in the transactions contemplated by the Purchase Agreement, including, but not limited to, the issuance of _ shares of Common Stock to Aspire as a commitment fee (the "**Commitment Shares**") and the sale of shares of Common Stock to Aspire up to the available amount under the Purchase Agreement (the "**Purchase Shares,**" and together with the Commitment Shares, the "**Aspire Shares**").

Transaction Documents

NOW, THEREFORE, BE IT RESOLVED, that the transactions described in the Purchase Agreement are hereby approved and the Chief Executive Officer and Chief Financial Officer (the "**Authorized Officers**") are severally authorized to execute and deliver the Purchase Agreement, and any other agreements or documents contemplated thereby including, without limitation, a registration rights agreement (the "**Registration Rights Agreement**") providing for the registration of the shares of the Company's Common Stock issuable in respect of the Purchase Agreement on behalf of Aspire, with such amendments, changes, additions and deletions as the Authorized Officers may deem to be appropriate and approve on behalf of, the Company, such approval to be conclusively evidenced by the signature of an Authorized Officer thereon; and

FURTHER RESOLVED, that the terms and provisions of the Registration Rights Agreement by and among the Company and Aspire are hereby approved and the Authorized Officers are authorized to execute and deliver the Registration Rights Agreement (pursuant to the terms of the Purchase Agreement), with such amendments, changes, additions and deletions as the Authorized Officer may deem appropriate and approve on behalf of, the Company, such approval to be conclusively evidenced by the signature of an Authorized Officer thereon; and

FURTHER RESOLVED, that the terms and provisions of the Form of Transfer Agent Instructions (the " **Instructions**") are hereby approved and the Authorized Officers are authorized to execute and deliver the Instructions (pursuant to the terms of the Purchase Agreement), with such amendments, changes, additions and deletions as the Authorized Officers may deem appropriate and approve on behalf of, the Company, such approval to be conclusively evidenced by the signature of an Authorized Officer thereon; and

Execution of Purchase Agreement

FURTHER RESOLVED, that the Company be and it hereby is authorized to execute the Purchase Agreement providing for the purchase of common stock of the Company having an aggregate value of up to $20,000,000; and

Issuance of Common Stock

FURTHER RESOLVED, that the Company is hereby authorized to issue the Commitment Shares to Aspire as Commitment Shares and that upon issuance of the Commitment Shares pursuant to the Purchase Agreement, the Commitment Shares shall be duly authorized, validly issued, fully paid and non-assessable; and

FURTHER RESOLVED, that the Company is hereby authorized to issue shares of Common Stock upon the purchase of Purchase Shares up to the available amount under the Purchase Agreement in accordance with the terms of the Purchase Agreement and that, upon issuance of the Purchase Shares pursuant to the Purchase Agreement, the Purchase Shares will be duly authorized, validly issued, fully paid and non-assessable; and

FURTHER RESOLVED, that the officers of the Company be, and each of them hereby is, authorized and directed, for and on behalf of the Company, to execute and deliver one or more stock certificates representing any Aspire Shares sold under the Purchase Agreement in such form as may be approved by such officers, or to cause any such Aspire Shares to be delivered through electronic book entry; and

Listing of Shares on the Nasdaq Capital Market

FURTHER RESOLVED, that the officers of the Company with the assistance of counsel be, and each of them hereby is, authorized and directed to take all necessary steps and do all other things necessary and appropriate to effect the listing of the Aspire Shares on the Nasdaq Capital Market; and

Approval of Actions

FURTHER RESOLVED, that, without limiting the foregoing, the Authorized Officers are, and each of them hereby is, authorized and directed to proceed on behalf of the Company and to take all such steps as deemed necessary or appropriate, with the advice and assistance of counsel, to cause the Company to consummate the agreements referred to herein and to perform its obligations under such agreements; and

FURTHER RESOLVED, that the Authorized Officers be, and each of them hereby is, authorized, empowered and directed on behalf of and in the name of the Company, to take or cause to be taken all such further actions and to execute and deliver or cause to be executed and delivered all such further agreements, amendments, documents, certificates, reports, schedules, applications, notices, letters and undertakings and to incur and pay all such fees and expenses as in their judgment shall be necessary, proper or desirable to carry into effect the purpose and intent of any and all of the foregoing resolutions, and that all actions heretofore taken by any officer or director of the Company in connection with the transactions contemplated by the agreements described herein are hereby approved, ratified and confirmed in all respects.

EXHIBIT C

FORM OF SECRETARY'S CERTIFICATE

This Secretary's Certificate (the "**Certificate**") is being delivered pursuant to Section 7(k) of that certain Common Stock Purchase Agreement dated as of March 2, 2018 (the "**Common Stock Purchase Agreement**"), by and between **RECRO PHARMA, INC.**, a Pennsylvania corporation (the "**Company**") and **ASPIRE CAPITAL FUND, LLC**, an Illinois limited liability company (the "**Buyer**"), pursuant to which the Company may sell to the Buyer up to Twenty Million Dollars ($20,000,000) of the Company's Common Stock, par value $0.01 (the "**Common Stock**"). Terms used herein and not otherwise defined shall have the meanings ascribed to them in the Common Stock Purchase Agreement.

The undersigned, _, Secretary of the Company, in his capacity as such, hereby certifies as follows:

1. I am the Secretary of the Company and make the statements contained in this Secretary's Certificate.

2. Attached hereto as Exhibit A and Exhibit B are true, correct and complete copies of the Company's Third Amended and Restated Bylaws ("**Bylaws**") and Second Amended and Restated Articles of Incorporation ("**Articles**"), in each case, as in effect through the date hereof, and no action has been taken by the Company, its directors, officers or shareholders, in contemplation of the filing of any further amendment relating to or affecting the Bylaws or Articles.

3. Attached hereto as Exhibit C are true, correct and complete copies of the resolutions duly adopted by the Board of Directors of the Company on _________, 2018 at which a quorum was present and acting throughout. Such resolutions have not been amended, modified or rescinded and remain in full force and effect and such resolutions are the only resolutions adopted by the Company's Board of Directors, or any committee thereof, or the shareholders of the Company relating to or affecting (i) the entering into and performance of the Common Stock Purchase Agreement, or the issuance, offering and sale of the Purchase Shares and the Commitment Shares and (ii) and the performance of the Company of its obligation under the Transaction Documents as contemplated therein.

4. As of the date hereof, the authorized, issued and reserved capital stock of the Company is as set forth on Exhibit D hereto.

IN WITNESS WHEREOF, I have hereunder signed my name on this _________ day of March, 2018.

_________, Secretary

The undersigned as the Chief Executive Officer of **RECRO PHARMA, INC.,** a Pennsylvania corporation, hereby certifies that _ is the duly elected, appointed, qualified and acting Secretary of **RECRO PHARMA, INC.**, and that the signature appearing above is his genuine signature.

Exhibit 21.1

LIST OF SUBSIDIARIES

Subsidiary	Ownership Percentage	Jurisdiction of Incorporation or Organization
Recro Gainesville LLC	100%	Massachusetts
Recro Enterprises, Inc.	100%	Delaware
Recro Ireland Limited	100%	Ireland

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Recro Pharma Inc.:

We consent to the incorporation by reference in the Registration Statements (No. 333-216581, 333-216579, 333-208750, 333-208749, 333-206309, and 333-194730) on Form S-8, (No. 333-206492 and 333-218487) on Form S-3, and (No. 333-201841) on Form S-1 of Recro Pharma, Inc. of our report dated March 2, 2018, with respect to the consolidated balance sheets of Recro Pharma, Inc. and subsidiaries as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive income (loss), shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2017, and the related notes (collectively, the "consolidated financial statements"), which report appears in the December 31, 2017 annual report on Form 10-K of Recro Pharma, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
March 2, 2018

Exhibit 31.1

CERTIFICATION

I, Gerri A. Henwood, certify that:

1. I have reviewed this Annual Report on Form 10-K of Recro Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reports (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2018

/s/ Gerri A. Henwood

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

Exhibit 31.2

CERTIFICATION

I, Michael Celano, certify that:

1. I have reviewed this Annual Report on Form 10-K of Recro Pharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):
   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2018

/s/ Michael Celano
Michael Celano
Chief Operating Officer

Exhibit 31.3

CERTIFICATION

I, Ryan D. Lake, certify that:

1. I have reviewed this Annual Report on Form 10-K of Recro Pharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reports (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent function):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 2, 2018

/s/ Ryan D. Lake

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

Exhibit 32.1

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

In connection with the Annual Report of Recro Pharma, Inc. (the “Company”) on Form 10-K for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to such officer’s knowledge:

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

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

Date: March 2, 2018

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

/s/ Michael Celano
Michael Celano
Chief Operating Officer

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