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

FORM 10-K

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2019

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

FOR THE TRANSITION PERIOD FROM _____ TO _____.

COMMISSION FILE NUMBER: 001-37348

Corbus Pharmaceuticals Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**46-4348039** **(I.R.S. Employer Identification No.)**
500 River Ridge Drive **Norwood, Massachusetts** **(Address of principal executive offices)**	**02062** **(Zip Code)**

(617) 963-0100
Registrant's telephone number, including area code:
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange where registered
Common Stock, par value $0.0001 per share	**CRBP**	**The NASDAQ Global 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 [X]

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 [X]

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 [X] No [ ]

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

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

Large accelerated filer [ ]	Accelerated filer [X]
Non-accelerated filer [ ]	Smaller reporting company [X]
	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 Act). Yes [ ] No [X]

As of June 30, 2019, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $390,133,740, based on the closing price of the registrant's common stock on June 30, 2019.

As of March 9, 2020, the number of shares outstanding of the registrant's common stock, $0.0001 par value per share, was 72,490,449.

Documents incorporated by reference

Portions of the registrant's proxy statement for the 2020 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2019, are incorporated by reference in Part III of this Form 10-K.

CORBUS PHARMACEUTICALS HOLDINGS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2019
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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our lack of operating history and history of operating losses;
- our current and future capital requirements and our ability to satisfy our capital needs;
- our ability to complete required clinical trials of our product and obtain approval from the FDA or other regulatory agents in different jurisdictions;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executive members;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements; and
- our ability to adequately support growth.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipate in our forward-looking statements. Please see "Risk Factors" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Item 1. BUSINESS

All references in this report to "Corbus," the "Company," "we," "us," or "our" mean Corbus Pharmaceuticals Holdings, Inc. and its subsidiaries unless we state otherwise or the context otherwise indicates.

Overview

We are a Phase 3, clinical-stage pharmaceutical company focused on the development and commercialization of novel therapeutics to treat chronic and serious inflammatory and fibrotic diseases with clear unmet medical needs by targeting the human endocannabinoid system (ECS). We are developing a pipeline of cannabinoid drug candidates which are rationally designed, synthetic, small molecule drugs which target the ECS to treat inflammatory and fibrotic diseases. Our focus on the ECS is backed by an ever-expanding body of knowledge on the biology of the ECS and its role as being a master regulator of inflammation and fibrosis. Our lead investigational drug candidate, lenabasum, is a novel, synthetic, oral, cannabinoid type 2 (CB2) agonist designed to resolve chronic inflammation, limit fibrosis and support tissue repair. We are currently developing lenabasum to treat four life threatening diseases: systemic sclerosis (SSc), dermatomyositis (DM), cystic fibrosis (CF) and systemic lupus erythematosus (SLE). In addition, we are developing a pipeline of experimental drug candidates from our library of novel compounds targeting the ECS. Our pipeline also includes CRB-4001, a 2nd generation, peripherally restricted cannabinoid receptor type 1 (CB1) inverse agonist designed to treat organ specific fibrotic liver diseases, such as nonalcoholic steatohepatitis, or NASH.

Lenabasum selectively binds to CB2 in the periphery, which is preferentially expressed on activated immune cells, fibroblasts and other cell types, including muscle and bone cells. Lenabasum stimulates the production of Specialized Pro-Resolving Lipid Mediators (SPMs) that act to resolve inflammation and halt fibrosis without immunosuppression by activating endogenous pathways. These pathways are activated in healthy individuals during the course of normal immune responses but are dysfunctional in patients with chronic inflammatory and fibrotic diseases. By its binding to CB2, lenabasum drives innate immune responses from the activation phase into the resolution phase. CB2 plays a central role in modulating and resolving inflammation by, in effect, turning heightened inflammation "off" and restoring homeostasis. This has been demonstrated in animal models lacking CB2 as well as humans with genetic polymorphism in the CB2 gene, as these exhibit excessive inflammation and fibrosis in response to activators of the innate immune system.

Lenabasum is currently being evaluated in a Phase 3 SSc study that has completed the enrollment of 365 patients with top-line data expected to be reported in the summer of 2020, a Phase 2b CF study that has completed the enrollment of 426 patients with topline data expected in the summer of 2020, and a Phase 3 study in DM that is expected to enroll 150 patients. In addition, we are conducting a Phase 2 SLE study funded by a grant through the National Institutes of Health, or NIH, that is expected to enroll 100 patients. Open-label extension studies are ongoing in SSc and DM for patients who completed the Phase 2 studies and Phase 3 studies in these indications. Lenabasum has generated positive clinical data in three consecutive Phase 2 studies in diffuse cutaneous SSc, CF and skin-predominant DM. Lenabasum has demonstrated acceptable safety and tolerability profiles in clinical studies to date.

The U.S. Food and Drug Administration, or FDA, has granted lenabasum Orphan Drug Designation as well as Fast Track Status for SSc and CF, and Orphan Drug Designation for DM. The European Medicines Authority, or EMA, has granted lenabasum Orphan Drug Designation for SSc, CF and DM.

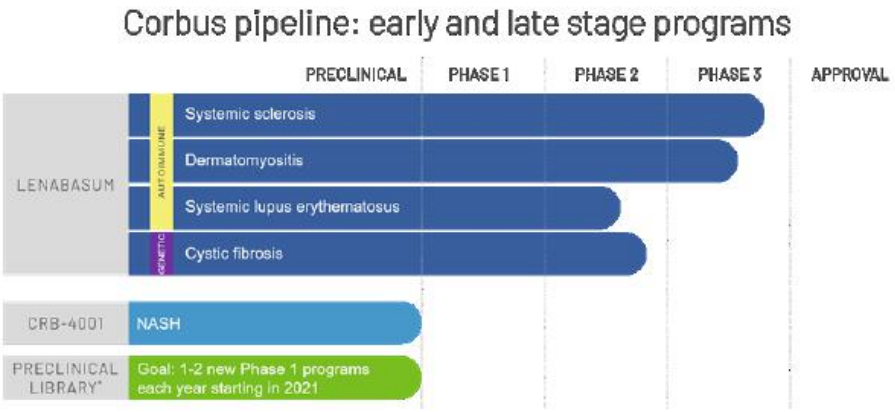
Since our inception, we have devoted substantially all of our efforts to business planning, research anddevelopment, recruiting management and technical staff, acquiring operating assets and raising capital. Our research and development activities have included conducting pre-clinical studies, developing manufacturing methods and the manufacturing of our drug lenabasum for clinical trials and conducting clinical studies in patients. Two of the four clinical programs for lenabasum are being supported by non-dilutive awards and grants. The NIH has funded the majority of the clinical development costs for the DM Phase 2 clinical trial and is funding the SLE Phase 2 clinical trial. In cystic fibrosis, the Phase 2b clinical trial is being supported by the 2018 CFF Award of up to $25 million, and the Phase 2 clinical trial was partially funded by a $5 million award from the Cystic Fibrosis Foundation Therapeutics, Inc., a non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation.

In September 2018, we acquired an exclusive worldwide license to develop, manufacture and market drug candidates from more than 600 compounds, targeting the endocannabinoid system from Jenrin Discovery LLC, or Jenrin. The pipeline includes CRB-4001, our peripherally-restricted, CB1 inverse agonist targeting liver, lung, heart and kidney fibrotic diseases. The current patent portfolio for CRB-4001 includes multiple issued patents and pending patent applications. CRB-4001 was developed in collaboration with and with financial support from the NIH. CRB-4001 was specifically designed to eliminate blood-brain barrier penetration and brain CB1 receptor occupancy that mediate the neuropsychiatric issues associated with first-generation CB1 inverse agonists such as rimonabant. Potential indications for CRB-4001 include NASH, primary biliary cholangitis, idiopathic pulmonary fibrosis, radiation-induced pulmonary fibrosis, myocardial fibrosis after myocardial infarction, and acute interstitial nephritis, among others.

On January 3, 2019, we entered into a strategic collaboration with Kaken Pharmaceutical Co., Ltd., or Kaken, for the development and commercialization in Japan of our investigational drug lenabasum for the treatment of SSc and DM, two rare and serious autoimmune diseases. Under the terms of the agreement, Kaken received an exclusive license to commercialize and market lenabasum in Japan for SSc and DM. In March 2019, Kaken made an upfront payment to us of $27 million. We will be eligible to receive up to an additional $173 million upon achievement of certain regulatory, development and sales milestones as well as double-digit royalties.

The development status of Corbus pipeline is summarized below:

Figure 1: Clinical development pipeline



Clinical Development-Lenabasum

Systemic Sclerosis (SSc)

Ongoing Phase 3 Study

In December 2017, we initiated a Phase 3 double-blind placebo-controlled multi-center international clinical study ("RESOLVE-1) in diffuse cutaneous SSc and we completed enrollment of 365 patients in May 2019. Topline data from this study are expected in summer of 2020. The RESOLVE-1 is a multi-national, 52-week study with subjects being randomized 1:1:1 to receive lenabasum 5 mg twice per day, lenabasum 20 mg twice per day or placebo twice per day.

The primary efficacy outcome of the RESOLVE-1 study is the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis (ACR CRISS). The ACR CRISS score is a composite measure of clinical improvement calculated from weighted changes from baseline in five core outcome measures commonly used to evaluate treatment effect in trials for SSc: modified Rodnan Skin core (mRSS), Health Assessment Questionnaire - Disability Index (HAQ-DI), forced vital capacity (FVC) percent predicted, and patient and physician global assessments of health related to SSc The study is also evaluating multiple secondary endpoints, including changes in mRSS, HAQ-DI, and FVC percent predicted. These same outcomes were evaluated in the Phase 2 study and are also outcomes for the ongoing open-label Phase 2 and Phase 3 extension studies. The open-label extension enables all the participants in the study to continue to receive lenabasum following the conclusion of the trial period.

Encouraging Data from Ongoing Open-Label Extension Study

Thirty-six subjects with diffuse cutaneous SSc received open-label dosing with lenabasum at 20 mg twice per day following 16 weeks participation in the preceding double-blinded placebo-controlled part of the lenabasum Phase 2 study. Patients had a mean of about 20 weeks off treatment from the end of lenabasum dosing during the placebo-controlled period before starting open-label dosing. Lenabasum was administered in addition to standard-of-care treatments for SSc, including concomitant immunosuppressive drugs in 92% of subjects.

Efficacy Outcomes

The ACR CRISS score (ACR CRISS), the primary outcome for Phase 3 RESOLVE-1, increased steadily over time with lenabasum open-label dosing and has maintained ≥ 0.95 from Month 12 through Month 25 in the OLE. Also the mRSS improved > 9.2 points during the same time. Patient and physician global assessments of health, skin symptoms, itch, and patient-reported disability and function showed either stabilization or continued improvement during the OLE from Month 12 through 24. No severe or serious adverse events (AE) or study discontinuations related to lenabasum to date in the OLE.

Figure 2: ACR CRISS Results from Phase 2 Study

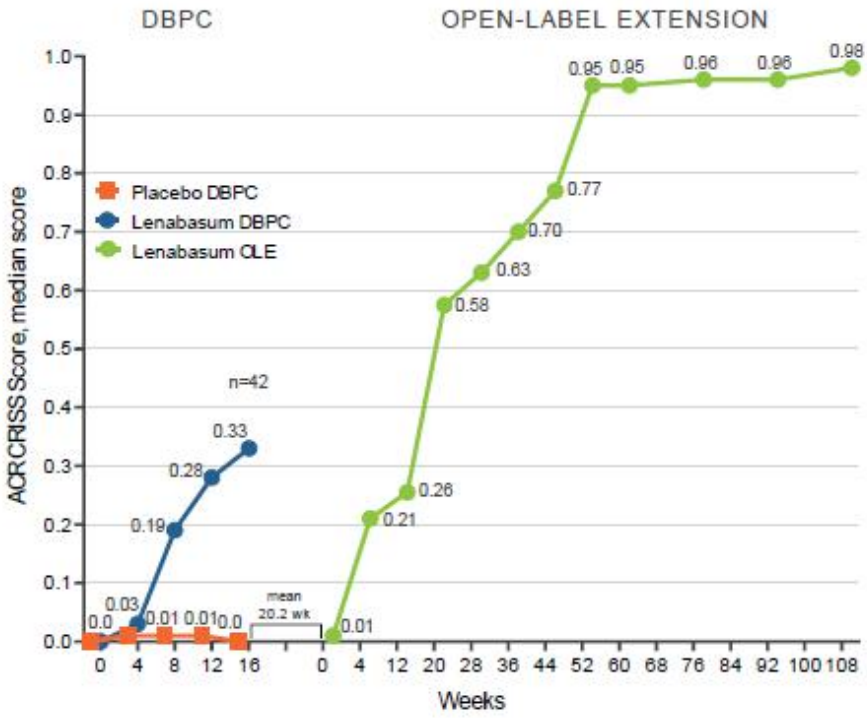
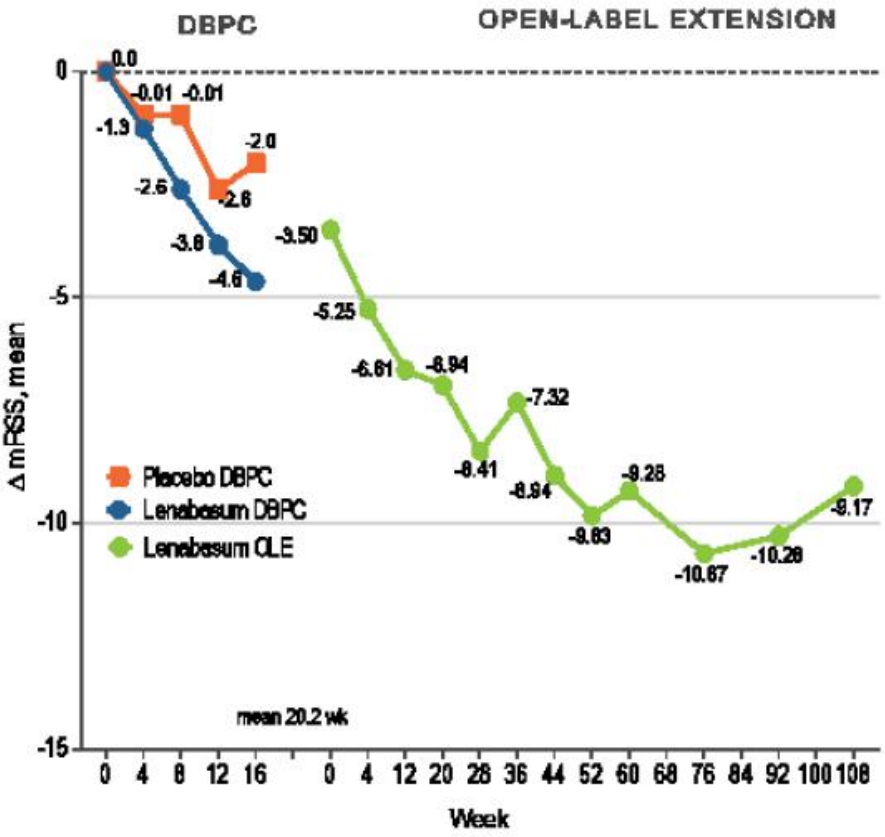


Figure 3: mRSS Results from Phase 2 Study



Safety

There have been no severe or serious adverse events (AEs) or study discontinuations related to lenabasum to date and no clinically significant laboratory abnormalities related to lenabasum in the Phase 2 study, and the safety and tolerability profile of lenabasum remains favorable after months of dosing in the open label extension.

Cystic Fibrosis (CF)

Ongoing Phase 2B Study

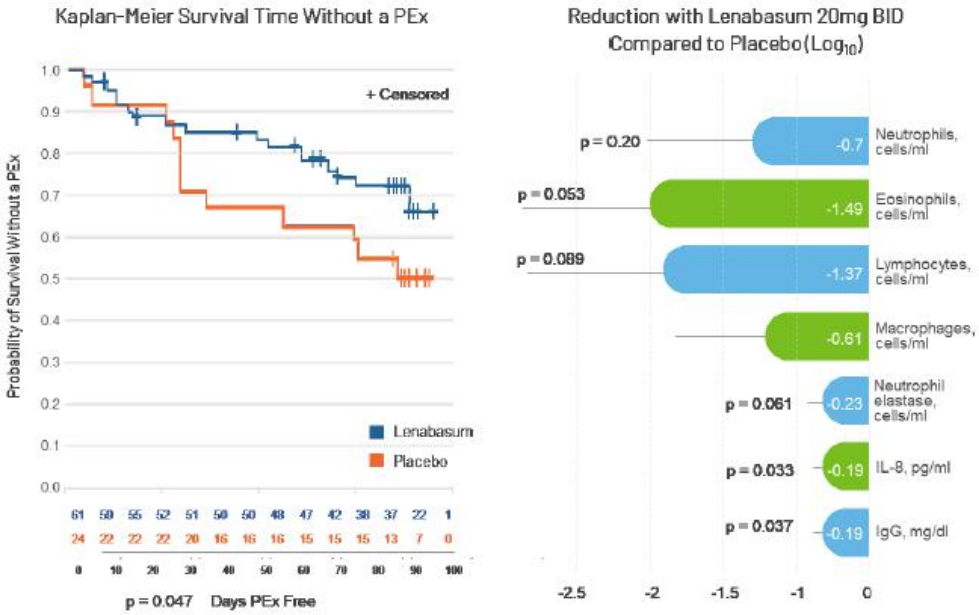
In January 2018, the Company initiated a Phase 2b study in CF which is being funded in part by a development award for up to $25 million from the Cystic Fibrosis Foundation (CFF) and the enrollment of 426 patients was completed in November 2019 in with top line data expected in the summer of 2020. The Phase 2b multicenter, double-blinded, randomized, placebo-controlled study has enrolled CF subjects who are at least 12 years of age and a history of increased risk for pulmonary exacerbations (PEx). The primary outcome is the event rate of PEx which is the average number of PEx per subject per time period. Secondary efficacy outcomes include other measures of PEx, change in Cystic Fibrosis Questionnaire-Revised Respiratory domain score and change in forced expiratory volume in 1 second (FEV1), % predicted. The study is a multi-center international study and subjects were randomized to one of three cohorts to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day for 28 weeks, with 4 weeks follow-up off active treatment. This Phase 2b CF study was designed with input from the therapeutic Development Network of the Cystic Fibrosis Foundation and the European Cystic Fibrosis Society Clinical Trials Network.

Positive Data from Phase 2 Cystic Fibrosis Study

In March 2017, the Company completed a double-blind placebo-controlled Phase 2 study in CF and reported positive results. The Phase 2 study evaluated multiple doses of lenabasum compared to placebo for the treatment of patients with CF. The 16-week study dosed 85 adult CF patients with baseline (FEV1) percent predicted ≥ 40%, who were enrolled without regard to their specific CFTR mutation or infecting pathogens and continued with all baseline treatment regimens.

Lenabasum successfully achieved the primary objective of the study by demonstrating an acceptable safety and tolerability profile at all doses with no serious or severe adverse events related to the study drug. Lenabasum cohorts showed a dose-dependent reduction in a number of acute PEx defined as those requiring intravenous (IV) antibiotics compared to placebo. Additionally, lenabasum caused a consistent reduction in multiple inflammatory cell types in sputum, including total leukocytes, neutrophils, eosinophils, and macrophages. Inflammatory mediators, including interleukin-8, neutrophil elastase, and immunoglobulin G, were also reduced in sputum by lenabasum in a dose-dependent manner. These patient data provide evidence of biological activity of lenabasum in resolving ongoing innate immune responses in lungs of CF patients and support the observed reduction in PEx.

Figure 4: Lenabasum treatment was associated with longer time to PEx in Phase 2 study and consistent reduction in key inflammatory biomarkers in sputum



The Cystic Fibrosis Foundation Therapeutics, Inc. (“CFFT”), the non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation supported the prior Phase 2 study with a $5 million development award. To date, the Company has received two development awards with total potential payments of up to $30 million from the CFF to support the clinical development of lenabasum in CF.

Dermatomyositis (DM)

Ongoing Phase 3 Study

In December 2018, we initiated a Phase 3 double-blind placebo-controlled multi-center international clinical study titled **D**ETER**M**INE in DM. The **D**ETER**M**INE study is a multi-center international trial expected to enroll approximately 150 subjects. The planned duration of treatment with study drug is 52 weeks. Subjects will be randomized to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day in a 2:1:2 ratio. The primary efficacy outcome at Week 52 will be American College of Rheumatology/European League Against Rheumatism 2016 Total Improvement Score (TIS), which is a weighted composite measure of improvement from baseline in six endpoints, including Physician Global Assessment of Disease Activity, Physician Global Assessment of Extramuscular Disease Activity, Patient Global Assessment of Disease Activity, Health Assessment Questionnaire (patient-reported disability), Manual Muscle Testing, and muscle enzymes. Evaluation of key organ involvement – muscle, skin, and lungs, will be included in secondary efficacy outcomes. Change from Baseline in the Cutaneous Dermatomyositis Activity and Severity index ("CDASI") composite activity score will be a secondary efficacy outcome.

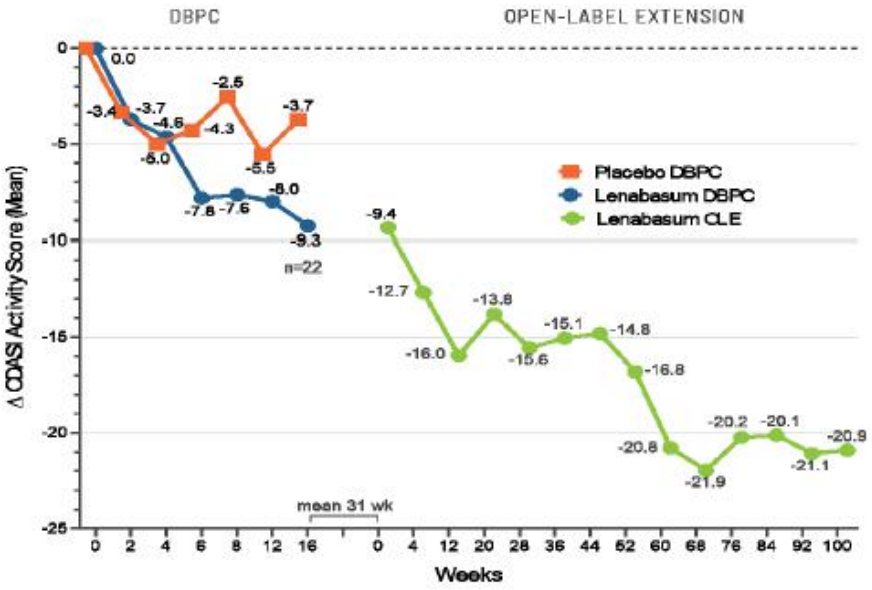
Encouraging Data from Ongoing Open-Label Extension Study

Twenty subjects with skin-predominant DM received open-label dosing with lenabasum at 20 mg twice per day following 16 weeks participation in the preceding double-blinded placebo-controlled part of the lenabasum Phase 2 study. Patients had a mean of about 31 weeks off treatment from the end of lenabasum dosing during the placebo-controlled period before starting open-label dosing. Lenabasum was administered in addition to standard-of-care treatments for DM, including concomitant immunosuppressive drugs in 85% of subjects.

Efficacy Outcomes

The CDASI activity score improved from study start by -20.9 points at 23 months in the open label extension study (OLE). An improvement of -4 to -5 points in CDASI activity score is considered medically important, and 72% of subjects achieved low skin activity (CDASI $\leq$ 14) at 23 months. Continued improvement was observed during the OLE in patient-reported global assessments of skin activity, skin symptoms, itch and hair loss and physician-reported global disease activity, physician assessment of extramuscular disease activity.

Figure 5: CDASI Activity Score During Open Label Extension

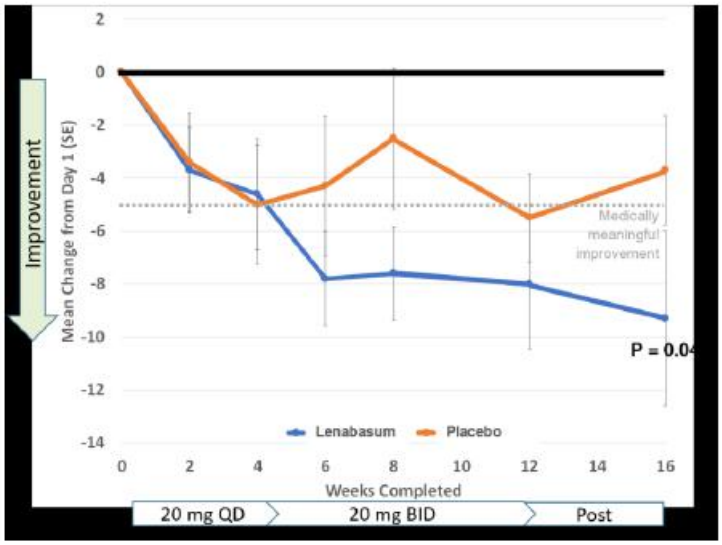


Positive Data from Phase 2 Dermatomyositis Study

In October 2017, the Company completed the double-blind, placebo-controlled portion of the Phase 2 study in skin-predominant DM and reported positive results. The mean improvement (reduction) in the primary efficacy outcome, the CDASI activity score, an, was 9.3 points for lenabasum treatment versus a reduction of 3.7 points for placebo treatment (p = 0.04, 2-sided MMRM) at sixteen weeks. Lenabasum also outperformed placebo in multiple secondary efficacy outcomes studied. Lenabasum was well tolerated with no severe or serious side effects associated with the drug. No subjects dropped out. The dermatomyositis trial was funded by a grant from the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health to the University of Pennsylvania Perelman School of Medicine.

The single center trial enrolled 22 adults at a 1 to 1 ratio of lenabasum to placebo cohorts. At baseline, subjects in each cohort had a mean CDASI activity score in the severe range and skin symptoms in the extremely severe range despite background treatment with immunosuppressive drugs in 19 of the 22 subjects. Demographic parameters, CDASI activity scores, patient-reported outcomes, and use of immunosuppressive drugs at baseline were similar for lenabasum and placebo cohorts. Subjects received lenabasum 20 mg QD through week 4, then lenabasum 20 mg BID through week 12 with safety and efficacy follow-up thereafter through week 16. All subjects remained on their background standard-of-care therapy throughout the study in DM.

Figure 6-Lenabasum Demonstrated Clinically Meaningful Improvement in CDASI



Systemic Lupus Erythematosus (SLE)

In December 2017 a Phase 2 clinical study of lenabasum was initiated for the treatment of systemic lupus erythematosus and patient dosing commenced in February 2018 and we expect to report top line data in 2020. The Phase 2 SLE clinical trial is being conducted by the Autoimmunity Centers of Excellence (ACE) program, which is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH).

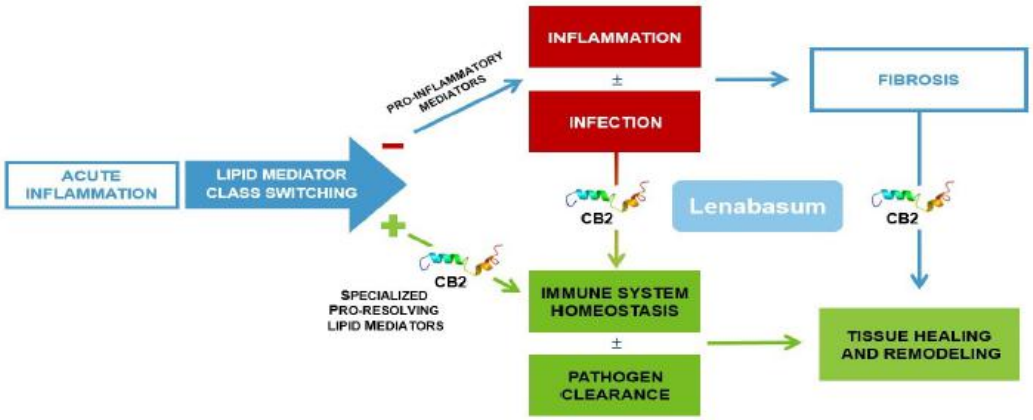
The randomized, double-blind, placebo-controlled, Phase 2 trial is being conducted in the U.S. and is expected to enroll 100 adult SLE patients with active musculoskeletal disease, which is the most common disease manifestation of SLE. Subjects will be randomized in a 1:1:1:1 ratio to one of four cohorts to receive placebo or three different doses of lenabasum for 3 months, with 1-month follow-up. The primary efficacy outcome assesses pain from active musculoskeletal disease, and secondary efficacy outcomes include other assessments of active musculoskeletal disease, overall disease activity using SLE Responder Index, SLE Disease Activity Index ("SLEDAI") and British Isles Lupus Activity Group ("BILAG") scoring systems, and patient-reported outcomes.

Lenabasum's Unique and Novel Mechanism of Action as a Pro-Resolving Drug

Lenabasum is a synthetic, rationally-designed, oral small-molecule drug that selectively binds to the cannabinoid receptor type 2, or CB2, found on activated immune cells, fibroblasts and other cell types including muscle and bone cells. Lenabasum stimulates the production of Specialized Pro-Resolving Lipid Mediators (SPMs) that act to resolve inflammation and halt fibrosis by activating endogenous pathways. These pathways are activated in healthy individuals during the course of normal immune responses but are dysfunctional in patients with chronic inflammatory and fibrotic diseases. Through its binding to the CB2 receptor, lenabasum drives innate immune responses from the activation phase through completion of the resolution phase. The CB2 receptor plays a central role in modulating and resolving inflammation by, in effect, turning heightened inflammation "off" and restoring homeostasis. This has been demonstrated in animal models lacking CB2 as well as humans suffering from polymorphism in the CB2 gene, as these exhibit abnormal immune responses and a propensity for chronic inflammation.

A key aspect of the body's innate immune response is its activation phase when inflammatory cells are recruited to the site of tissue infection/injury whereupon these cells act to target the infection and/or respond to tissue damage. The next phase in a normal innate immune response is its resolution phase, during which the nature of the infiltrating immune cells changes from pro-inflammatory to pro-resolving, the infectious pathogens are eliminated, residual cellular debris and immune cells are cleared from the tissue, and tissue repair processes are eventually halted when they are no longer needed. In chronic inflammatory and fibrotic diseases, the innate immune responses are "stuck" in the initial activation phase. This failure to progress through the resolution phase causes chronic tissue infiltration with inflammatory cells and chronic activation of healing processes that cause tissue scarring, or fibrosis. The key event that propels an innate immune response from its activation phase to its resolution phase is a "class switch" from production of pro-inflammatory lipid mediators such as prostaglandins and leukotrienes to a family of SPMs (Figure 1) which include lipoxins, resolvins, protectins, and marescins. If an innate immune response persists in the activation phase and does not progress through resolution, chronic inflammation and fibrosis can result, causing organ dysfunction, organ failure, severe morbidity and even death. There are hundreds of life-long chronic and incurable inflammatory diseases.

Figure 7-Lenabasum's Mechanism of Action



Lenabasum is designed to restore immune system homeostasis, by harnessing the body's own physiologic pathways to transition the innate immune response from the activation phase to the resolution phase. If the innate immune response is "stuck" in the activation phase, tissue damage, fibrosis and persistent infection are expected consequences. Endogenous progression of the innate immune response through its resolution phase has been shown to clear inflammation, stop fibrosis, and promote pathogen clearance. Lenabasum's unique mechanism of action is different than anti-inflammatory drugs that inhibit the production or functions of distinct pro-inflammatory mediators that initiate or are active during the activation phase. Activation of an innate immune response is necessary to clear infections, however drugs that interfere with the activation phase carry the risk of immunosuppression and may have other undesirable side effects. In contrast, lenabasum is designed to transition an innate immune response from its activation phase to resolution phase. Lenabasum's CB2 agonist activity initiates a class switch in bioactive lipid mediators from inflammation-activating mediators to pro-resolving mediators. Lenabasum acts to impact and activate multiple pathways including:

- Increase in production of SPMs and anti-inflammatory eicosanoids, with a concomitant decrease in production of pro-inflammatory eicosanoids.
- Increase in production of anti-inflammatory cytokines, coupled with a decrease in production of pro-inflammatory cytokines and pro-fibrotic growth factors.
- Increase in influx of non-inflammatory macrophages with a decrease in influx and accumulation of inflammatory cells and pro-fibrotic myofibroblasts.

- Increase in bacterial clearance. SPMs stimulate production of bactericidal peptides, enhance phagocytosis and killing of bacteria by neutrophils and macrophages.
- Increase in apoptosis of inflammatory cells, including neutrophil and pro-fibrotic cells, including fibroblasts.
- Increase in clearance of apoptotic cells and cellular debris by non-inflammatory macrophages.

Effect of Lenabasum in a Human Model of Inflammatory Resolution

Dr. Derek Gilroy, Professor of Experimental Inflammation and Pharmacology at University College of London evaluated the effects of lenabasum in a clinical research model of inflammation and its resolution in healthy volunteers. In this model, inflammation was triggered in healthy individuals by the subcutaneous injection of heat-killed E. coli. Blood flow to the site of inflammation was measured with laser Doppler techniques. Suction blisters were generated over the site of inflammation, and cells and inflammatory mediators were measured in the blister fluid at different times after the injection of E. coli. In this study 22 subjects received either lenabasum at 5 mg or 20 mg twice a day or placebo prior to the procedure.

The data demonstrated that both doses of lenabasum exerted potent anti-inflammatory effects by inhibiting neutrophil infiltration and increased the clearance of bacteria as measured by local endotoxin levels, both key determinants of inflammation. Controlling neutrophils is considered highly important for treating many diseases driven by chronic inflammation. In addition to inhibiting neutrophil accumulation, lenabasum also enhanced clearance of the injected bacteria. The data were published in January 2018 in the peer-reviewed “Clinical Pharmacology & Therapeutics” journal in a paper entitled: “Potent anti-inflammatory and pro-resolving effects of lenabasum in a human model of self-resolving acute inflammation. The findings in this paper provide additional evidence for lenabasum’s unique mechanism of action to modulate the trafficking of key harmful effector cells to the site of infection and injury without compromising internal host defense mechanisms, and instead enhancing it. This dual mechanism of action of lenabasum combines the inhibition of lipid mediators that normally reduce the immune system’s ability to clear bacteria with the inhibition of pro-inflammatory lipid mediators. This unique activity of lenabasum ultimately drives the inflammatory response down the pro-resolution pathway.

Figure 8- Lenabasum Increases Pro-Resolving Lipid Mediators in Humans

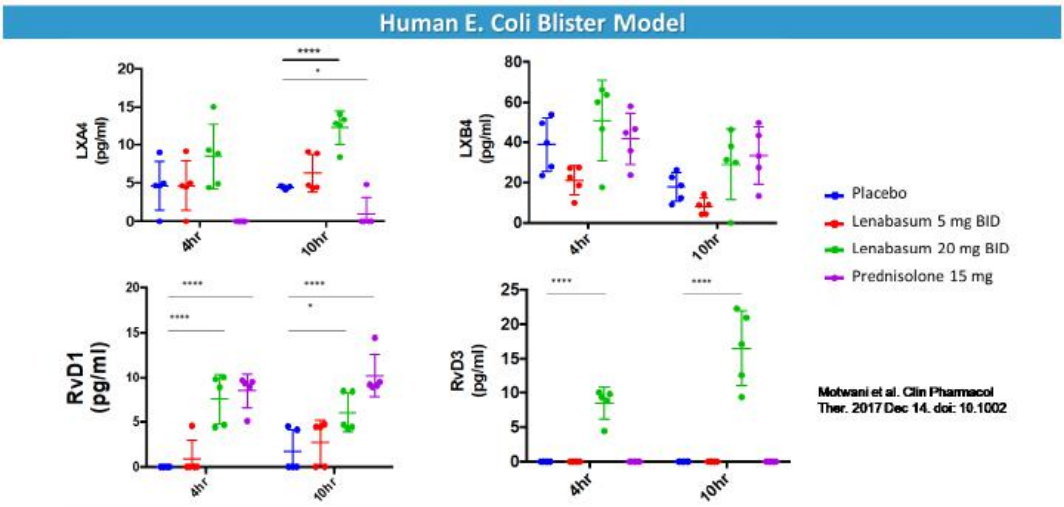
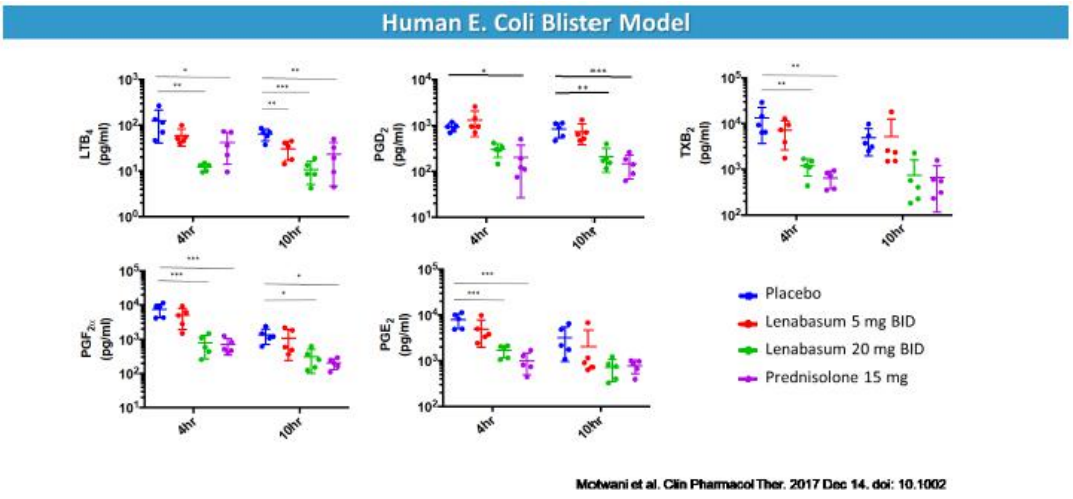


Figure 11- Lenabasum also Decreases Inflammatory Lipid Mediators in Humans



Data from this human clinical model demonstrated that lenabasum activates the resolution of innate immune responses and is the first experimental therapeutic shown to activate the "pro-resolution" pathway in humans. These results are consistent with previous findings from experiments that evaluated lenabasum's effects in animal models of inflammation and support lenabasum's potential to deliver therapeutic benefit in chronic inflammatory diseases as a first-in-class pro-resolution drug. The results identify the CB2 receptor, the therapeutic target of lenabasum, as a key link between the innate immune response and the endocannabinoid system acting as an upstream activator of the resolution of innate immunity. The top dose of lenabasum in this study at 20 mg twice a day is the same as the highest dose in the Phase 3 SSc clinical trial and the Phase 2b CF trial.

Clinical Development-CRB-4001 and other synthetic cannabinoid drugs

Corbus is developing CRB-4001, 2nd generation, peripherally restricted selective (CB1) inverse agonist for nonalcoholic steatohepatitis (NASH) and other fibrotic diseases. CRB-4001 was developed in collaboration with and financial support from the National Institutes of Health (NIH). CRB-4001 was specifically designed to eliminate blood-brain barrier penetration and brain CB1 receptor occupancy that mediate the neuropsychiatric issues associated with first-generation CB1 inverse agonists, such as rimonabant. Corbus expects data from its Phase 1 safety study in 2020.

We are also evaluating and characterizing compounds from of our compound library to select additional clinical candidates to move forward into clinical studies. The next clinical candidate from our proprietary platform will be selected in 2020.

Market Opportunity for Lenabasum in Inflammatory and Fibrotic Diseases

There are many different chronic, serious inflammatory and fibrotic diseases that could be addressed by treatment with lenabasum. Some examples of chronic, serious diseases characterized by inflammation with variable degrees of fibrosis include genetic diseases such as cystic fibrosis, nonalcoholic steatohepatitis ("NASH"), myelofibrosis, lung diseases including idiopathic pulmonary fibrosis, bronchiolitis obliterans, and sarcoidosis and autoimmune diseases including systemic sclerosis, systemic lupus erythematosus, myositis, rheumatoid arthritis, vasculitis, primary biliary cirrhosis.

Lenabasum Market Opportunity for Current Indications Being Developed

Autoimmune Disorders

Systemic Sclerosis

Systemic sclerosis (SSc) is a chronic, systemic autoimmune disease characterized by activation of innate and adaptive immune systems, an obliterative, proliferative vasculopathy of small blood vessels, and fibrosis of the skin and multiple internal organs. Approximately 200,000 people in the U.S., Europe and Japan have SSc. The disease affects mainly adults (80% of SSc patients are women) with mean age of onset about 46 years of age in the U.S. and the majority of patients between 45-64 years of age.

A commonly used system classifies SSc patients into those with more wide-spread skin thickening (diffuse cutaneous SSc, about 35% of patients) and those with more restricted skin thickening (limited cutaneous SSc, about 65% of patients). There is significant overlap in the clinical manifestations for these two groups of SSc patients and no known significant differences in disease pathogenesis.

SSc can affect multiple internal organs in the body, including the lungs, heart, kidneys, joints, muscles, esophagus, stomach and intestines. Clinically apparent organ involvement that occurs in more than a third of these patients includes thickened skin, Raynaud's phenomenon, esophageal symptoms, pulmonary fibrosis, restrictive lung disease, edematous skin, joint contractures, digital ulcers, and muscle weakness. Less frequently occurring, yet life-threatening manifestations include pulmonary artery hypertension (about 1 in 5 patients), cardiac conduction blocks (about 1 in 10 patients), and renal crisis (about 1 in 50 patients). In the U.S., SSc is the deadliest of the systemic autoimmune diseases. The median disease duration for an individual who dies of SSc is 7.1 years from the onset of symptoms. About 85% of deaths caused by SSc are the result of pulmonary fibrosis, pulmonary artery hypertension, or cardiovascular disease, such as sudden death.

In SSc the innate immune system fails to transition from the activation phase to the resolution phase. Individuals with SSc who have interstitial lung disease have an imbalance of bioactive lipid mediators, causing a predominance of inflammatory mediators versus resolving mediators. The preponderance of inflammatory mediators correlates positively with the degree of inflammation in the lungs and negatively with forced vital capacity, a measure of lung fibrosis. Excessive activation of the pathways which cause fibrosis including TGFβ, myofibroblast accumulation, and production of collagen and other extracellular matrix proteins are all present in SSc.

There is no cure for systemic sclerosis, and there are no FDA-approved treatments for this disease. Drugs such as methotrexate, mycophenolate and cyclophosphamide are often prescribed to treat symptoms and/or address organ specific manifestations associated with SSc. These immunosuppressive drugs are not specifically FDA approved for SSc, do not treat the totality of the disease, and may be associated with significant side effects, such as serious infections.

We believe there is general agreement in the SSc community that an effective anti-inflammatory and anti-fibrotic drug that addresses the totality of the disease and help patients function and feel better would address a significant unmet medical need in SSc, especially a drug that is orally administered, can be used chronically with other commonly prescribed medications for SSc, and is not immunosuppressive. We believe such a therapy would be positively received by the market.

Dermatomyositis

Dermatomyositis (DM) is a serious and rare autoimmune idiopathic inflammatory myopathy with characteristic cutaneous findings. About 80,000 individuals in the U.S., Europe and Japan suffer from dermatomyositis. DM usually strikes adults, with most common age of adult onset between 50-60 years.

This systemic disorder most frequently affects the skin and muscles, and DM can also include interstitial lung disease/restrictive lung disease, arthritis, gastrointestinal and cardiac involvement. Inflammatory muscle disease associated with DM can cause discomfort and significant weakness of the proximal muscles of the arms and legs and of the trunk. Dermatomyositis can include damaging inflammation elsewhere in the body, for example: lung inflammation that leads to lung fibrosis and restrictive lung disease; heart inflammation that causes arrhythmia, congestive heart failure, and pericarditis, inflammation of muscles in the esophagus that causes swallowing problems or aspiration pneumonia, and arthritis. DM patients may have active skin disease despite successful treatment of their muscle and/or lung disease. The skin findings in DM can be disfiguring and are inflammatory rashes characterized by redness and itching in exposed areas of the skin, around the eyes, on the hands, and in a "shawl" distribution on the scalp, hands, upper back, and photo-exposed areas. Due to this chronic inflammation, patients with DM have an increased risk of malignancy, most commonly in older patients. By itself, skin involvement in DM has a large negative impact on quality of life, comparable to that of cutaneous lupus erythematosus and vulvodynia, and much higher than those of many dermatologic diseases. The pathophysiology of DM is consistent with a patient's inherent inability to adequately resolve innate immune responses.

There is no cure for DM, a disease that continues to progressively worsen over time. Typically, people with DM are prescribed drugs that suppress the immune system. These treatments may be associated with significant side effects, such as serious infections. FDA-approved treatments for DM include systemic corticosteroids and adrenocorticotropic hormone analogue.

We believe that an effective drug that controls inflammation in the skin, muscles, and other organs will address a significant unmet medical need in DM, particularly a drug that is orally administered, can be used chronically with other commonly prescribed medications for the disease, and is not immunosuppressive.

Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is a prototypical autoimmune disease with a wide array of clinical manifestations, including arthritis, rash, photosensitivity, oral ulcers, pleuritis, pericarditis, kidney problems, seizures and psychosis and blood cell abnormalities. About 550,000 individuals in the U.S., Europe and Japan suffer from SLE. The musculoskeletal system is the most commonly involved system in SLE. Patients with SLE have an increased frequency of related autoimmune problems, such as Sjogren's syndrome and antiphospholipid syndrome that require additional treatments. SLE may occur with other autoimmune conditions, such as thyroiditis, hemolytic anemia, and idiopathic thrombocytopenia purpura. Accelerated atherosclerosis among SLE patients is responsible for premature mortality.

The pathology of SLE involves chronic activation of the innate immune system by immune complexes, with activation of the complement cascade, increased production of type 1 interferons and other mediators of inflammation and resultant tissue inflammation and damage.

Medicines specifically approved by the FDA for treatment of SLE are aspirin, hydroxychloroquine, corticosteroids (for example, prednisone), the corticotropin injection Acthar® and the immunosuppressive drug Benlysta®. Other drugs that are not specifically FDA approved for SLE but are often prescribed by physicians include methotrexate, mycophenolate, azathioprine and cyclophosphamide. These treatments may be associated with significant side effects, such as serious infections.

We believe that an effective drug that controls inflammation in the joints and skin as well as improves overall disease activity will address a significant unmet medical need in SLE, particularly a drug that is orally administered, can be used chronically with other commonly prescribed medications for the disease, and is not immunosuppressive.

Cystic Fibrosis

Cystic fibrosis (CF) is a life-long, progressive, debilitating, and life-threatening autosomal recessive disease. Cystic fibrosis is caused by mutations in the gene Cystic Fibrosis Transmembrane Conductance Regulator (CFTR). The CFTR serves as a central hub to modulate transport, trafficking, and signaling in cells. Given multiple roles of CFTR in cellular activation and homeostasis, mutation of the CFTR give rise to multiple disorders in respiratory, digestive and reproductive organs.

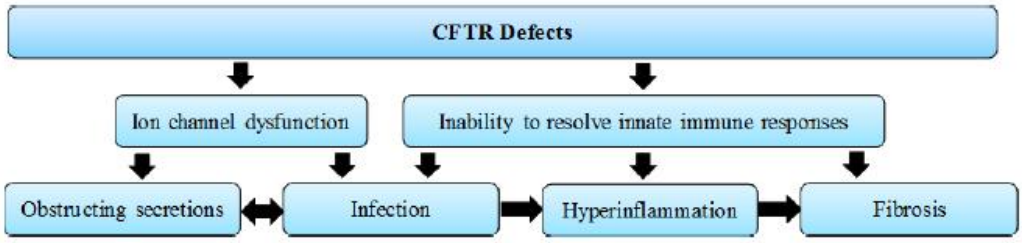
The current median life expectancy of cystic fibrosis patients is about 40 years. According to the Cystic Fibrosis Foundation, 30,000 Americans and a total of 70,000 people in the U.S. and Europe suffer from cystic fibrosis.

The CFTR mutations lead to defective ion transport, with reduced chloride and bicarbonate secretion and sodium hyper-absorption, followed by water hyper-absorption, by airway epithelia and other cell types. The resultant reduced height of epithelial lining fluid and decreased hydration of mucus results in abnormally thick and sticky mucus, which obstructs the lumen into which the mucus is secreted and reduces mucociliary clearance of bacteria. The dysfunction in ion transport in CF patients is reflected in abnormal sweat chloride levels.

The negative effects caused by CFTR gene mutations are not restricted to ion channels, but also extend to dysfunction of the innate immune system. The nature of the abnormalities in CF are consistent with inability of innate immune responses to make the transition out of the activation phase and into and through the resolution phase. Bioactive lipid mediators (SPMs) that initiate the transition to resolution phase of innate immune responses have been found to be deficient relative to pro-inflammatory lipid mediators that initiate its activation phase, and this reduction correlates with poor recovery of lung function following an acute pulmonary exacerbation in children. The preponderance of activated neutrophils and pro-inflammatory macrophages in inflamed tissue, reduced neutrophil apoptosis, high levels of neutrophil proteases that reflect persistent neutrophil activation, reduced clearance of neutrophils by macrophages, ineffective clearance of certain bacteria such as *P. aeruginosa*, and excessive activation of fibrotic pathways all show the inability of individuals with CF to resolve their innate immune responses.

An overview of the disease progression in cystic fibrosis is provided in Figure 10.

Figure 10: Factors involved in cystic fibrosis progression



As a result of obstructing secretions, recurrent infections, hyper-inflammation, and activated fibrotic pathways in the lungs, individuals with CF develop bronchiectasis, pulmonary fibrosis, mixed obstructive/restrictive lung disease, and, eventually, respiratory failure. They may also have chronic sinusitis and nasal polyps. The same pathophysiologic events of obstruction, infection, chronic inflammation, and tissue damage/fibrosis occur in the gastrointestinal system, which can lead to bowel obstructions, fat malabsorption, bacterial overgrowth, gut dysmotility, malnutrition, growth retardation, low weight, pancreatic insufficiency, cystic fibrosis-related diabetes, gallstones, and liver failure including cirrhosis. Adult males with cystic fibrosis have degeneration of the ductus deferens and sterility. End-stage organ involvement in cystic fibrosis is sometimes treated with transplantation, especially lung transplantation.

Current therapies for cystic fibrosis include mucolytics to breakdown mucus, antibiotics to fight bacterial infection, and drugs that act to restore some functionality to the faulty CFTR protein in patients, including Kalydeco® Orkambi®, Symdeco® and Trikafta®. Drugs that are designed to partially restore ion channel functions of mutant CFTR protein are not necessarily able to correct the dysfunction of the innate immune system. For example, ivacaftor treatment has not been associated with reduction in sputum neutrophils or neutrophil derived proteases in CF patients.

All CF patients appear to have dysfunction in resolution of the innate immune system, no matter which CFTR mutations a given patient has. This is borne out by the incidence of pulmonary exacerbations which according to the CF registry occur at an event rate of 0.64 times per patient per year. On average, patients spend nearly 18 days hospitalized for pulmonary exacerbations per year. A pulmonary exacerbation is acute worsening of the patient's day-to-day signs and symptoms of lung disease and is associated with worsening of inflammation at the start of the exacerbation. Failure to resolve lung inflammation during a pulmonary exacerbation is associated with treatment failure, such as need to change antibiotics, prolonged antibiotic therapy, early recurrent of pulmonary exacerbation, and failure to recover lung function lost during the exacerbation. Pulmonary exacerbations in CF are associated with reduced survival, lung function, and patient quality of life and increased health-care burden. The annual average pulmonary exacerbation hospitalization related costs in the U.S. vary from $30,000 for a "mild" exacerbation to as high as $120,000 in patients with severe lung disease. Currently, there are no approved drugs used to address pulmonary exacerbations, a key driver of morbidity and mortality in cystic fibrosis.

We believe there is general agreement in the CF community that an effective drug that will reduce hyper-inflammation and help reduce the rate of pulmonary exacerbations would address a significant unmet medical need in CF, especially a drug that is orally administered, can be used chronically with other prescribed medications for CF, is not immunosuppressive, and has anti-fibrotic effects.

Current Treatment Alternatives for Chronic, Serious Diseases Characterized by Chronic Inflammation and Fibrosis

Drugs currently used to treat chronic serious inflammatory and fibrotic diseases are divided broadly into several groups: non-steroidal anti-inflammatory drugs (NSAIDS), anti-malarial agents, systemic corticosteroids, and other immunosuppressive agents. The choice of agent or combination generally depends upon the underlying disease, and physician and patient preferences.

The potency of NSAIDs in the treatment of chronic, serious diseases, inflammatory and fibrotic diseases is often too limited to control disease activity, requiring patients to receive additional treatment with anti-malarial drugs, systemic corticosteroids or immunosuppressive agents. Anti-malarial therapy is used as a baseline treatment for chronic inflammation in certain autoimmune diseases, typically SLE and DM, especially in patients with milder manifestations of disease. Anti-malarial therapy is frequently ineffective in controlling chronic, serious inflammation, or can cause adverse drug reactions. Antimalarial-refractory disease is then treated with systemic therapies that may cause additional toxicity, including systemic corticosteroids and immunosuppressive agents.

Systemic corticosteroids are commonly prescribed for treatment of chronic, serious diseases characterized by chronic inflammation and fibrosis, such as cystic fibrosis, SSc, and DM. Chronic corticosteroid use is limited by toxicities that include growth retardation, iatrogenic Cushings's Disease, hypertension, high glucose levels/diabetes, obesity, brittle bones/osteoporosis, aseptic necrosis of bone, immunosuppression/increased infection, glaucoma, depression, and psychosis. Thus, safer yet potent alternatives to steroids have long been sought.

Multiple other immunosuppressive drugs are used to treat chronic, serious, inflammatory diseases, to achieve disease control and to curtail the need for corticosteroids. These include biological agents, such as monoclonal antibodies or fusion proteins, which target a very specific molecule in a key disease pathway. These drugs have several disadvantages including parental administration and increased associated incidence of malignancy and infection. Non-biologic immunosuppressive agents that are used to treat chronic, serious inflammation include methotrexate, mycophenolate, leflunomide, cyclophosphamide, and azathioprine, among others. Intravenous immunoglobulin is used occasionally to treat refractory chronic, serious inflammatory diseases.

Lenabasum As a Pro Resolving Drug with a Novel Mechanism of Action Has Safety Advantages versus Anti-Inflammatory Drugs, Steroids and Immunosuppressive Agents

Corticosteroids and NSAIDs exert their effect by inhibiting the activation of inflammation. In simple terms, both classes of drugs inhibit inflammation by "interfering" with the biochemical pathways in the cell that promote and sustain inflammation. For example, NSAIDs directly inhibit the activity of the COX 1 and COX 2 enzymes that are responsible for generating pro-inflammatory eicosanoids. A drawback of this approach is that it one arm of the eicosanoid pathway (e.g. COX but not LOX) is inhibited resulting in a build-up in LOX-derived inflammatory mediators which leads to gastrointestinal and cardiovascular side effects (termed "molecular shunting"). Lenabasum on the other hand triggers endogenous pathways that resolves inflammation and halts fibrosis without immunosuppression Therefore lenabasum potentially offers a new and unique mechanism to treat a spectrum of rare, chronic, serious inflammatory and fibrotic diseases.

Autoimmune Disorders

Systemic Sclerosis

Cytotoxic and immunosuppressive medications are used to control overall disease activity in SSc. In a one-year study of 2,739 SSc patients in the U.S., 44.3% received corticosteroids, 4.8% received mycophenolate mofetil, 2.7% received cyclophosphamide, and 0.5% received cyclosporine. In a report of 7,655 patients in the European Scleroderma Trials and Research Group database, the percentage of SSc patients receiving immunosuppressant treatments were: prednisone (43.5%) with median dose of 8 mg/day; cyclophosphamide (15.9%); methotrexate (13.7%); azathioprine (6.4%); mycophenolate mofetil (4.2%), d-penicillamine (2.1%), and rituximab (1%).

DM

Current medications for DM involve both treatments to reduce overall disease activity and specific treatments to control the muscle disease and the skin disease. The muscle component is treated by administering corticosteroids, typically with an immunosuppressive agent. The skin component of the disease is treated by avoiding sun exposure and by using sunscreens and photoprotective clothing, as well as with topical corticosteroids, antimalarial agents such as hydroxychloroquine and immunosuppressive medications such as methotrexate, azathioprine, mycophenolate mofetil, or intravenous immunoglobulin.

Systemic Lupus Erythematosus

Similar to DM, current medications for SLE involve treatments to reduce overall disease activity and specific treatments for a given organ involvement. Commonly used medications include NSAIDs, topical corticosteroids, antimalarial agents, prednisone, belimumab, and other immunosuppressive medications such as mycophenolate, methotrexate, azathioprine, and cyclophosphamide.

Cystic Fibrosis

The importance of treating inflammation in cystic fibrosis is confirmed in the Cystic Fibrosis Foundation's Strategic Plan, 2014-2018. While treatment with systemic corticosteroids and ibuprofen are effective in improving the symptoms of cystic fibrosis, the side effects associated with chronic treatment using these drugs are significant. Specifically, long term usage of oral corticosteroids in children are associated with glucose intolerance, cataract formation, multiple bone fractures secondary to osteoporosis or osteopenia, Cushing disease effects, and anorexia nervosa as well as growth retardation. The use of high dose ibuprofen is limited by the years of treatment it takes to show benefit, a need to monitor levels closely in the patient, and the increased risk of gastrointestinal bleeding. As a result, these drugs have limited long-term use in cystic fibrosis.

Other therapies routinely used by cystic fibrosis patients routinely include antibiotics, such as Cayston from Gilead and TOBI from Novartis, and mucolytics, such as Pulmozyme from Genentech. In addition, Vertex currently markets the only approved drugs that specifically target the defective CFTR protein; Kalydeco, Orkambi Symdeko and Tricafta.

Competition

For autoimmune disorders such as SSc, DM and SLE, physicians treat patients with a number of drugs including potent immunosuppressants and cytotoxics to try to reduce the autoimmune response characteristic of the disease. These drugs have not proven to be very effective, thus there remains a high unmet need for safe and effective drugs to treat these autoimmune disorders. Several companies, including Boehringer Ingelheim, Galapagos, GlaxoSmithkline, Bristol Myers, Sanofi, Kadmon Holdings and Emerald Health, are actively working to develop new drugs for treating the inflammation and/or fibrosis in SSc. To the best of our knowledge, lenabasum offers a unique mode of action to treat SSc being one of the few oral drugs with the potential to resolve inflammation and halt fibrosis without immunosuppression.

There are numerous drug therapies currently used to treat CF patients, targeting different aspects of this complex disease. Inhaled and oral antibiotics address the pulmonary microbial infection. Mucolytics address the accumulation of mucus in the lungs. Bronchodilators and hydration agents are also used to help improve pulmonary function. Targeting of the inflammatory component of the disease is currently done by high dose Ibuprofen and oral corticosteroids. While these offer some clinical benefit, they are not used chronically due to their adverse side effects which include immunosuppression and metabolic changes (steroids) as well as the risk of gastrointestinal bleeding (ibuprofen). Thus, there is a clear and urgent unmet medical need for safe and effective inflammation-targeting drugs for the chronic treatment of CF that could potentially have a beneficial impact on morbidity and mortality. An emerging and growing area of CF therapy has been the development and commercialization of correctors and potentiators of CFTR by Vertex (Kalydeco® Orkambi®, and Tricafta®).

Sales and Marketing for Lenabasum

We are developing our marketing, commercial operation, distribution, market access and reimbursement capabilities in anticipation of potential FDA approval for lenabasum. Our intent is to commercialize lenabasum ourselves in the United States with a targeted customer-facing organization to call on treating specialists and payers. In Europe we are evaluating potential partnerships as well as considering the option of commercializing ourselves. In Japan we granted exclusive license rights to Kaken Pharmaceutical Co., Ltd., or Kaken, for the commercialization of lenabasum for the treatment of SSc and DM. Under the terms of our agreement with Kaken, Kaken made an upfront payment to us of $27 million and we are eligible to receive up to an additional $173 million upon achievement of certain regulatory, development and sales milestones as well as double-digit royalties.

Research and Development

We incurred expenses of approximately $88,605,000 and $48,614,000 for research and development activities for the years ended December 31, 2019 and 2018, respectively. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs for lenabasum.

Intellectual Property

We have filed patent applications directed to lenabasum, compositions and methods for treating disease using lenabasum. If granted, the resulting patents would expire on dates ranging from 2031 to 2034, subject to extension under certain circumstances. The patent application filings are directed to:

- Compositions including an improved ultrapure version of lenabasum and uses of the compositions for the treatment of fibrotic conditions and inflammatory conditions;
- The use of lenabasum in the treatment of fibrotic diseases; and
- Lenabasum formulations and uses of the formulations for the treatment of disease.

Issued Patents

On August 6, 2019, the U.S. Patent and Trademark Office (“USPTO”) issued U.S. Patent No. 10,369,131 to the Company with claims covering the use of pharmaceutical compositions comprising lenabasum for the treatment of dermatomyositis. The patent provides exclusivity in the U.S. for this use of lenabasum to February 12, 2034.

On December 18, 2018, USPTO issued U.S. Patent No. 10,154,986 to the Company with claims covering pharmaceutical compositions of lenabasum. The patent provides exclusivity in the U.S. for this use of lenabasum compositions to February 12, 2034.

On October 3, 2018, the USPTO issued U.S. Patent No. 10,085,964 to the Company with claims covering the use of pharmaceutical compositions comprising lenabasum for the treatment of all fibrotic diseases, including Corbus' lead indications systemic sclerosis, dermatomyositis, cystic fibrosis and others. The patent provides exclusivity in the U.S. for this use of lenabasum to February 12, 2034.

On October 31, 2017, the USPTO issued U.S. Patent No. 9,801,849 to the Company with claims covering the use of pharmaceutical compositions comprising lenabasum, Corbus' lead product in development for the treatment of inflammatory diseases. The patent provides exclusivity in the U.S. for this use of lenabasum to February 12, 2034.

On November 27, 2017, the USPTO issued U.S. Patent No. 9,820,964 to the Company with claims covering the use of pharmaceutical compositions comprising lenabasum for the treatment of fibrotic diseases, encompassing the Company's lead indications: systemic sclerosis, DM, cystic fibrosis as well as others. The patent provides intellectual property protection in the United States for this use of lenabasum to February 12, 2034.

On September 20, 2018, we entered in an exclusive license agreement with Jenrin Discovery, LLC which provides us with an exclusive worldwide license to develop and market cannabinoid compounds covered by the Jenrin issued patents and patent applications that cover the composition and method of use of selective cannabinoid receptor modulators. The Jenrin intellectual property portfolio includes fifteen granted U.S. patents and 23 granted or pending foreign patents and applications. This portfolio includes U.S. Patent No 9,987,253, which granted with claims covering the cannabinoid receptor blocker CRB-4001 and methods of using the same for treating obesity, diabetes, inflammatory disorders, cardiometabolic disorders, hepatic disorders, and/or cancers. The licensed intellectual property portfolio provides intellectual property protection in the United States for CRB-4001 to July of 2033, not including any potential patent term extension.

Lenabasum has been granted Orphan Drug Designation for cystic fibrosis, dermatomyositis and systemic sclerosis in the U.S. and in the European Union. In addition, in systemic sclerosis and in cystic fibrosis, Lenabasum has been granted a Fast Track Designation by the FDA. We will be seeking orphan drug status for lenabasum in Japan for systemic sclerosis and eventually in DM. Orphan designation for lenabasum may be pursued for other inflammatory diseases in the U.S. and in Europe. Orphan drug status provides seven years of market exclusivity in the U.S. and ten years in Europe and Japan beginning on the date of drug approval.

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection for lenabasum and to operate without infringing the proprietary right of others and to prevent others from infringing our proprietary rights. We strive to protect our intellectual property through a combination of patents and trademarks as well as through the confidentiality provisions in our contracts. With respect to lenabasum, we endeavor to obtain and maintain patent protection in the U.S. and internationally on all patentable aspects of the drug. We cannot be sure that the patents will be granted with respect to any patent applications we may own or license in the future, nor can we be sure that any patents issued or licensed to us in the future will be useful in protecting our technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Relating to Our Intellectual Property Rights."

In addition to patent protection, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, aspects of our proprietary technology platform are based on unpatented trade secrets and know-how related to the manufacturing of lenabasum. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also plan to seek trademark protection in the U.S. and outside of the U.S. where available and when appropriate. We intend to use these registered marks in connection with our pharmaceutical research and development as well as our product candidates.

Manufacturing and Supply for Lenabasum

We have developed and validated a good manufacturing practice, or GMP, process to manufacture lenabasum active pharmaceutical ingredient ("API") and drug product through our contract manufacturers. Our existing API contract manufacturer has produced multi-Kg scale bulk batches under GMP for our on-going clinical studies and is under agreement to produce sufficient API required prior to submitting an NDA filing with the FDA. We do not own or operate manufacturing facilities for the production of lenabasum. We expect to depend on third-party suppliers and manufacturing organizations for all of our clinical trial quantities of raw materials and drug substance. Lenabasum is a synthetic molecule and there are readily available supplies of all raw materials necessary for the manufacture of lenabasum.

Regulatory Matters

Government Regulation

The process of obtaining regulatory approvals and the subsequent 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 requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the US FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Any product development activities related to lenabasum or products that we may develop or acquire in the future will be subject to extensive regulation by various government authorities, including the FDA, other federal, state and local agencies and comparable regulatory authorities in other countries, which regulate the design, research, clinical and non-clinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products and devices. Generally, before a new drug can be sold, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. The data are often generated in two distinct development states: pre-clinical and clinical.

Development of Drugs in the U.S.

Lenabasum or other products that we may develop or acquire in the future must be approved by the FDA before they may be legally marketed in the United States. For new chemical entities, the pre-clinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies that support subsequent clinical testing. These pre-clinical laboratory and animal tests are often performed under the FDA's Good Laboratory Practices regulations. A drug's sponsor must submit the result of the pre-clinical tests, together with manufacturing information, analytical data and any available clinical data or literature and a proposed clinical protocol to the FDA as part of an IND application, which is a request for authorization from the FDA to administer an investigational drug or biological product to humans. Similar filings are required in other countries.

The clinical stage of development can generally be divided into three sequential phases that may overlap, Phase 1, Phase 2 and Phase 3 clinical trials. In Phase 1, generally, small numbers of healthy volunteers are initially exposed to single escalating doses and then multiple escalating doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action and general safety of the drug. Phase 2 trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits, common short-term side effects and risks. Phase 2 studies are typically well-controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. Phase 3 trials are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand subjects and are closely controlled and monitored. In addition to these Phase 1-3 trials, other trials may be conducted to gather additional safety, pharmacokinetic and pharmacodynamic information., Pharmaceutical products with active ingredients equal or similar to those already approved by the FDA often have more streamlined development programs than compounds entirely new to the agency, often skipping Phase 1 and 2 trials.

A clinical plan must be submitted to the FDA prior to commencement of a clinical trial. If the FDA has concerns about the clinical plan or the safety of the proposed studies, they may suspend or terminate the study at any time. Studies must be conducted in accordance with good clinical practice and reporting of study progress and any adverse experiences is required. Studies are also subject to review by independent institutional review boards responsible for overseeing studies at particular sites and protecting human research study subjects. An independent institutional review board may also suspend or terminate a study once initiated. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that once begun, issues will not arise that could cause the trial to be suspended or terminated.

Post-approval studies, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. Sometimes, these studies are used to gain additional experience from the treatment of patients in the intended therapeutic condition. In certain instances, the FDA may mandate the performance of Phase 4 studies. In other situations, post-approval studies aim to gain additional indications for a medication.

Special Protocol Assessment

The Federal Food, Drug, and Cosmetic Act directs the FDA to meet with sponsors, pursuant to a sponsor's written request, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an efficacy claim in an NDA. If an agreement is reached, the FDA will reduce the agreement to writing and make it part of the administrative record. This agreement is called a special protocol assessment, or SPA. While the FDA's guidance on SPAs states that documented SPAs should be considered binding on the review division, the FDA has latitude to change its assessment if certain exceptions apply. Exceptions include public health concerns emerging that were unrecognized at the time of the protocol assessment, identification of a substantial scientific issue essential to the safety or efficacy testing that later comes to light, a sponsor's failure to follow the protocol agreed upon, or the FDA's reliance on data, assumptions or information that are determined to be wrong.

Review and Approval in the U.S.

Following pivotal or Phase 3 trial completion, data are analyzed to determine safety and efficacy. Data are then filed with the FDA in a New Drug Application, or an NDA, along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. In the United States, FDA approval of an NDA must be obtained before marketing a pharmaceutical product. The NDA must contain proof of safety, purity, potency and efficacy, which entails extensive pre-clinical and clinical testing.

The FDA will likely re-analyze the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of applications by the FDA is extensive and time consuming and may take several years to complete. The FDA may conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with current good manufacturing practice requirements and may also audit data from clinical and pre-clinical trials.

There is no assurance that the FDA will act favorably or quickly in making such reviews and significant difficulties or costs may be encountered in our efforts to obtain FDA approvals. The FDA may require that certain contraindications, warnings or precautions be including in the product labeling, or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance programs to monitor the safety of approved products that have been commercialized. Further, the FDA may place conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $500,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. We have received orphan drug designation for lenabasum for cystic fibrosis and systemic sclerosis. There can be no assurance that we will receive orphan drug designation for lenabasum for DM, or additional orphan diseases.

Drug Development in Europe

In the European Union, our future products may also be subject to extensive regulatory requirements. Similar to the U.S., the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the U.S., the various phases of pre-clinical and clinical research in the European Union are subject to significant regulatory controls.

Review and Approval in the European Union

In the European Union, approval of new medicinal products can be obtained through one of three processes: the mutual recognition procedure, the centralized procedure and the decentralized procedure. We intend to determine which process we will follow, if any, in the future.

Mutual Recognition Procedure: An applicant submits an application in one European Union member state, known as the reference member state. Once the reference member state has granted the marketing authorization, the applicant may choose to submit applications in other concerned member states, requesting them to mutually recognize the marketing authorizations already granted. Under this mutual recognition process, authorities in other concerned member states have 55 days to raise objections, which must then be resolved by discussion among the concerned member states, the reference member state and the applicant within 90 days of the commencement of the mutual recognition procedure. If any disagreement remains, all considerations by authorities in the concerned member states are suspended and the disagreement is resolved through an arbitration process. The mutual recognition procedure results in separate national marketing authorizations in the reference member state.

Centralized Procedure: This procedure is currently mandatory for products developed by means of a biotechnological process and optional for new active substances and other "innovative medicinal products with novel characteristics." Under this procedure, an application is submitted to the European Agency for the Evaluation of Medical Products. Two European Union member states are appointed to conduct an initial evaluation of each application. These countries each prepare an assessment report that is then used as the basis of a scientific opinion of the Committee on Proprietary Medical Products. If this opinion is favorable, it is sent to the European Commission, which drafts a decision. After consulting with the member states, the European Commission adopts a decision and grants a marketing authorization, which is valid throughout the European Union and confers the same rights and obligations in each of the member states as a marketing authorization granted by that member state.

Decentralized Procedure: The most recently introduced of the three processes for obtaining approval of new medicinal processes in the European Union, the decentralized procedure is similar to the mutual recognition procedure described above, but with differences in the timing that key documents are provided to concerned member states by the reference member state, the overall timing of the procedure and the possibility of, among other things, "clock stops" during the procedure.

Post-Marketing Requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA and other federal and state regulatory authorities, including, among other things, monitoring and recordkeeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations not described in the drug's approved labeling (known as "off-label use"), and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. The FDA regulations require the products be manufactured in specific approved facilities and in accordance with current good manufacturing practices, and NDA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with current good manufacturing practice and other laws. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms. These firms are subject to inspections by the FDA at any time, and the discovery of violative conditions could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. These regulations include:

- the federal healthcare program anti-kickback law which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

● federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other government reimbursement programs that are false or fraudulent. The government may assert that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback law or related to off-label promotion constitutes a false or fraudulent claim for purposes of the federal false claims laws;

● the Federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members; and

● the Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"—independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

● applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act.

● The Lanham Act and federal antitrust laws.

● state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, traceability, and storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products

The handling of any controlled substances must comply with the U.S. Controlled Substances Act and the Controlled Substances Import and Export Act. In the U.S., our product candidate, lenabasum, is currently classified as Schedule I controlled substance as defined in the Controlled Substance Act ("CSA"). This designation is based on lenabasum's chemical structure and pharmacology (namely, it being a synthetic endocannabinoid mimetic that binds to the CB2 receptor). Even though lenabasum's mechanism of action is to modulate the immune system and results to date from clinical studies have demonstrated the drug has no psychotropic effects (which we believe is unlike other members of its chemical class), the DEA classifies lenabasum as a Schedule I substance.

Schedule I controlled substances are pharmaceutical products subject to specific regulations under the CSA, that establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. All parties responsible for the manufacturing, distribution and testing the drug in clinical studies must apply for and obtain a license from the DEA before they are permitted to perform these activities with lenabasum. Furthermore, these parties must have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All licensed facilities are required to renew their registrations annually if they intend to continue to work with our drug. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. We have been working with our manufacturers, distributors, exporters and clinical sites to obtain the necessary licenses to work with lenabasum. The parties responsible for the manufacturing, distribution and export of lenabasum have already applied for and have been granted DEA licenses and a number of institutions responsible for conducting our current clinical studies have also been granted DEA licenses.

Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. The requirement for state registrations could also result in delay of the manufacturing, distribution of lenabasum or in the completion of our current clinical studies. We and our manufacturing vendors and clinical sites must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Third-Party Payer Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our drug candidates that ultimately may obtain regulatory approval. In both the United States and foreign markets, our ability to commercialize our product candidates successfully, and to attract commercialization partners for our product candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payers, including, in the United States, governmental payers such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the CMS, through local fiscal intermediaries and carriers that administer coverage and reimbursement for certain healthcare items and services furnished to the elderly and disabled. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured 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 payer has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. Private payers often rely on the lead of the governmental payers in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of 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. Prices at which we or our customers seek reimbursement for our product candidates can be subject to challenge, reduction or denial by the government and other payers.

The United States Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our product candidates profitably. For example, the two-year spending law signed by the President of United States on February 9, 2018 includes a provision raising the manufacturer discount to 70% in 2019 in the Medicare Part D coverage gap, also known as the “donut hole.” Under prior law, manufacturers were required to provide a 50% discount on prescription drugs purchased in the donut hole. Manufacturers of branded drugs will face much higher liabilities from donut hole payments beginning in 2019, estimated at multiple billions of dollars for some of the largest companies.

The cost of pharmaceuticals continues to generate substantial governmental and third-party payer interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payers also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and operate profitably.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Employees

We had 141 full-time employees at December 31, 2019. All of our employees are engaged in administration, finance, clinical, manufacturing, regulatory and business development functions. We believe our relations with our employees are good. We anticipate that the number of employees will grow as we continue to develop our product candidates. In addition, we utilize and will continue to utilize consultants, clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, manufacturing and regulatory functions.

Corporate Information

Corbus Pharmaceuticals, Inc. (formerly known as JB Therapeutics Inc.), was incorporated on April 24, 2009 under the laws of the State of Delaware. On April 11, 2014, JB Therapeutics, Inc. completed a merger with Corbus Pharmaceuticals Holdings, Inc. and changed its name to Corbus Pharmaceuticals, Inc. Upon the consummation of the merger, Corbus Pharmaceuticals, Inc. became a wholly owned subsidiary of Corbus Pharmaceuticals Holdings, Inc. which continues to operate the business of Corbus Pharmaceuticals, Inc. Our principal executive offices are located at 500 River Ridge Drive, Norwood, Massachusetts 02062, and our telephone number is (619) 963-0100. Our website address is www.corbuspharma.com.

We make available free of charge on or through the Investor Relations link on our website,www.corbuspharma.com, access to press releases and investor presentations, as well as all materials that we file electronically with the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after electronically filing such materials with, or furnishing them to, the SEC. During the period covered by this Form 10-K, we made all such materials available through our website as soon as reasonably practicable after filing such materials with the SEC. In addition, the SEC maintains an Internet website, www.sec.gov, that contains reports, proxy and information statements and other information that we file electronically with the SEC.

This report and the information incorporated herein by reference contain references to trademarks, service marks and trade names owned by us or other companies. Solely for convenience, trademarks, service marks and trade names referred to in this report and the information incorporated herein, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. We do not intend our use or display of other companies' trade names, service marks or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Other trademarks, trade names and service marks appearing in this report are the property of their respective owners.

ITEM 1A. RISK FACTORS

An investment in our common stock is speculative and illiquid and involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize, our business, financial condition and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

Risk Related to our Company and our Business

Risks Related to Our Financial Position and Need for Capital

We are a clinical stage pharmaceutical company with a limited operating history.

We are a clinical stage pharmaceutical company with a limited operating history. We must complete clinical studies and receive regulatory approval of a New Drug Application, or NDA, before commercial sales of a product can commence. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in the early stages of development, especially clinical pharmaceutical companies such as ours. Potential investors should carefully consider the risks and uncertainties that a company with a limited operating history will face. In particular, potential investors should consider that we cannot assure you that we will be able to:

- successfully implement or execute our current business plan, and we cannot assure you that our business plan is sound;
- successfully manufacture our clinical products and establish commercial drug supply;
- obtain Drug Enforcement Administration, or DEA, licenses necessary for the manufacturing of lenabasum and for evaluating lenabasum in our clinical trials;
- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of our drug candidates, including lenabasum and CRB-4001;
- secure market exclusivity and/or adequate intellectual property protection for our drug candidates;
- attract and retain an experienced management and advisory team;
- secure acceptance of our drug candidates in the medical community and with third party payors and consumers;
- launch commercial sales of our drug candidates, whether alone or in collaboration with others; and
- raise sufficient funds in the capital markets to effectuate our business plan.

If we cannot successfully execute any one of the foregoing, our business may not succeed and your investment will be adversely affected.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future. We may never become profitable or, if we achieve profitability, be able to sustain profitability.

We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize any of our drug candidates. To date, we have not generated any revenue from our drug candidates and we expect to incur significant expense to complete our clinical program for our drug candidates in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the United States or internationally. Even if we are able to commercialize our drug candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net losses for the years ended December 31, 2019 and December 31, 2018 were approximately $71,454,000 and $55,672,000, respectively. As of December 31, 2019, we had an accumulated deficit of approximately $192.8 million.

If we were to obtain FDA approval for lenabasum, we would expect that our research and development expenses will continue to increase as we advance clinical trials for additional indications. We may elect to pursue FDA approval for lenabasum in other indications and for other drug candidates, which will result in significant additional research and development expenses. As a result, we expect to continue to incur substantial losses for the foreseeable future, and these losses will increase. We are uncertain when or if we will be able to achieve or sustain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

We have incurred recurring losses since inception and as of December 31, 2019, had an accumulated deficit of approximately $192.8 million. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of our product candidates and preclinical and clinical programs, strategic alliances and the development of our administrative organization. We expect the cash and cash equivalents of approximately $31.7 million at December 31, 2019 plus the approximately $43.0 million of net proceeds from the February 2020 Offering and the remaining $7.5 million of proceeds that we expect to receive under the 2018 Award before the end of the fourth quarter of 2020 to be sufficient to meet our operating and capital requirements into the fourth quarter of 2020, based on planned expenditures. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, sales and marketing and research and development activities are forward-looking statements and involve risks and uncertainties. The consolidated financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Our ability to continue as a going concern is dependent on our ability to raise additional equity or debt capital or spin-off non-core assets to raise additional cash. Should we be unable to raise sufficient additional capital, we may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities. We will need to raise significant additional capital to continue to fund the clinical trials for lenabasum and CRB-4001. We may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common stock. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate some or all of our planned clinical trials. These factors among others create a substantial doubt about our ability to continue as a going concern.

Our cash or cash equivalents will only fund our operations for a limited time and we will need to raise additional capital to support our development and commercialization efforts.

We are currently operating at a loss and expect our operating costs will increase significantly as we incur further costs related to preclinical development and the clinical trials for our drug candidates. As of December 31, 2019, we held cash and cash equivalents of approximately $31.7 million.

On January 26, 2018, we entered into the Cystic Fibrosis Program Related Investment Agreement (the "Investment Agreement") with the Cystic Fibrosis Foundation ("CFF"), a non-profit drug discovery and development corporation, pursuant to which we received a development award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b clinical trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis, of which we received $17.5 million to date. The remainder of the 2018 CFF Award is payable to us incrementally upon the achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement and we expect to receive the remainder before the end of the fourth quarter of 2020.

On January 3, 2019, we entered into a strategic collaboration with Kaken Pharmaceutical Co., Ltd. ("Kaken") for the development and commercialization in Japan of lenabasum for the treatment of SSc and DM. Under the terms of the agreement, Kaken receives an exclusive license to commercialize and market lenabasum in Japan for SSc and DM. Kaken made an upfront payment to us of $27 million. We are eligible to receive in addition up to $173 million upon achievement of certain regulatory, development and sales milestones as well as double-digit royalties.

On January 30, 2019, we consummated an underwritten public offering of shares of our common stock pursuant to which we sold an aggregate of 6,198,500 shares of its common stock at a purchase price of $6.50 per share with gross proceeds to us totaling $40,290,250, less estimated issuance costs incurred of approximately $2,572,000 ("January 2019 Offering"). On February 11, 2020, we consummated an underwritten public offering of shares of our common stock pursuant to which we sold an aggregate of 7,666,667 shares of our common stock at a purchase price of $6.00 per share with gross proceeds to us totaling $46,000,000, less estimated issuance costs incurred of approximately $3,010,000 ("February 2020 2019 Offering").

We expect the cash and cash equivalents of approximately $31.7 million at December 31, 2019 plus the approximately $43.0 million of net proceeds from the February 2020 Offering and the remaining $7.5 million of proceeds that we expect to receive under the 2018 Award before the end of the fourth quarter of 2020, to be sufficient to meet our operating and capital requirements into the fourth quarter of 2020, based on planned expenditures.

Other than the Investment Agreement, we do not currently have any arrangements or credit facilities in place as a source of funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all, including pursuant to the Investment Agreement due to the dependency of our receiving future payments thereunder on our achieving certain milestones described therein. If we are not successful in raising additional capital, we may not be able to continue as a going concern. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt.

Equity financing, if obtained, could result in dilution to our then existing stockholders and/or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. In addition, if we are unable to secure sufficient capital to fund our operations, we may choose to pursue, as an alternative, strategic collaborations that could require us to share commercial rights to our drug candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. If we choose to pursue additional indications and/or geographies for our drug candidates or otherwise expand more rapidly than we presently anticipate we may also need to raise additional capital sooner than expected.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We depend heavily on the success of lenabasum. If we are unable to generate revenues from lenabasum, our ability to create stockholder value will be limited.

Our most advanced product candidate currently is lenabasum, for which we have completed Phase 1 safety studies and Phase 2 clinical studies and which we are evaluating in subsequent clinical studies. We do not generate revenues from any FDA approved drug products and have no other product candidates in development other than CRB-4001 and the other compounds we licensed from Jenrin, which are in the early stages of development. There is no guarantee that our clinical trials will be successful or that we will continue with clinical studies to support an approval from the FDA of any of our product candidates for any indication. We note that most drug candidates never reach the clinical development stage and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business currently depends heavily on the successful development, regulatory approval and commercialization of lenabasum, which may never occur.

Outbreaks of communicable diseases, including the coronavirus COVID-19, may materially and adversely affect our business, financial condition and results of operations.

We face risks related to health epidemics or outbreaks of communicable diseases, for example, the recent outbreak around the world, including in China and Italy, of the highly transmissible and pathogenic coronavirus COVID-19. The outbreak of such communicable diseases could result in a widespread health crisis that could adversely affect general commercial activity and the economies and financial markets of many countries.

Since some of our business partners and manufacturing operations are in China and Italy, including manufacturing for our commercial and clinical active pharmaceutical ingredient, the continued impact resulting from the COVID-19 outbreak in these areas or in other areas where we have operations, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected could adversely affect our business, financial condition or results of operations. For example, an outbreak could significantly disrupt our business and our ability to complete our clinical trials by limiting our ability to travel or ship materials within or outside China or Italy or forcing temporary closure of facilities that we rely upon.

We face risks related to health epidemics and outbreaks, including the COVID-19 coronavirus, which could significantly disrupt our preclinical studies and clinical trials, and therefore our receipt of necessary regulatory approvals could be delayed or prevented.

In December 2019, a novel strain of coronavirus COVID-19 was reported to have surfaced in Wuhan, China. The extent to which COVID-19 may impact our preclinical and clinical trial operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration and geographic reach of the outbreak, the severity of COVID-19, and the effectiveness of actions to contain and treat COVID-19. We are currently conducting our clinical trials in multiple countries, including South Korea and Italy, and enrollment in certain of our trials, including our Phase 3 DETERMINE study, is ongoing. The continued spread of COVID-19 globally could adversely impact our clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Disruptions or restrictions on our ability to travel to monitor data from our clinical trials, or to conduct clinical trials, or the ability of patients enrolled in our studies to travel, or the ability of staff at study sites to travel, as well as temporary closures of our facilities or the facilities of our clinical trials partners and their contract manufacturers, would negatively impact our clinical trial activities. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, including the collection of data from our clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us. Similarly, our preclinical trials could be delayed and/or disrupted by the outbreak. As a result, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses and have a material adverse effect on our financial results.

If we are not able to obtain any required regulatory approvals for our drug candidates, we will not be able to commercialize our product candidates and our ability to generate revenue will be limited.

Our clinical trials may be unsuccessful, which would materially harm our business. Even if our ongoing clinical trials are successful, we will be required to conduct additional clinical trials to establish the safety and efficacy of our drug candidates, before a New Drug Application, or NDA, can be filed with the FDA for marketing approval of any of our drug candidates.

Clinical testing is expensive, is difficult to design and implement, can take many years to complete and is uncertain as to outcome. Success in early phases of pre-clinical and clinical trials does not ensure that later clinical trials will be successful, and interim results of a clinical trial do not necessarily predict final results. A failure of one or more of our clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent our ability to receive regulatory approval or commercialize our drug candidates. The research, testing, manufacturing, labeling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market any of our drug candidates as prescription pharmaceutical products in the United States until we receive approval of an NDA from the FDA or in foreign markets until we receive the requisite approval from comparable regulatory authorities in such countries. In the United States, the FDA generally requires the completion of clinical trials of each drug to establish its safety and efficacy and extensive pharmaceutical development to ensure its quality before an NDA is approved. Regulatory authorities in other jurisdictions impose similar requirements. Of the large number of drugs in development, only a small percentage result in the submission of an NDA to the FDA and even fewer are eventually approved for commercialization. We have never submitted an NDA to the FDA or any comparable applications to other regulatory authorities. If our development efforts for our drug candidates, including regulatory approval, are not successful for our planned indications, or if adequate demand for our drug candidates is not generated, our business will be harmed.

Receipt of necessary regulatory approval is subject to a number of risks, including the following:

- the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidates;
- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, the European Medicines Agency, or EMA, or other comparable foreign regulatory authorities for marketing approval;
- the dosing of our drug candidates in a particular clinical trial may not be at an optimal level;
- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidates;
- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval; and
- the FDA or comparable foreign regulatory authorities may decide that the clinical trial endpoints we have chosen such as ACR CRSS score at week 52, the statistical analysis plans that we use, or any other parameter that we rely on to show the safety and efficacy of our drugs, are not parameters that can be used to support approval of our products.

Failure to obtain regulatory approval for any of our drug candidates for the foregoing or any other reasons will prevent us from commercializing such product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with the endpoints that we have chosen to use in our clinical trials, our assessment of the results of our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidates. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate’s safety and efficacy for each indication. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of regulatory authorities. Changes in the regulatory approval policy during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for any of our drug candidates in any indication will prevent us from commercializing such product candidates, and our ability to generate revenue will be materially impaired.

Clinical drug development involves 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 testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials may not be predictive of the results of later-stage clinical trials. We cannot assure you that the FDA will view the results as we do or that any future trials of our drug candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our drug candidates may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for our drug candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics, including demographic factors and health status.

Even if we receive regulatory approval for our drug candidates, we still may not be able to successfully commercialize any of our products, and the revenue that we generate from sales, if any, may be limited.

If approved for marketing, the commercial success of our drug candidates will depend upon their acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of our drug candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy;
- relative convenience, pill burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our drug candidates and of the target patient population to try new therapies;
- safety, tolerability and efficacy of our drug candidates compared to competing products;
- the introduction of any new products that may in the future become available to treat indications for which our drug candidates may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which our drug candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our drug candidates in applicable treatment guidelines;

- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If any of our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our drug candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render our drug candidates not commercially viable. For example, regulatory authorities may approve our drug candidates for fewer or more limited indications than we request, may not approve the prices we intend to charge for our drug candidates, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve our drug candidates with labels that do not include the labeling claims necessary or desirable for the successful commercialization of a particular indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals, such as risk management plans and a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our drug candidates. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our drug candidates.

Even if we obtain marketing approval for our drug candidates, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our drug candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates.

Even if we obtain United States regulatory approval of our drug candidates for an indication, the FDA may still impose significant restrictions on their indicated uses or marketing or the conditions of approval, or impose ongoing requirements for potentially costly and time-consuming post-approval studies, including Phase 4 clinical trials, and post-market surveillance to monitor safety and efficacy. Our drug candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with the FDA, continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval, continued compliance with the CSA and ongoing review by the DEA. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, if any of our drug candidates are approved for an indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for any of our drug candidates, physicians may nevertheless legally prescribe such products to their patients in a manner that is inconsistent with the approved label. However, if we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the facility where the product is manufactured, or if we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension of, or imposition of restrictions on, operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our drug candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

The collaboration and license agreement, or the Collaboration Agreement, with Kaken Pharmaceuticals Co., Ltd., or Kaken, is important to our business. If we or Kaken fail to adequately perform under the Collaboration Agreement, or if we or Kaken terminate the Collaboration Agreement, the development and commercialization of lenabasum for the treatment of SSc and DM in Japan would be delayed or terminated and our business would be adversely affected.

On January 3, 2019, we entered into the Collaboration Agreement with Kaken, pursuant to which we granted to Kaken an exclusive license to commercialize and market lenabasum for the prevention and treatment of DM and SSc in Japan. Our ability to generate revenue under the Collaboration Agreement will depend in large part on our success in further clinical development of lenabasum and Kaken's success in achieving regulatory approval for, and commercializing lenabasum, in Japan. Such efforts are subject to significant uncertainty. We have no control over the resources, time and effort that Kaken may devote to the commercialization of lenabasum. Any of several events or factors could have a material adverse effect on our ability to generate revenue from Kaken's commercialization of lenabasum in Japan. For example, Kaken:

- may not achieve satisfactory levels of market acceptance and reimbursement by physicians, patients and third-party payers for lenabasum for the treatment of DM and SSc;
- may not compete successfully against other products and therapies for DM and SSc;
- may have to comply with additional requests and recommendations from foreign regulatory authorities;
- may not make all regulatory filings and obtain all necessary approvals from foreign regulatory agencies and all commercially necessary reimbursement approvals;
- may not commit sufficient resources to the marketing and distribution of lenabasum, whether for competitive or strategic reasons or otherwise due to a change in business priorities; and
- may cease to perform its obligations under the terms of the Collaboration Agreement.

In addition, pursuant to the Collaboration Agreement, we and Kaken have agreed to negotiate in good faith to enter into a supply agreement and a quality agreement. There can be no assurance that we will be able to reach mutually agreeable terms on such agreements with Kaken, and the absence of agreement on such terms would prevent us from gaining the expected benefit of the Collaboration Agreement.

Further, we and Kaken agreed to provide mutual indemnification against losses in connection with third-party claims arising out of breaches of or inaccuracies in the Collaboration Agreement, gross negligence or willful misconduct, and the development or commercialization of lenabasum pursuant to the Collaboration Agreement. Conflicts may arise in connection with these indemnification obligations.

After a specified period of time, Kaken may unilaterally terminate the Collaboration Agreement on 180 days' prior written notice without any reason and without any further commitment. Kaken may also terminate in the event of certain safety concerns and clinical failures, and either we or Kaken may terminate in the case of the other party's material breach or insolvency. Termination of the Collaboration Agreement could cause significant delays in our product candidate development and commercialization efforts, which could prevent us from commercializing lenabasum without first expanding our internal capabilities or entering into another agreement with a third party. Any suitable alternative collaboration or license agreement would take considerable time to negotiate and could also be on less favorable terms to us.

We have entered into, and may in the future enter into, collaboration agreements for the licensing, development and ultimate commercialization of some of our drug candidates. In such cases, we will depend greatly on our third-party collaborators to license, develop and commercialize such drug candidates, and they may not meet our expectations.

We may enter into further co-development and commercialization partnerships for our drug candidates where appropriate. The process of identifying collaborators and negotiating collaboration agreements for the licensing, development and ultimate commercialization of some of our drug candidates may cause delays and increased costs. We may not be able to enter into collaboration agreements on terms favorable to us or at all. Furthermore, some of those agreements may give substantial responsibility over our drug candidates to the collaborator. Some collaborators may be unable or unwilling to devote sufficient resources to develop our drug candidates as their agreements require. They often face business risks similar to ours, and this could interfere with their efforts. Also, collaborators may choose to devote their resources to products that compete with ours. If a collaborator does not successfully develop any one of our products, we will need to find another collaborator to do so. The success of our search for a new collaborator will depend on our legal right to do so at the time and whether the product remains commercially viable.

If we enter into collaboration agreements for one or more of our drug candidates, the success of such drug candidates will depend in great part upon our and our collaborators' success in promoting them as superior to other treatment alternatives. We believe that our drug candidates can be proven to offer disease treatment with notable advantages over drugs in terms of patient compliance and effectiveness. However, there can be no assurance that we will be able to prove these advantages or that the advantages will be sufficient to support the successful commercialization of our drug candidates.

We currently have a limited sales and marketing organization. If we are unable to secure a sales and marketing partner or establish satisfactory sales and marketing capabilities, we may not successfully commercialize our drug candidates.

At present, we have just started building a commercial organization in order to commercialize products that are approved for commercial sales. We must either collaborate with third parties that have such commercial infrastructure or continue to develop our own sales and marketing infrastructure. If we are not successful in entering into appropriate collaboration arrangements, or recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing our drug candidates, which would adversely affect our business, operating results and financial condition.

We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure we may not realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize our drug candidates without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our drug candidates;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make our drug candidates obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our drug candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval for our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell our drug candidates. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, under the Medicare Modernization Act, or MMA, Medicare Part D provides coverage to the elderly and disabled for outpatient prescription drugs by approving and subsidizing prescription drug plans offered by private insurers. The MMA also authorizes Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. The Part D plans use their formulary leverage to negotiate rebates and other price concessions from drug manufacturers. Also under the MMA, Medicare Part B provides coverage to the elderly and disabled for physician-administered drugs on the basis of the drug's average sales price, a price that is calculated according to regulatory requirements and that the manufacturer reports to Medicare quarterly.

Both Congress and the Centers for Medicare & Medicaid Services (CMS), the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. For example, under the 2010 Affordable Care Act, drug manufacturers are required to provide a 50% discount on prescriptions for branded drugs filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." There have been legislative proposals to repeal the "non-interference" provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors.

The 2010 Affordable Care Act is intended to broaden access to health insurance and reduce or constrain the growth of healthcare spending. Further, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also increased the amount of the rebates drug manufacturers must pay to state Medicaid programs, required that Medicaid rebates be paid on managed Medicaid utilization, and increased the additional rebate on "line extensions" (such as extended release formulations) of solid oral dosage forms of branded products. The law also contains substantial provisions affecting fraud and abuse compliance and transparency, which may require us to modify our business practices with healthcare practitioners, and incur substantial costs to ensure compliance.

The President and the majority party in both Houses of the U.S. Congress have indicated their desire to repeal the Affordable Care Act. It is unclear whether, when and how that repeal will be effectuated and what the effect on the healthcare sector will be. In addition to the potential repeal of the Affordable Care Act, there are indications that the Medicaid program may be restructured, which could lead to revisions in Medicaid coverage for prescription drugs. While we are unable to predict what legislation, if any, may potentially be enacted, to the extent that future changes affect how our product candidates could be paid for and/or reimbursed by the government and private payers, our business could be adversely affected.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 included, among other things, provisions that have led to 2% across-the-board reductions in Medicare payment amounts. Several states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

Our future growth depends, in part, on our ability to enter into and succeed in markets outside of the United States, where we may choose to rely on third party collaborations and will be subject to additional regulatory and commercial burdens, risks and other uncertainties.

Our future profitability will depend, in part, on our ability to gain approval of and commercialize our drug candidates in non-U.S. markets. In some or all of these non-U.S. markets, we intend to enter into licensing and contractual collaborations with third parties, such as Kaken, to handle some or all of the tasks and responsibilities necessary to succeed. Our activities in non-U.S. markets are subject to additional risks and uncertainties, including:

- our ability to enter into favorable licensing and contractual arrangements with our partners;
- our ability to select partners who are capable of achieving success at the tasks they agree to perform;
- obtaining timely and sufficient favorable approval terms for our drug candidates;
- obtaining favorable pricing and reimbursement;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

International sales of our drug candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, and trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market our drug candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

The FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct may be subject to significant liability. Similarly, industry codes in the European Union and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We are, and will be, completely dependent on third parties to manufacture our drug candidates, and our commercialization of our drug candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our drug candidates or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredients of our drug candidates, or the finished drug products, for use in our clinical trials or for commercial product, if any. As a result, we will be obligated to rely on contract manufacturers if and when our drug candidates are approved for commercialization.

We currently rely on a single foreign supplier for manufacturing the starting chemical intermediates and finished bulk drug product for lenabasum. We also rely on a single foreign supplier for the manufacturing of the finished lenabasum capsules. The facilities used by our two contract manufacturers to manufacture lenabasum must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDAs to the FDA. We do not control the manufacturing processes of, and are completely dependent on, our two contract manufacturing partners for compliance with cGMPs for manufacture of all active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our drug candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of lenabasum or our other product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market our drug candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market our drug candidates.

If for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our active pharmaceutical ingredient, or API, or our finished products or should cease doing business with us, we could experience significant interruptions in the supply of our drug candidates or may not be able to create a supply of our drug candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of our drug candidates might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply our drug candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of our drug candidates if we decided to transfer the manufacture of our drug candidates to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our drug candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to manufacture our drug candidates at commercial scale on a cost-effective basis. If the commercial-scale manufacturing costs of our drug candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

There are risks associated with scaling up manufacturing to commercial scale. If our contract manufacturers are unable to manufacture our drug candidates on a commercial scale, this could potentially delay regulatory approval and commercialization or materially adversely affect our results of operations.

There are risks associated with scaling up manufacturing to commercial volumes including, among others, cost overruns, technical problems with process scale-up, process reproducibility, stability issues, and lot consistency. Even if we obtain regulatory approval for our drug candidates, there is no assurance that our contract manufacturers will be able to manufacture the approved products to specifications acceptable to the FDA or other regulatory authorities, to produce them in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of approved products for commercialization, either on a timely basis or at all, our commercialization efforts would be impaired, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our lead product candidate, lenabasum, is currently classified as a Schedule I controlled substance subject to U.S. controlled substance laws and regulations, including regulations of the Drug Enforcement Agency and the U.S. Food and Drug Administration. Failure to obtain the necessary licenses and registrations and failure to comply with these laws could result in the delay in the manufacturing and distribution of lenabasum and could delay the completion of clinical studies. Such delays and the cost of compliance with these laws and regulations, could adversely affect our business operations and our financial condition.

In the United States, our lead product candidate, lenabasum, is currently classified as a Schedule I controlled substance as defined in the Controlled Substance Act, or CSA. This designation is based on lenabasum's chemical structure and pharmacology (namely, it being a synthetic endocannabinoid mimetic that binds to the CB2 receptor). Even though lenabasum's mechanism of action is to modulate the immune system and results to date from clinical trials indicate that the drug has no psychotropic effects (which we believe is unlike other members of its chemical class), the DEA classifies lenabasum as a Schedule I substance.

Schedule I controlled substances are pharmaceutical products subject to specific regulations under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. All parties responsible for the manufacturing, distribution and testing of the drug in clinical studies must apply for and obtain a license from the DEA before they are permitted to perform these activities with lenabasum. Furthermore, these parties must have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All licensed facilities are required to renew their registrations annually if they intend to continue to work with our drug. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. We have been working with our manufacturers, distributors, exporters and clinical sites to obtain the necessary licenses to work with lenabasum. The parties responsible for the manufacturing, distribution and export of lenabasum have already applied for and have been granted DEA licenses and a number of institutions responsible for conducting our current clinical studies have also been granted DEA licenses. However, the failure to maintain the necessary registrations, and the delay or failure of additional clinical sites to obtain DEA registrations, could delay the manufacturing, distribution and export of lenabasum and could delay the completion of the clinical studies. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, could result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings. In addition, if the FDA, DEA, or any foreign regulatory authority determines that lenabasum may have potential for abuse, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of lenabasum.

Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug based on federal action, other states schedule drugs through rulemaking or a legislative action. The requirement for state registrations could also result in delay of the manufacturing and distribution of lenabasum or in the completion of our clinical studies. We and our manufacturing vendors and clinical sites must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

The manufacturing and distribution of lenabasum is subject to the DEA's annual manufacturing and procurement quota requirements. The annual quota allocated to us or our contract manufacturers for the controlled substances in lenabasum may not be sufficient to complete clinical trials. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and operations.

While lenabasum is a Schedule I controlled substance, if lenabasum is approved for medical use by the FDA, it will have satisfied the "accepted medical use" requirement of the CSA. If and when lenabasum receives FDA approval, the DEA will make a scheduling determination and place lenabasum in a schedule other than Schedule I or declassify it in order for it to be prescribed to patients in the United States. As part of the scheduling determination, FDA will assess the abuse and dependence potential of lenabasum and make a scheduling recommendation to DEA. If approved by the FDA, the length of time the DEA takes to complete the rescheduling or declassification of lenabasum is uncertain and could be lengthy and we will not be able to sell the drug until the rescheduling is complete. Any delays in the rescheduling could have a material adverse impact on our results of operations.

Delays in shipping our drug candidates could have a material adverse effect on our business, results of operations and financial condition.

The import and export of our drug candidates requires import and export licenses. In addition, because lenabasum is currently a Schedule I controlled substance in the United States, in addition to the FDA and U.S. Customs and Border Protection, its import and export is also regulated by the DEA. We may not be granted, or if granted, maintain, such licenses for import or export from the authorities these regulatory agencies. Even if we obtain the relevant licenses, shipments of our drug candidates may be held up in transit by any of these authorities, which could cause significant delays and may lead to product batches which no longer meet specifications for use in clinical trials or commercial distribution. Such events could result in delayed development timelines, increased expenses and partial or total loss of revenue from our drug candidates.

We expect that we will rely on third parties to assist us in conducting clinical trials for our drug candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business would be substantially harmed.

We expect to enter into agreements with third-party CROs to assist us in conducting and managing our clinical programs, including contracting with clinical sites to perform our clinical studies. We plan to rely on these parties for execution of clinical studies for our drug candidates and we will control only certain aspects of conducting the clinical studies. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage and assist us with the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, or if they breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of our drug candidates for the subject indications may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for our drug candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Any termination or suspension of or delays in the commencement or completion of any necessary studies of our drug candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to:

- the FDA failing to grant permission to proceed and placing the clinical study on hold;
- subjects failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing any of our drug candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our drug candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports of similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGCP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;

- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of a trial.

Product development costs for our drug candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, any IRBs, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of our drug candidates, our commercial prospects may be materially harmed and our ability to generate product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our drug candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of our drug candidates could be significantly reduced.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We have been granted orphan drug designation in the United States and in the European Union for lenabasum for the treatment of CF, SSc and DM. Upon receipt of regulatory approval, orphan drug status will provide us with seven years of market exclusivity in the United States under the Orphan Drug Act. However, there is no guarantee that the FDA will grant orphan drug designation for any of our drug candidates for any future indication, which would make us ineligible for the additional exclusivity and other benefits of orphan drug designation. Moreover, there can be no assurance that another company also holding orphan drug designation for the same indication or which may receive orphan drug designation in the future will not receive approval prior to us, in which case our competitor would have the benefit of the seven years of market exclusivity, and we would be unable to commercialize our product for the same indication until the expiration of such seven-year period. Even if we are the first to obtain approval for the orphan drug indication, there are circumstances under which a competing product may be approved for the same indication during our seven-year period of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the Unites States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan designation does not convey any advantage in or shorten the duration of regulatory review and approval process. In addition to the potential period of exclusivity, orphan designation makes a company eligible for grant funding of up to $400,000 per year for four years to defray costs of clinical trial expenses, tax credits for clinical research expenses and potential exemption from the FDA application user fee.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as (i) the drug's orphan designation is revoked; (ii) its marketing approval is withdrawn; (iii) the orphan exclusivity holder consents to the approval of another applicant's product; (iv) the orphan exclusivity holder is unable to assure the availability of a sufficient quantity of drug; or (v) a showing of clinical superiority to the product with orphan exclusivity by a competitor product. If a drug designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan drug exclusivity. There can be no assurance that we will receive orphan drug designation for any of our drug candidates for any additional indications, if we elect to seek such designation.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for lenabasum for the treatment of cystic fibrosis and systemic sclerosis in the United States and European Union and may seek fast track designation or priority review of applications for approval of our product candidate for future indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even if we do receive fast track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Any breakthrough therapy designation granted by the FDA for our product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidate will receive marketing approval.

We have applied for, and may in the future apply for, a breakthrough therapy designation of our product candidates for future indications. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met.

Designation of a product candidate as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe our product candidate meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Third-party coverage and reimbursement and health care cost containment initiatives and treatment guidelines may constrain our future revenues.

Our ability to successfully market our drug candidates will depend in part on the level of reimbursement that government health administration authorities, private health coverage insurers and other organizations provide for the cost of our products and related treatments. Countries in which our drug candidates are expected to be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. We may not be able to sell our drug candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact our development of products including:

- failing to approve or challenging the prices charged for health care products;
- introducing reimportation schemes from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

If the FDA determines that endpoints we have chosen for our RESOLVE-1 Phase 3 clinical trial in SSc do not sufficiently demonstrate the efficacy of lenabasum for the treatment of SSc, we may not receive regulatory approval for lenabasum for the treatment of SSc even if the results of our RESOLVE-1 Phase 3 clinical trial are positive.

In April 2019, we announced that we changed the primary efficacy endpoint of our ongoing RESOLVE-1 Phase 3 trial for SSc in the U.S. to the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis, or ACR CRISS, score at Week 52 from the previous primary endpoint, change in modified Rodnan Skin core, or mRSS. We made this change following a Type C meeting with the FDA, which we had asked for in order to seek the FDA's feedback on this and certain other changes in the RESOLVE-1 trial protocol. In considering our requested change, the FDA noted drawbacks in both the mRSS and ACR CRISS as primary endpoints. The FDA informed us that while it could not agree to using the ACR CRISS score as a primary endpoint at that time, it recognized it was at our discretion and risk to change the primary endpoint to ACR CRISS. Also during the Type C meeting, the FDA stated that components of ACR CRISS, which include mRSS, reflect relevant aspects of SSc, and it will consider the totality of the data during review of any marketing application in SSc. In addition, the FDA stated that it was interested in working with us to develop a more interpretable and meaningful ACR CRISS instrument for use as a study endpoint in patients with SSc. Although we believe that using the ACR CRISS instrument as the primary efficacy endpoint for the RESOLVE-1 Phase 3 trial increases our probability of obtaining FDA approval of lenabasum for the treatment of SSc in the U.S., there can be no guarantee that the FDA will approve lenabasum based on the endpoints we have chosen for the RESOLVE-1 Phase 3 trial. The FDA may determine the endpoints that we have chosen to use in our RESOLVE-1 Phase 3 trial do not sufficiently demonstrate the efficacy of lenabasum even if the results of the clinical trial are positive.

Risks Relating to Our Intellectual Property Rights

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on maintaining and obtaining additional patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable in our pending applications or, the enforceability of our existing and future patents. Our pending patent applications for lenabasum and its uses may never be approved by United States or foreign patent offices and the existing patents and patent applications relating to lenabasum and related technologies may be challenged, invalidated or circumvented by third parties and may not protect us against competitors with similar products or technologies.

The degree of our current and future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to lenabasum, or important to our business. We cannot be certain that any patents or patent application owned by a third party will not have priority over patents and patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before United States or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases when we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to maintain or obtain additional patent protection or trade secret protection for lenabasum or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

We have in-licensed a portion of our intellectual property, and if we fail to comply with our obligations under these arrangements, we could lose such intellectual property rights or owe damages to the licensor of such intellectual property.

We are a party to a license agreement with Jenrin pursuant to which we licensed the exclusive worldwide rights to develop, manufacture and market drug candidates from Jenrin. This agreement is important to our business, and we may enter into additional license agreements in the future. Certain of our in-licensed intellectual property covers, or may cover, CRB-4001 and other potential developmental candidates. Our existing license agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under any such agreement, we may owe damages, our licensor may have a right to terminate the affected license, and our ability to utilize the affected intellectual property in our product discovery and development efforts and our ability to enter into collaboration or marketing agreements for an affected product candidate may be adversely affected.

Lenabasum and our other product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of lenabasum or any of our other product candidates. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize lenabasum or our other product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market lenabasum or any other product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign lenabasum or any other product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing lenabasum or another product candidate, which could harm our business, financial condition and operating results.

A number of companies, including several major pharmaceutical companies, have conducted research on anti-inflammatory and anti-fibrosis therapies which resulted in the filing of many patent applications related to this research. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims.

If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the United States Patent and Trademark Office, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not aware of any asserted third-party claims challenging inventorship on our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, strategic partners, commercial counterparties or other third parties associated with us or one of our predecessors in ownership of lenabasum have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we cannot fully control the enforcement of these policies by third parties with which we contract, nor can we be certain that assignment agreements between us and our employees, between us and our counterparties, or between our counterparties and their employees or between our predecessors of ownership and their employees and counterparties, will effectively protect our interests as to any party who conceives or develops intellectual property that we regard as our own. Among other issues, the assignment of intellectual property rights may not be self-executing, the assignment agreements may be breached, or we may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. As we approach potential commercialization of our product candidates, we are more closely analyzing all facts that we believe might be used to assert an inventorship claim against us. Determinations like these involve complex sets of fact and applications of sometimes-unsettled patent law, resulting in inherent uncertainties regarding ownership rights. Determining the history of development of certain of our intellectual property is made more difficult by the fact that certain of our intellectual property was developed by other companies for other indications before being acquired by us. Consequently, we cannot be sure that we have all of the documentary records relevant to such an analysis. In the course of our analysis we identified a potential issue regarding incomplete inventorship on certain aspects of our lenabasum portfolio that were developed prior to our acquisition of lenabasum. Since identifying this potential issue, we reached agreement with the relevant third-party co-inventors and received assignments of such co-inventors' rights in and to the relevant patents.

If claims challenging inventorship are made against us, we may need to resort to litigation to resolve those claims. If we fail in defending against any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of valuable intellectual property rights or the right to assert those rights against third-parties marketing competing products. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

There are risks to our Intellectual Property based on our international business operations.

We may face risks to our technology and intellectual property as a result of our conducting business outside of the United States, including as a result of our license and collaboration agreement with Kaken, and particularly in jurisdictions that do not have comparable levels of protection of corporate proprietary information and assets such as intellectual property, trademarks, trade secrets, know-how and customer information and records. While these risks are common to many companies, conducting business in certain foreign jurisdictions, housing technology, data and intellectual property abroad, or licensing technology to joint ventures with foreign partners may have more significant exposure. Pursuant to our license and collaboration agreement with Kaken, we have granted Kaken an exclusive license to commercialize lenabasum in Japan, and an exclusive, worldwide license for the development and manufacturing of lenabasum in connection with Kaken's commercialization efforts. As a result, and in the event Kaken partners with other companies in other foreign jurisdictions in connection with the development and manufacturing of lenabasum, we may be exposed to material risks of theft of our proprietary information and other intellectual property, including technical data, manufacturing processes, data sets or other sensitive information. For example, our products or components may be reverse engineered by other business partners or other parties, which could result in our patents being infringed or our know-how or trade secrets stolen. The risk can be by direct intrusion wherein technology and intellectual property is stolen or compromised through cyber intrusions or physical theft through corporate espionage, including with the assistance of insiders, or via more indirect routes.

General Company-Related Risks

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

As of December 31, 2019, we had 141 full-time employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our drug candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

Future capital raises may dilute our existing stockholders' ownership and/or have other adverse effects on our operations.

If we raise additional capital by issuing equity securities, our existing stockholders' percentage ownership will be reduced and these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Yuval Cohen, our Chief Executive Officer, Barbara White, our Chief Medical Officer, Craig Millian, our Chief Commercial Officer, Robert Discordia, our Chief Operating Officer, and Sean Moran, our Chief Financial Officer would adversely impact our business prospects.

Our ability to compete in the highly competitive pharmaceuticals industry depends in large part upon our ability to attract highly qualified managerial, scientific and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in the price of our common stock that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Our management team has expertise in many different aspects of drug development and commercialization. However, we will need to hire additional personnel as we further develop our drug candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. We have entered into employment agreements with certain of our executive officers. However, these employment arrangements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. The loss of the services of any of our executive officers or other key employees could potentially harm our business, operating results or financial condition. In particular, we believe that the loss of the services of Yuval Cohen, Ph.D., our Chief Executive Officer, Barbara White, M.D., our Chief Medical Officer, Craig Millian, our Chief Commercial Officer and Sean Moran, C.P.A., M.B.A., our Chief Financial Officer, would have a material adverse effect on our business. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level, and senior managers as well as junior, mid-level, and senior scientific and medical personnel.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

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

We face a potential risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize our drug candidates. For example, we may be sued if any product we develop or any materials that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drug candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- the inability to commercialize our drug candidates; and
- a decline in the value of our stock.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We intend to obtain product liability insurance covering our clinical trials. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We may acquire businesses, assets or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses, assets or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks Related to our Common Stock

Our affiliates may control our company for the foreseeable future, including the outcome of matters requiring stockholder approval.

Our officers, directors, and five percent stockholders collectively owned approximately 26.3% of our outstanding shares of common stock as of December 31, 2019. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. Certain of these individuals also have significant control over our business, policies and affairs as officers or directors of our company. Therefore, you should not invest in reliance on your ability to have any control over our company.

An active, liquid trading market for our common stock may not be sustained.

Presently, our common stock is traded on the Nasdaq Global Market, or Nasdaq, and as we are in our early stages, an investment in our company may require a long-term commitment, with no certainty of return. If we are unable to maintain an active, liquid active trading market:

- investors may have difficulty buying and selling or obtaining market quotations;
- market visibility for shares of our common stock may be limited; and
- a lack of visibility for shares of our common stock may have a depressive effect on the market price for shares of our common stock.

The lack of an active market could impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We are currently listed on the Nasdaq Global Market. If we are unable to maintain listing of our securities on the Nasdaq Global Market or any stock exchange, our stock price could be adversely affected and the liquidity of our stock and our ability to obtain financing could be impaired and it may be more difficult for our stockholders to sell their securities.

Although our common stock is currently listed on the Nasdaq Global Market, we may not be able to continue to meet the exchange's minimum listing requirements or those of any other national exchange. If we are unable to maintain listing on Nasdaq or if a liquid market for our common stock does not develop or is sustained, our common stock may remain thinly traded.

The Listing Rules of Nasdaq require listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, we should fail to maintain compliance with these listing standards and Nasdaq should delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our stockholders:

- the liquidity of our common stock;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of investors in general that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

The market price of our common stock may be significantly volatile.

The market price for our common stock may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;
- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices of biotechnology companies like ours have been highly volatile due to factors, including, but not limited to:

- any delay or failure to conduct a clinical trial for our product or receive approval from the FDA and other regulatory agencies;
- developments or disputes concerning a company's intellectual property rights;
- technological innovations of such companies or their competitors;
- changes in market valuations of similar companies;
- announcements by such companies or their competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; and
- failure to complete significant transactions or collaborate with vendors in manufacturing a product.

The securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock.

Future sales of shares by existing stockholders could cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

As of December 31, 2019, we had outstanding options to purchase an aggregate of 13,245,366 shares of our common stock at a weighted average exercise price of $5.19 per share and warrants to purchase an aggregate of 1,000,000 shares of our common stock at a weighted average exercise price of $13.20 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our investors have purchased their shares.

We incur significant costs and devote substantial management time as a result of operating as a public company, and we expect those costs to increase, particularly after we are no longer an "emerging growth company."

As a public company, we incur significant legal, accounting and other expenses. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. In addition, we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We currently do not have an internal audit function, and we will need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

There may be limitations on the effectiveness of our internal controls, and a failure of our control systems to prevent error or fraud may materially harm our company.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

As of December 31, 2019, we have identified material weaknesses in our internal control over financial reporting related to our control environment over the internal control activities and our information technology general controls. If our steps are insufficient to successfully remediate these material weaknesses and otherwise maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be adversely affected.

Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. 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, have been detected. Failure of our control systems to detect or prevent error or fraud could materially adversely impact us.

Our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We may not be able to complete our evaluation and testing of our internal control over financial reporting and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our common stock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal control and procedures on a quarterly basis.

Our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

Upon dissolution of our company, you may not recoup all or any portion of your investment.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities and distributions required to be made to holders of any outstanding preferred stock will then be distributed to the stockholders of common stock on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As a result of our merger in April 2014 with Corbus Pharmaceuticals, Inc., our wholly-owned subsidiary, our ability to utilize our federal net operating loss, carryforwards and federal tax credit prior to that date may be limited under Sections 382 of the Internal Revenue Code. The limitations apply if an "ownership change," as defined by Section 382, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

The 2017 comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new tax legislation, or the Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate 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 of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures. We continue to examine the impact this tax reform legislation may have on our business. 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. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. This periodic report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation.

Our certificate of incorporation, as amended, allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. We anticipate that our board of directors will have the authority to issue up to 10,000,000 shares of our preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation and the right to receive dividend payments before dividends are distributed to the holders of common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Item 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

Item 2. PROPERTIES

Our principal offices are located at 500 River Ridge Drive, Norwood, MA 02062 and consisted of 63,256 square feet of leased office space at December 31. 2019. The lease term for this office space ends on October 31, 2026.

The following table summarizes the Company's maturities of operating lease liabilities as of December 31, 2019:

2020	$	1,265,760
2021		1,605,121
2022		1,652,563
2023		1,700,005
2024		1,747,447
Thereafter		3,483,034
Total lease payments	$	11,453,930
Less: imputed interest		(2,760,957)
Total	$	8,692,973

Item 3. LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings. However, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business.

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 currently listed on theNasdaq Global Market under the symbol "CRBP." Our shares of common stock began trading on theNasdaq Capital Market under the symbol "CRBP" effective April 16, 2015.

Dividends

We have never declared or paid cash dividends on our common stock. We do not intend to declare or pay cash dividends on our common stock for the foreseeable future, but currently intend to retain any future earnings to fund the development and growth of our business. The payment of cash dividends if any, on the common stock will rest solely within the discretion of our board of directors and will depend, among other things, upon our earnings, capital requirements, financial condition, and other relevant factors.

Record Holders

As of March 9, 2020, there are approximately 89 record holders of shares

Item 6. SELECTED FINANCIAL DATA

Not applicable.

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and the related notes and the other financial information included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report, particularly those under "Risk Factors."

Overview

We are a Phase 3, clinical stage pharmaceutical company, focused on the development and commercialization of novel therapeutics to treat rare, chronic and serious inflammatory and fibrotic diseases with clear unmet medical needs. Our product lenabasum is a novel synthetic, oral, endocannabinoid drug designed to resolve chronic inflammation and fibrotic processes. We are currently developing lenabasum to treat four life-threatening diseases: systemic sclerosis (SSc), cystic fibrosis (CF), dermatomyositis (DM) and systemic lupus erythematosus (SLE).

Lenabasum is a synthetic, rationally-designed oral small-molecule drug that selectively binds to the cannabinoid receptor type 2, or CB2, found on activated immune cells, fibroblasts and other cell types including muscle and bone cells. Lenabasum stimulates the production of Specialized Pro-Resolving Lipid Mediators (SPMs) that act to resolve inflammation and halt fibrosis by activating endogenous pathways. These pathways are activated in healthy individuals during the course of normal immune responses but are dysfunctional in patients with chronic inflammatory and fibrotic diseases. By its binding to CB2, lenabasum drives innate immune responses from the activation phase into the resolution phase. CB2 plays a central role in modulating and resolving inflammation by, in effect, turning heightened inflammation "off" and restoring homeostasis. This has been demonstrated in animal models lacking CB2 as well as humans with genetic polymorphism in the CB2 gene, as these exhibit excessive inflammation and fibrosis in response to activators of the innate immune system.

Lenabasum has generated positive clinical data in three consecutive Phase 2 studies in diffuse cutaneous SSc, CF and skin-predominant DM. Lenabasum is currently being evaluated in a Phase 3 SSc study that has enrolled 365 patients, a Phase 2b CF study that is expected to enroll 415 patients (that is being supported by a development award for up to $25 million (the "2018 CFF Award") from the Cystic Fibrosis Foundation ("CFF")), and a Phase 2 SLE study that is expected to enroll 100 patients and is being funded by a grant through the National Institutes of Health ("NIH"). In DM, we received guidance from the FDA on the protocol design for the next clinical study, and announced the commencement of an international Phase 3 study on December 17, 2018. This trial is a 1-year, double-blind, randomized, placebo-controlled study testing efficacy and safety of lenabasum in approximately 150 adults with DM. Subjects are randomized to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day in a 2:1:2 ratio. The primary efficacy outcome is American College of Rheumatology/European League Against Rheumatism 2016 Total Improvement Score ("TIS") in adult dermatomyositis and polymyositis, a composite measure of improvement from baseline in six endpoints: Physician Global Assessment of Disease Activity, Physician Global Assessment of Extramuscular Disease Activity, Patient Global Assessment of Disease Activity, Health Assessment Questionnaire (patient-reported disability), Manual Muscle Testing, and muscle enzymes. Change in the Cutaneous Dermatomyositis Activity and Severity Index ("CDASI") activity score is a secondary efficacy outcome. Open-label extension studies are ongoing in SSc and DM following the completion of the Phase 2 studies in these indications.

The U.S. Food and Drug Administration, or the FDA, has granted lenabasum Orphan Designation as well as Fast Track Status for SSc and CF, and Orphan Drug Designation for DM. The European Medicines Authority, or the EMA, has granted lenabasum Orphan Designation for SSc, CF and DM.

Since our inception, we have devoted substantially all of our efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. Our research and development activities have included conducting pre-clinical studies, developing manufacturing methods and the manufacturing of our drug lenabasum for clinical trials and conducting clinical studies in patients. Two of the four clinical programs for lenabasum are being supported by non-dilutive awards and grants. The National Institutes of Health, or NIH, has funded the majority of the clinical development costs for the DM Phase 2 clinical trial and is funding the SLE Phase 2 clinical trials. In cystic fibrosis, the Phase 2b clinical trial is being supported by the 2018 CFF Award and the Phase 2 clinical trial was partially funded by a $5 million award (the "2015 CFFT Award Agreement") from the Cystic Fibrosis Foundation Therapeutics, Inc., or CFFT, a non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation.

In September 2018, we acquired an exclusive worldwide license (the "Jenrin Agreement") to develop, manufacture and market drug candidates from more than 600 compounds targeting the endocannabinoid system from Jenrin Discovery LLC ("Jenrin"). The pipeline includes CRB-4001, Jenrin's 2nd generation, peripherally-restricted, CB1 inverse agonist targeting liver, lung, heart and kidney fibrotic diseases. The current portfolio for CRB-4001 includes multiple issued and pending patent applications. CRB-4001 was developed in collaboration with and with financial support from the NIH. CRB-4001 was specifically designed to eliminate blood-brain barrier penetration and brain CB1 receptor occupancy that mediate the neuropsychiatric issues associated with first-generation CB1 inverse agonists such as rimonabant. Potential indications for CRB-4001 include NASH, primary biliary cholangitis, idiopathic pulmonary fibrosis, radiation-induced pulmonary fibrosis, myocardial fibrosis after myocardial infarction, and acute interstitial nephritis, among others.

On January 3, 2019, we entered into a strategic collaboration with Kaken Pharmaceutical Co., Ltd. ("Kaken") for the development and commercialization in Japan of our investigational drug lenabasum for the treatment of systemic sclerosis ("SSc") and dermatomyositis ("DM"), two rare and serious autoimmune diseases. Under the terms of the agreement, Kaken receives an exclusive license to commercialize and market lenabasum in Japan for SSc and DM. In March 2019, Kaken made an upfront payment to us of $27 million. We will be eligible to receive in addition up to $173 million upon achievement of certain regulatory, development and sales milestones as well as double- digit royalties.

On January 30, 2019, we consummated an underwritten public offering of shares of our common stock pursuant to which we sold an aggregate of 6,198,500 shares of our common stock at a purchase price of $6.50 per share with gross proceeds to us totaling approximately $40.3 million, less estimated issuance costs incurred of approximately $2.6 million.

On February 11, 2020, we consummated an underwritten public offering of shares of our common stock pursuant to which we sold an aggregate of 7,666,667 shares of our common stock at a purchase price of $6.00 per share with gross proceeds to us totaling approximately $46.0 million, less estimated issuance costs incurred of approximately $3.0 million.

Financial Operations Overview

We are a clinical stage pharmaceutical company and have not generated any revenues from the sale of products. We have never been profitable and at December 31, 2019, we had an accumulated deficit of approximately $192.8 million. Our net losses for the years ended December 31, 2019 and 2018 were approximately $71,454,000 and $55,672,000, respectively.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase significantly in connection with our ongoing activities to develop, seek regulatory approval of and commercialize lenabasum. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include government grants and collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses will increase substantially in 2020 and in the future in connection with our ongoing activities, as we:

- conduct clinical trials for lenabasum in scleroderma, cystic fibrosis, DM, systemic lupus erythematosus and other indications;
- continue our research and development efforts;
- manufacture clinical study materials and develop commercial scale manufacturing capabilities;
- seek regulatory approval for our product candidates;
- add personnel to support development of our product candidates; and
- operate as a public company.

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the 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.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to stock-based compensation expense. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms 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.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

Revenue Recognition

In May 2014, the FASB issued guidance codified in *Accounting Standards Codification (ASC) 606, Revenue Recognition — Revenue from Contracts with Customers* ("ASC 606") which amends the guidance in former *ASC 605, Revenue Recognition* ("ASC 605"), and is effective for public companies for annual and interim periods beginning after December 15, 2017. Specifically, the new standard differs from ASC 605 in many respects, such as in the accounting for variable consideration received, including milestone payments or contingent payments. Under our accounting policy prior to the adoption of ASC 606 in the first quarter of 2018, milestone payments were initially recognized only in the period that the payment-triggering event occurred or was achieved. ASC 606, however, may require a company to recognize such payments before the payment-triggering event is completely achieved based on the company's estimate of the amount of consideration to which it will be entitled in exchange for transferring the services, subject to management's assessment of whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

We adopted ASC 606 in the first quarter of 2018 using the modified retrospective method according to which the cumulative effect of initially applying ASC 606 is recognized at the date of initial application, and elected to utilize a practical expedient and did not restate contracts that were completed as of the date of adoption. Since we have concluded our performance obligations and have completed recognizing revenue under the 2015 CFFT Award discussed in the third quarter of 2017, there was no cumulative effect to record at the date of our adoption of ASC 606 and no revenue to recognize for the first quarter of 2018 related to the 2015 CFFT Award.

Revenue from awards for the years ended December 31, 2019 and 2018 was $9,143,568 and $4,822,272, respectively, recognized in accordance with ASC 606 and pertains only to the 2018 CFF Award. Revenue from licenses for the year ended December 31, 2019 included the recognition of the $27,000,000 upfront payment received from Kaken in March 2019 for which we satisfied the combined performance obligation by June 30, 2019, upon which we recognized the $27,000,000 as revenue in the second quarter of 2019. No revenue from licenses was recognized for the year ended December 31, 2018.

We will assess any new agreements we enter into under ASC 606, including whether such agreements fall under the scope of such standard. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The five-step model is applied to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Revenue associated with the performance obligation is being recognized as revenue as the research and development services are provided using an input method, according to the costs incurred as related to the research and development activities and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The research and development services related to this performance obligation are expected to be performed over an approximately two year and nine month period expected to be completed in the third quarter of 2020. Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion. Amounts recognized as revenue, but not yet received or invoiced are generally recognized as contract assets.

Revenue

To date, we have not generated any revenues from the sales of products. We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for the marketing of lenabasum, which we expect will take a number of years and is subject to significant uncertainty.

We recognized $9,143,568 and $4,822,272 of revenue from awards in the years ended December 31, 2019 and 2018, respectively.

Amounts recognized in revenue from awards for the years ended December 31, 2019 and 2018 were in connection with our entry on January 26, 2018 into the Cystic Fibrosis Program Related Investment Agreement ("Investment Agreement) with the Cystic Fibrosis Foundation ("CFF"), a non-profit drug discovery and development corporation, pursuant to which we received a development award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b Clinical Trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis of which we received $6.25 million in the first quarter of 2018 and an additional $6.25 million in the second quarter of 2018. In April 2019 we became entitled to receive an additional $5 million upon our achievement of a milestone related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. We received payment from the CFF for this milestone achievement in May 2019. The $7.5 million remainder of the 2018 CFF Award is payable to us incrementally upon the achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement, and we expect to receive the remainder before the end of the fourth quarter of 2020.

Additionally, revenue from licenses for the year ended December 31, 2019 included the recognition of the $27,000,000 upfront payment received from Kaken in March 2019 for which we satisfied the combined performance obligation by June 30, 2019, upon which we recognized the $27,000,000 as revenue in the second quarter of 2019. No revenue from licenses was recognized for the year ended December 31, 2018.

Research and Development

Research and development expenses are incurred for the development of lenabasum and consist primarily of payroll and payments to contract research and development companies. To date, these costs are related to generating pre-clinical data and the cost of manufacturing lenabasum for clinical trials and conducting clinical trials. These costs are expected to increase significantly in the future as lenabasum is continued to be evaluated in additional later stage clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll, rent and professional services such as accounting and legal services. We anticipate that our general and administrative expenses will increase significantly during 2020 as we increase our headcount to support our continued research and development and the potential commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, and tax-related services associated with maintaining compliance with NASDAQ exchange listing and SEC requirements, director and officer insurance, and investor relations costs associated with being a public company.

Other Income, Net

Other income, net consists primarily refundable research and development tax credits that were earned on certain research and development expenses we incurred primarily outside of the United States. Other income, net also consists of interest income we earn on interest-bearing accounts, interest expense incurred on our outstanding debt, and realized and unrealized foreign currency exchange gains and losses.

Critical Accounting Policies and Estimates

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the 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.

On an ongoing basis, we evaluate our estimates and judgments for all assets and liabilities, including those related to stock-based compensation expense, accrued research and development expense, and operating lease right of use assets and liabilities. We base our estimates and judgments on historical experience, current economic and industry conditions and on various other factors that are believed to be reasonable under the circumstances. This forms 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.

We believe that full consideration has been given to all relevant circumstances that we may be subject to, and the consolidated financial statements accurately reflect our best estimate of the results of operations, financial position and cash flows for the periods presented.

Accrued Research and Development Expenses

As part of the process of preparing financial statements, we are required to estimate and accrue expenses, the largest of which are research and development expenses. This process involves: communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost; estimating and accruing expenses in our financial statements as of each balance sheet date based on facts and circumstances known to us at the time; and periodically confirming the accuracy of our estimates with selected service providers and making adjustments, if necessary.

Examples of estimated research and development expenses that we accrue include:

- fees paid to CROs in connection with nonclinical studies;
- fees paid to contract manufacturers in connection with the production of lenabasum for clinical trials;
- fees paid to CRO and research institutions in connection with conducting of clinical studies; and
- professional service fees for consulting and related services.

We base our expense accruals related to clinical studies on our estimates of the services performed pursuant to contracts with multiple research institutions and clinical research organizations that conduct and manage clinical studies on our behalf. The financial terms of these agreements vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors, such as the successful enrollment of patients and the completion of clinical study milestones. Our service providers invoice us monthly in arrears for services performed. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

To date, we have not experienced significant changes in our estimates of accrued research and development expenses following each applicable reporting period. However, due to the nature of estimates, we cannot assure you that we will not make changes to our estimates in the future as we become aware of additional information regarding the status or conduct of our clinical studies and other research activities.

Stock-Based Compensation

Stock options are granted with an exercise price at no less than fair market value at the date of the grant. The stock options normally expire ten years from the date of grant. Stock option awards vest upon terms determined by our board of directors.

We recognize compensation costs resulting from the issuance of stock-based awards to employees, members of our Board of directors and consultants. The fair value of each option grant was estimated as of the date of grant using the Black-Scholes option-pricing model. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Due to our limited operating history, we estimated our volatility in consideration of a number of factors, including the volatility of comparable public companies and, commencing in 2015, we also included the volatility of our own common stock. We use historical data, as well as subsequent events occurring prior to the issuance of the consolidated financial statements, to estimate option exercise and employee forfeitures within the valuation model. The expected term of options granted to employees under our stock plans is based on the average of the contractual term (generally 10 years) and the vesting period (generally 48 months). The expected term of options granted under the 2014 Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is based on the average of the 6.25 years. For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option. We estimate the forfeiture rate at the time of grant and revise it, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on management's expectation through industry knowledge and historical data. We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. Accordingly, we have assumed no dividend yield for purposes of estimating the fair value of our share-based compensation.

The following assumptions were used to estimate the fair value of stock options granted using the Black-Scholes option pricing model for the years ended December 31, 2019 and 2018 is as follows:

	2019	2018
Risk free interest rate	2.33%	2.53%
Expected dividend yield	0%	0%
Expected term in years	6.25	6.25
Expected volatility	86.98%	87.70%
Estimated forfeiture rate	4.85%	5.00%

Results of Operations

Comparison of Year Ended 2019 to 2018

Revenue from Awards and Licenses. We have recognized approximately $36,144,000 and $4,882,000 of revenue from awards and licenses in the years ended December 31, 2019 and 2018, respectively.

Revenue from awards for the years ended December 31, 2019 and 2018 was $9,143,568 and $4,822,272, respectively, recognized in accordance with ASC 606 and pertains only to the 2018 CFF Award. We received an aggregate of $12.5 million during the year ended December 31, 2018 and an additional $5.0 million during the year ended December 31, 2019 upon our achievement of milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. The remainder of the 2018 CFF Award is payable to us incrementally upon the achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement.

Revenue for the year ended December 31, 2019 also included the recognition of revenue from licenses for the $27,000,000 upfront payment received from Kaken in March 2019 for which we satisfied the combined performance obligation by June 30, 2019, upon which we recognized the $27,000,000 as revenue in the second quarter of 2019.

We assessed the 2018 CFF Award and the Kaken collaboration agreement for accounting under ASC 606. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Research and Development. Research and Development expenses for the year ended December 31, 2019 totaled approximately $89,605,000, an increase of $40,991,000 over the $48,614,000 recorded for the year ended December 31, 2018. The increase in fiscal 2019 as compared to fiscal 2018 was primarily attributable to increases of $32,479,000 in clinical trial costs, $6,031,000 in compensation costs, and $2,481,000 in stock-based compensation expense.

During 2018, the Company formed a subsidiary in each of the United Kingdom and Australia and approximately 46% of research and development expenses recorded for the year ended December 31, 2019 was recorded in these entities.

General and Administrative. General and Administrative expense for the year ended December 31, 2019 totaled approximately $23,643,000, an increase of $10,687,000 over the $12,956,000 recorded for the year ended December 31, 2018. The increase was primarily attributable to the $2,700,000 we recorded in the first quarter of 2019 related to the amount we owed to CFF as a royalty payment equal to 10% of any amounts we received as payment under the collaboration agreement with Kaken. Additional increases include approximately $3,439,000 in compensation costs, $1,891,000 in stock-based compensation expense, $809,000 in consulting costs, $547,000 in facility and insurance costs, $507,000 in temporary help and recruiting costs, and $320,000 in software as a service costs, partially offset by an aggregate net increase of approximately $474,000 for other general and administrative expenses.

Other Income, Net. Other income, net for 2019 was approximately $5,651,000 as compared to approximately $1,076,000 recorded for 2018. The increase of $4,575,000 in 2019 as compared to 2018 was primarily attributable to approximately $4,581,000 of cash paid to us in second half of 2019 from taxing authorities for refundable research and development tax credits that were earned on certain research and development expenses we incurred primarily outside of the United States. We also had an increase in net interest income of approximately $245,000 due to increased cash balances in 2019 as compared to 2018, offset partially by decreases in foreign currency exchange transaction gains of approximately $251,000.

Liquidity and Capital Resources

Since inception, we have experienced negative cash flows from operations. We have financed our operations primarily through sales of equity-related securities. In addition, the majority of the costs of the Phase 2 DM and SLE clinical trials have been or are expected to be funded by NIH grants, and our Phase 2 cystic fibrosis clinical trial was partially funded by the 2015 CFFT Award. Our Phase 2b cystic fibrosis trial is being supported by the 2018 CFF Award. At December 31, 2019, our accumulated deficit since inception was approximately $192,824,000.

At December 31, 2019, we had total current assets of approximately $38,155,000 and current liabilities of approximately $34,887,000 resulting in working capital of approximately $3,267,000. Of our total cash and cash equivalents of $31.7 million at December 31, 2019, $31.3 million was held within the United States.

Net cash used in operating activities for the year ended December 31, 2019 was approximately $45,721,000, which includes a net loss of approximately $71,454,000, adjusted for non-cash expenses of approximately $13,257,000 principally related to stock-based compensation expense of $11,982,000, depreciation and amortization expense of $739,000 and operating lease ROU asset amortization of $490,000, and approximately $12,476,000 of cash provided by net working capital items, principally related to the receipt of $5,000,000 under the 2018 CFF Award during 2019 and increases in accounts payable and accrued expenses.

Cash used in investing activities for the year ended December 31, 2019 totaled approximately $2,743,000, which was largely related to construction costs and purchases of furniture and fixtures to build out our office space that we began to occupy a portion of at the end of the third quarter of 2019 and the remainder in the fourth quarter of 2019.

Cash provided by financing activities for the year ended December 31, 2019 totaled approximately $38,463,000. On January 30, 2019, we consummated an underwritten public offering of shares of our common stock pursuant to which we sold an aggregate of 6,198,500 shares of our common stock, including 808,500 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a purchase price of $6.50 per share with gross proceeds to us totaling approximately $40.3 million, less issuance costs paid of approximately $2.6 million.

During the year ended December 31, 2019, we also received proceeds of approximately $386,810 from the issuance of 107,029 shares of our common stock upon the exercise of stock options to purchase common stock. Cash provided by financing activities for the year ended December 31, 2019 included proceeds from issuances of notes payable of $963,514, partially offset by principal payments on notes payable of $605,160 in connection with our loan agreements with financing companies. The terms of the loan that we entered into in November 2018 stipulated equal monthly payments of principal and interest payments of $49,857 over a ten-month period. Interest accrued on this loan at an annual rate of 3.07% and the loan was paid in full in August 2019. In November 2019, we entered into a loan agreement with a financing company for $963,514 to finance one of our insurance policies. The terms of the loan stipulate equal monthly payments of principal and interest payments of $109,413 over a nine-month period. Interest accrues on this loan at an annual rate of 5.25%.

On February 11, 2020, we consummated an underwritten public offering of shares of our common stock pursuant to which we sold an aggregate of 7,666,667 shares of our common stock at a purchase price of $6.00 per share with gross proceeds to us totaling $46,000,000, less estimated issuance costs incurred of approximately $3,010,000. ("February 2020 Offering").

We expect our cash and cash equivalents of approximately $31.7 million at December 31, 2019 together with net proceeds of $43 million from the public offering completed in February 2020 an the remaining milestones of $7.5 million in milestone payments that we expect to receive under the 2018 CFF Award before the end of the fourth quarter of 2020, to be sufficient to meet our operating and capital requirements into the fourth quarter of 2020, based on current planned expenditures. The $7.5 million remainder of the up to $25 million 2018 CFF Award is payable to us incrementally upon the achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement.

We will need to raise significant additional capital to continue to fund operations and the clinical trials for lenabasum. Should we be unable to raise sufficient additional capital, we may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities. We will need to raise significant additional capital to continue to fund the clinical trials for lenabasum and CRB-4001. We may seek to sell common stock, preferred stock or convertible debt securities, enter into a credit facility or another form of third-party funding or seek other debt financing. In addition, we may seek to raise cash through collaborative agreements or from government grants. The sale of equity and convertible debt securities may result in dilution to our stockholders and certain of those securities may have rights senior to those of our common shares. If we raise additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict our operations. Any other third-party funding arrangement could require us to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of our clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to us. Lack of necessary funds may require us, among other things, to delay, scale back or eliminate expenses including some or all of our planned clinical trials.

Contractual Obligations and Commitments

The following table presents information about our known contractual obligations as of December 31, 2019. It does not reflect contractual obligations that may have arisen or may arise after that date. Except for historical facts, the information in this section is forward-looking information.

	Payments due by period				
Contractual Obligations	**Total**	**2020**	**Fiscal 2021-2022**	**Fiscal 2023-2024**	**After Fiscal 2024**
Operating lease obligations	$ 11,453,930	$ 1,265,760	$ 3,257,684	$ 3,447,452	$ 3,483,034

On February 26, 2019, we amended our lease ("February 2019 Lease Agreement") pursuant to which an additional 30,023 square feet of office space ("New Premises") will be leased by us in the same building for an aggregate total of 62,756 square feet of leased office space ("Total Premises"). Per ASC 842, the February 2019 Lease Agreement constitutes a modification as it extends the original lease term and increases the scope of the lease (additional space provided under the amendment), which requires evaluation of the remeasurement of the lease liability and corresponding ROU asset. Accordingly, we reassessed the classification of the Leased Premises and remeasured the lease liability on the basis of the extended lease term using the 20 additional monthly rent payments and the incremental borrowing rate at the effective date of the modification of 9%. The remeasurement for the modification resulted in an increase to the lease liability and the ROU asset of approximately $855,000. We determined that the New Premises will be treated as a new standalone operating lease under ASC 842 and recorded a lease liability and a right-of-use asset of approximately $2.7 million for this lease.

Per the terms of the February 2019 Lease Agreement, the landlord agreed to reimburse us for $990,759 of leasehold improvements. The reimbursements are being recognized as a reduction of rent expense over the term of the lease. Additionally, the February 2019 Lease Agreement required a standby irrevocable letter of credit of $369,900, which may be reduced, if we are not in default under the February 2019 Lease Agreement, to $277,425 and $184,950 on the third and fourth anniversary of the commencement date, respectively.

On October 25, 2019, we amended our lease ("October 2019 Lease Amendment") pursuant to which the term of the lease was extended through November 30, 2026 and the existing office space under lease was expanded by 500 square feet for an aggregate total of 63,256 square feet of leased office space ("Amended Total Premises"). Per ASC 842, the October 2019 Lease Amendment constitutes a modification as it extends the original lease term and increases the scope of the lease (additional space provided under the amendment), which requires evaluation of the remeasurement of the lease liability and corresponding ROU asset. The additional space did not result in a separate contract as the rent increase was determined not to be commensurate with the standalone price for the additional right of use. Accordingly, we reassessed the classification of the Amended Total Premises, which resulted in operating classification, and remeasured the lease liability on the basis of the extended lease term using the additional monthly rent payments and the incremental borrowing rate at the effective date of the modification of 8%. The remeasurement for the modification resulted in an increase to the lease liability and the ROU asset of approximately $381,000 that was recorded in the fourth quarter of 2019.

Pursuant to the terms of our non-cancelable lease agreements in effect at December 31, 2019, the following table summarizes our maturities of operating lease liabilities as of December 31, 2019:

2020	$ 1,265,760
2021	1,605,121
2022	1,652,563
2023	1,700,005
2024	1,747,447
Thereafter	3,483,034
Total lease payments	$ 11,453,930
Less: imputed interest	(2,760,957)
Total	$ 8,692,973

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for pre-clinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material. As of December 31, 2019, other than our leases in the table above, we had no material Contractual Obligations or Commitments that will affect our future liquidity.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors, other than future royalty payments under development award agreements discussed as follows:

Collaboration Agreement with Kaken

Pursuant to the terms of the Kaken Agreement, we will bear the cost of, and be responsible for, among other things, conducting the clinical studies and other developmental activities for the Licensed Products in the Initial Indications in the Territory, and Kaken will bear the cost of, and be responsible for, among other things, preparing and filing applications for regulatory approval in the Territory and for commercializing Licensed Products in the Territory, and will use commercially reasonable efforts to commercialize Licensed Products and obtain pricing approval for Licensed Products in the Territory.

In consideration of the license and other rights granted by us, Kaken paid us a $27,000,000 upfront cash payment in March 2019 and is obligated to pay potential milestone payments to us totaling up to approximately $173,000,000 for the achievement of certain development, sales and regulatory milestones. In addition, during the Royalty Term (as defined below), Kaken is obligated to pay us royalties on sales of Licensed Products in the Territory, under certain conditions, in the double digits, which royalty shall be reduced in certain circumstances. In particular, for so long as we supply Licensed Products to Kaken pursuant to a supply agreement to be entered into by the parties, royalty payments shall be payable for each unit of Licensed Product that we supply as a percentage of the Japanese National Health Insurance price of the Licensed Product. During any time in which a supply agreement is not in effect, royalty payments shall be changed to a rate to be agreed upon by the parties in good faith.

The Agreement will remain in effect on a Licensed Product-by-Licensed product basis and will expire upon the expiration of the Royalty Term for the final Licensed Product. The "Royalty Term" means the period beginning on the date of the first commercial sale of the Licensed Product in Japan and ends on the latest of (i) the expiration of the last valid claim of the royalty patents covering such Licensed Product in Japan, (ii) the expiration of regulatory exclusivity for such Licensed Product for such Initial Indication in Japan, or (iii) ten (10) years after the first commercial sale of such Licensed Product for such Initial Indication in Japan. The Agreement may be terminated by either party for material breach, upon a party's insolvency or bankruptcy or upon a challenge by one party of any patents of the other party, and Kaken may terminate in specified situations, including for a safety concern or clinical failure, or at its convenience following the second anniversary of the first commercial sale of a Licensed Product in either of the Initial Indications in the Territory, with 180 days' notice.

License Agreement with Jenrin

Pursuant to the terms of the Jenrin Agreement, we are obligated to pay potential milestone payments to Jenrin totaling up to $18.4 million for each compound we elect to develop based upon the achievement of specified development and regulatory milestones. In addition, we are obligated to pay Jenrin royalties in the mid, single digits based on net sales of any Licensed Products, as defined in the Jenrin Agreement, subject to specified reductions.

The Jenrin Agreement terminates on a country-by-country basis and product-by-product basis upon the expiration of the royalty term for such product in such country. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on the later of seven years from such first commercial sale or the expiration of the last to expire of the applicable patents in that country. The Jenrin Agreement may be terminated earlier in specified situations, including termination for uncured material breach of the Jenrin Agreement by either party, termination by Jenrin in specified circumstances, termination by Corbus with advance notice and termination upon a party's insolvency or bankruptcy.

2018 CFF Award

Pursuant to the terms of the Investment Agreement, we are obligated to make certain royalty payments to CFF, including a royalty payment of one and one-half times the amount of the 2018 CFF Award, payable in cash within sixty days upon the first receipt of approval of lenabasum in the United States and a second royalty payment of one and one-half times the amount of the 2018 CFF Award upon approval in another major market, as set forth in the Investment Agreement (the "Approval Royalty"). At our election, we may satisfy the first of the two Approval Royalties in registered shares of our common stock. Additionally, we will owe to CFF a royalty payment equal to 10% of any amounts we receive as payment under the collaboration agreement with Kaken, provided that the total royalties that we will be required to pay under the Investment Agreement resulting from income from licenses or sales subject to the Investment Agreement are capped at five times the total amount of the 2018 CFF Award, and we may credit such royalties against any royalties on net sales otherwise owed to CFF under the Investment Agreement. Accordingly, we were required to pay CFF $2,700,000 in May 2019, which is within 60 days of our receipt of the $27,000,000 upfront cash payment from Kaken described below.

Additionally, we are obligated to make (i) royalty payments to CFF of two and one-half percent of net sales from lenabasum due within sixty days after any quarter in which such net sales occur in the Field, as defined in the Investment Agreement, (ii) royalty payments to CFF of one percent of net sales of Non-Field Products, as defined in the Investment Agreement due within sixty days after any quarter in which such net sales occur, and (iii) royalty payments to CFF of ten percent of any amount that we and our stockholders receive in connection with the license, sale, or other transfer to a third party of lenabasum, if indicated for the treatment or prevention of CF, or a change of control transaction, except that such payment shall not exceed five times the amount of the 2018 CFF Award, with such payments to be credited against any other net sales royalty payments due. Either CFF or we may terminate the Investment Agreement for cause, which includes our material failure to achieve certain commercialization and development milestones. Our payment obligations survive the termination of the Investment Agreement.

2015 CFFT Award

Pursuant to the terms of the 2015 CFFT Award agreement, we are obligated to make royalty payments to CFFT contingent upon commercialization of lenabasum in the Field of Use (as defined in the 2015 CFFT Award Agreement) as follows: (i) a royalty payment equal to five times the amount we receive under the 2015 CFFT Award Agreement, up to $25 million, payable in three equal annual installments following the first commercial sale of lenabasum, the first of which is due within 90 days following the first commercial sale of lenabasum, (ii) a royalty payment to CFFT equal to the amount we receive under the 2015 CFFT Award Agreement, up to $5 million, due in the first calendar year in which the aggregate cumulative net sales of lenabasum in the Field of Use exceed $500 million, and (iii) royalty payment(s) to CFFT of up to approximately $15 million if we transfer, sell or license lenabasum in the Field of Use other than for certain clinical or development purposes, or if we enter into a change of control transaction, with such payment(s) to be credited against the royalty payments due upon commercialization. The Field of Use is defined in the CFFT Award Agreement as the treatment in humans of CF, asbestosis, bronchiectasis, byssinosis, chronic bronchitis/COPD hypersensitivity pneumonitis, pneumoconiosis, primary ciliary dyskinesis, sarcoidosis and silicosis. Either CFFT or we may terminate the 2015 CFFT Award Agreement for cause, which includes our material failure to achieve certain commercialization and development milestones. Our payment obligations, if any, would survive the termination of the 2015 CFFT Award Agreement.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is limited to our cash and cash equivalents, all of which have maturities of three months or less. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We do not have other derivative financial instruments.

Foreign Exchange Risk

The majority of our operations are based in the United States and, accordingly our transactions are denominated in U.S. Dollars. However, we have foreign currency exposures related to our cash valued in the United Kingdom in British Pounds and Euros and our cash valued in Australia in Australian Dollars because our functional currency is the U.S. Dollar in our foreign-based subsidiaries. Our foreign denominated assets and liabilities are remeasured each reporting period with any exchange gains and losses recorded in our consolidated statements of operations.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See pages F-1 through F-25 following the Exhibit Index of this Annual Report on Form 10-K.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Our Disclosure Controls

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that material information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, our chief executive officer and our chief financial officer, to allow timely decisions regarding required disclosure. We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13(a)-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2019, our disclosure controls and procedures were not effective due to material weaknesses in our internal controls over financial reporting, which are described below under "Management's Report on Internal Control Over Financial Reporting."

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the framework in *Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission*. Based on this evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2019 due to the material weaknesses described below.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

We did not maintain an effective control environment over the internal control activities to ensure the processing of and reporting of transactions are complete, accurate and timely. Specifically, we have not properly designed and implemented a sufficient level of precision in management review controls and controls surrounding accruals of research, product development and clinical obligations and purchasing, including presentation and disclosure in the consolidated financial statements.

There were also ineffective information technology general controls ("ITGCs") governing user access over certain information technology ("IT") systems that support our financial reporting processes and personnel that could impact internal control over financial reporting. As a result, business process automated and manual controls that were dependent on the affected ITGCs related to the in-scope financial applications were ineffective because they could have been adversely impacted.

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

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by EisnerAmper LLP, an independent registered public accounting firm, as stated in their report included in the Financial Statements section of this Annual Report on Form 10-K.

Changes in Internal Controls over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f)) under the Exchange Act) that occurred during the fourth quarter ended December 31, 2019, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. OTHER INFORMATION

None

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information required by this item is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION

Information required by this item is incorporated herein by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by this item is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by this item is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information required by this item is incorporated by reference to our Proxy Statement for the 2020 Annual Meeting of Stockholders.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) List of Documents filed as part of this Report

(1) Consolidated Financial Statements

The financial statements and related notes, together with the report of EisnerAmper LLP appear at pages F-1 through F-26 following the Exhibit List as required by Part II, Item 8 "Financial Statements and Supplementary Data" of this Form 10-K.

(2) Financial Statement Schedules.

Schedules are omitted because they are either not required, not applicable, or the information is otherwise included.

(3) Exhibits

The Company has filed with this report or incorporated by reference herein certain exhibits as specified below pursuant to Rule 12b-32 under the Exchange Act. See Exhibit Index following the signature page to this report for a complete list of documents filed with this report.

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on May 26, 2017).
3.2	Amended and Restated Bylaws of the Company (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed with the SEC on May 26, 2017).
4.1	Form of Merger Warrant (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.2	Form of Replacement Warrant (incorporated by reference to Exhibit 4.2 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.3	Form of Investor Warrant (incorporated by reference to Exhibit 4.3 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.4	Form of Additional Replacement Warrant (incorporated by reference to Exhibit 4.4 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.5	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.5 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.6	Registration Rights Agreement (incorporated by reference to Exhibit 4.6 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014).
4.7	Specimen Common Stock Certificate, $0.0001 par value (incorporated herein by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-3 filed with the SEC on November 10, 2015).
4.8	Warrant to Purchase Common Stock, dated as of January 26, 2018, issued to the Cystic Fibrosis Foundation (incorporated herein by reference to Exhibit 4.8 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2018).
4.9	Description of Capital Stock*

10.1	2014 Equity Compensation Plan (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.2	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.3	Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.7 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.4	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). †
10.5	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.15 of the Company's Registration Statement on Amendment No. 1 to Form S-1 filed with the SEC on September 30, 2014). †
10.6	Award Agreement, dated April 9, 2015, between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company (incorporated herein by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on May 13, 2015).#
10.7	Consulting Agreement, dated September 20, 2016, between Company and Orchestra Medical Ventures, LLC (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 21, 2016).
10.8	Lease, dated May 30, 2014, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.9	First Amendment to Lease, dated August 27, 2015, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.10	Second Amendment to Lease, dated March 30, 2016, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.11	Third Amendment to Lease, dated September 13, 2016, between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed with the SEC on November 10, 2016).
10.12	Lease Agreement, dated August 21, 2017, by and between Corbus Pharmaceuticals, Inc. and River Ridge Limited Partnership (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on August 22, 2017).
10.13	Guarantee, dated August 21, 2017, by Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on August 22, 2017).

10.14	Cystic Fibrosis Program Related Investment Agreement, dated January 26, 2018, between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company (incorporated herein by reference to Exhibit 10.33 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2018).#
10.15	Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Yuval Cohen, dated April 11, 2018 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2018).†
10.16	Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Mark Tepper, dated April 11, 2018 (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2018).†
10.17	Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Barbara White, dated April 11, 2018 (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2018).†
10.18	Second Amended and Restated Employment Agreement between Corbus Pharmaceuticals Holdings, Inc. and Sean Moran, dated April 11, 2018 (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on April 13, 2018).†
10.19	License Agreement, dated as of September 20, 2018, between Corbus Pharmaceuticals, Inc. and Jenrin Discovery, LLC (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on November 8, 2018).#
10.20	Collaboration and License Agreement, dated January 3, 2019, between Corbus Pharmaceuticals, Inc. and Kaken Pharmaceutical Co., Ltd. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on January 3, 2019).#
10.21	Lease Amendment No. 1, dated as of February 26, 2019, among River Ridge Limited Partnership, Corbus Pharmaceuticals, Inc. and Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.40 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2019).
10.22	Offer Letter, dated as of February 19, 2019, between Craig Millian and Corbus Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.40 of the Company's Annual Report on Form 10-K filed with the SEC on March 12, 2019).
10.23	Separation and General Release Agreement between Corbus Pharmaceuticals Holdings, Inc. and Mark Tepper, dated March 31, 2019 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 1, 2019).
10.24	Consulting Agreement between Corbus Pharmaceuticals Holdings, Inc. and Mark Tepper, dated March 31, 2019 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 1, 2019).
10.25	Lease Amendment No. 2, dated as of October 25, 2019, among River Ridge Limited Partnership, Corbus Pharmaceuticals, Inc. and Corbus Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed with the SEC on November 7, 2019).

21.1	List of Subsidiaries of the Company.*
23.1	Consent of EisnerAmper LLP.*
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).*
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).*
32.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).**
32.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or Rule 15d-14(b).**
101.INS	XBRL Instance Document.*
101.SCH	XBRL Taxonomy Extension Schema Document.*
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.*
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.*
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.*

* Filed herewith.

** Furnished, not filed.

Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.

† Indicates a management contract or compensation plan, contract or arrangement.

Item 16. FORM 10-K SUMMARY

None.

SIGNATURES

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

CORBUS PHARMACEUTICALS HOLDINGS, INC.

Date: March 16, 2020

By: */s/ YUVAL COHEN*
Name: Yuval Cohen
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ YUVAL COHEN Yuval Cohen	Chief Executive Officer and Director (Principal Executive Officer)	March 16, 2020
/s/ SEAN MORAN Sean Moran	Chief Financial Officer (Principal Financial and Accounting Officer)	March 16, 2020
/s/ ALAN HOLMER Alan Holmer	Director	March 16, 2020
/s/ DAVID HOCHMAN David Hochman	Director	March 16, 2020
/s/ JOHN JENKINS John Jenkins	Director	March 16, 2020
/s/ AVERY CATLIN Avery Catlin	Director	March 16, 2020
/s/ RACHELLE JACQUES Rachelle Jacques	Director	March 16, 2020
/s/ PETER SALZMAN Peter Salzman	Director	March 16, 2020

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Corbus Pharmaceuticals Holdings, Inc. and Subsidiaries

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Corbus Pharmaceuticals Holdings, Inc. and Subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018, and the consolidated results of their operations and their cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2019 based on criteria established in *Internal Control - Integrated Framework* (*2013*) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 16, 2020 expressed an adverse opinion.

Going Concern

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

Change in Accounting Principle

As discussed in Note 3 to the financial statements, the Company has changed its method of accounting for Leases in 2019 due to the adoption of Accounting Standards Codification Topic 842, *Leases.*

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the 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 financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2014.

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 16, 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Corbus Pharmaceuticals Holdings, Inc. and Subsidiaries

Opinion on Internal Control over Financial Reporting

We have audited Corbus Pharmaceuticals Holdings, Inc. and Subsidiaries (the "Company") internal control over financial reporting as of December 31, 2019, based on criteria established in the *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, because of the effect of the material weaknesses described in the following paragraph on the achievement of the objectives of the control criteria, Corbus Pharmaceuticals Holdings, Inc. and Subsidiaries has not maintained effective internal control over financial reporting as of December 31, 2019, based on criteria established in the *Internal Control - Integrated Framework (2013)* issued by COSO.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment:

The Company did not maintain an effective control environment over the internal control activities to ensure the processing of and reporting of transactions are complete, accurate and timely. Specifically, the Company has not properly designed and implemented a sufficient level of precision in management review controls and controls surrounding accruals of research, product development and clinical obligations and purchasing, including presentation and disclosure in the consolidated financial statements.

There were also ineffective information technology general controls ("ITGCs") governing user access over certain information technology ("IT") systems that support our financial reporting processes and personnel that could impact internal control over financial reporting. As a result, business process automated and manual controls that were dependent on the affected ITGCs related to the in-scope financial applications were ineffective because they could have been adversely impacted.

These material weaknesses were considered in determining the nature, timing, and extent of the audit tests applied in our audit of the December 31, 2019 financial statements, and this report does not affect our report dated March 16, 2020, on those financial statements.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of Corbus Pharmaceuticals Holdings, Inc. and Subsidiaries as of December 31 2019 and 2018, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes, and our report dated March 16, 2020 expressed an unqualified opinion.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

An entity's internal control over financial reporting is a process designed 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. An entity's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the entity; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and directors of the entity; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of 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 or procedures may deteriorate.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 16, 2020

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Balance Sheets

	December 31,	
	2019	**2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,748,686	$ 41,748,468
Prepaid expenses and other current assets	3,724,932	2,491,844
Contract asset	2,681,065	—
Total current assets	38,154,683	44,240,312
Property and equipment, net	5,083,865	2,705,206
Operating lease right of use assets	5,818,983	—
Other assets	84,968	43,823
Total assets	$ 49,142,499	$ 46,989,341
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Notes payable	$ 752,659	$ 394,305
Accounts payable	11,091,363	6,345,335
Accrued expenses	22,447,939	9,851,191
Deferred revenue, current	—	1,462,503
Operating lease liabilities, current	595,745	—
Deferred rent, current	—	35,996
Total current liabilities	34,887,706	18,089,330
Operating lease liabilities, noncurrent	8,097,228	—
Deferred rent, noncurrent	—	1,375,891
Total liabilities	42,984,934	19,465,221
Commitments and Contingencies		
Stockholders' equity		
Preferred Stock $0.0001 par value:10,000,000 shares authorized, no shares issued and outstanding at December 31, 2019 and 2018	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized at December 31, 2019 and 2018, 64,672,893 and 57,247,496 shares issued and outstanding at December 31, 2019 and 2018, respectively	6,467	5,725
Additional paid-in capital	198,975,056	148,888,635
Accumulated deficit	(192,823,958)	(121,370,240)
Total stockholders' equity	6,157,565	27,524,120
Total liabilities and stockholders' equity	$ 49,142,499	$ 46,989,341

The accompanying notes are an integral part of these Consolidated Financial Statements.

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Operations

	For the Years Ended December 31,	
	2019	**2018**
Revenue from awards and licenses	$ 36,143,568	$ 4,822,272
Operating expenses:		
Research and development	89,604,790	48,613,957
General and administrative	23,643,357	12,956,022
Total operating expenses	113,248,147	61,569,979
Operating loss	(77,104,579)	(56,747,707)
Other income (expense), net:		
Other income	4,581,838	—
Interest income, net	1,227,643	982,777
Foreign currency exchange gain (loss)	(158,620)	92,791
Other income, net	5,650,861	1,075,568
Net loss	$ (71,453,718)	$ (55,672,139)
Net loss per share, basic and diluted	$ (1.12)	$ (0.98)
Weighted average number of common shares outstanding, basic and diluted	63,899,184	56,999,741

The accompanying notes are an integral part of these Consolidated Financial Statements.

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance at December 31, 2017	55,603,427	$ 5,560	$ 123,476,102	$ (65,698,101)	$ 57,783,561
Stock-based compensation expense	—	—	7,609,508	—	7,609,508
Issuance of common stock, net of issuance costs of $464,680	1,500,000	150	11,235,170	—	11,235,320
Issuance of common stock upon exercise of stock options	139,069	14	347,631	—	347,645
Issuance of common stock upon exercise of warrants	5,000	1	4,999	—	5,000
Fair value of warrant issued in connection with Investment Agreement	—	—	6,215,225	—	6,215,225
Net Loss				(55,672,139)	(55,672,139)
Balance at December 31, 2018	57,247,496	$ 5,725	$ 148,888,635	$ (121,370,240)	$ 27,524,120
Stock-based compensation expense	—	—	11,981,655	—	11,981,655
Issuance of common stock, net of issuance costs of $2,571,552	6,198,500	620	37,718,078	—	37,718,698
Issuance of common stock upon exercise of stock options	107,029	10	386,800	—	386,810
Issuance of common stock upon exercise of warrants	1,119,868	112	(112)	—	—
Net Loss				(71,453,718)	(71,453,718)
Balance at December 31, 2019	64,672,893	$ 6,467	$ 198,975,056	$ (192,823,958)	$ 6,157,565

The accompanying notes are an integral part of these Consolidated Financial Statements.

Corbus Pharmaceuticals Holdings, Inc.
Consolidated Statements of Cash Flows

	2019	2018
Cash flows from operating activities:		
Net loss	$ (71,453,718)	$ (55,672,139)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	11,981,655	7,609,508
Depreciation and amortization	739,378	493,938
Loss on foreign exchange	45,833	70,448
Operating lease right of use asset amortization	490,406	—
Deferred rent	—	422,337
Changes in operating assets and liabilities:		
Decrease in customer receivable	5,000,000	12,500,000
Decrease (increase) in prepaid expenses and other current assets	(1,233,088)	281,625
Increase in contract asset	(2,681,065)	—
Increase in other assets	(41,145)	(3,047)
Increase in accounts payable	4,366,439	3,904,021
Increase in accrued expenses	12,555,384	5,113,551
Decrease in deferred revenue	(6,462,503)	(4,787,497)
Increase in operating lease liabilities	971,696	—
Net cash used in operating activities	(45,720,728)	(30,067,255)
Cash flows from investing activities:		
Purchases of property and equipment	(2,742,541)	(2,300,416)
Net cash used in investing activities	(2,742,541)	(2,300,416)
Cash flows from financing activities:		
Proceeds from issuance of notes payable	963,514	491,629
Principal payments on notes payable	(605,160)	(430,184)
Proceeds from issuance of common stock	40,677,060	12,052,645
Issuance costs paid for common stock financings	(2,571,552)	(690,181)
Principal payments under capital lease obligations	(375)	(4,256)
Net cash provided by financing activities	38,463,487	11,419,653
Net decrease in cash and cash equivalents	(9,999,782)	(20,948,018)
Cash and cash equivalents at beginning of the year	41,748,468	62,696,486
Cash and cash equivalents, at end of the year	$ 31,748,686	41,748,468
Supplemental disclosure of cash flow information and non cash transactions:		
Cash paid during the period for interest	$ 29,448	10,437
Fair value of warrant issued in connection with Investment Agreement	$ —	6,215,225
Purchases of property and equipment included in accounts payable or accrued expenses	$ 376,664	1,168
Right of use assets obtained in exchange for lease obligation upon adoption of ASU 2016-02, net of deferred rent	2,399,524	—
Right of use assets obtained in exchange for lease obligation upon entry into lease agreements	3,909,865	—
Write off of fully amortized leasehold improvements	$ —	191,244

The accompanying notes are an integral part of these Consolidated Financial Statements.

1. NATURE OF OPERATIONS

Business

Corbus Pharmaceuticals Holdings, Inc. ("the Company") is a clinical stage pharmaceutical company, focused on the development and commercialization of novel therapeutics to treat rare, chronic, and serious inflammatory and fibrotic diseases. Since its inception, the Company has devoted substantially all of its efforts to business planning, research and development, recruiting management and technical staff, acquiring operating assets and raising capital. The Company's business is subject to significant risks and uncertainties and the Company will be dependent on raising substantial additional capital before it becomes profitable and it may never achieve profitability.

2. LIQUIDITY AND GOING CONCERN

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses since inception and as of December 31, 2019, had an accumulated deficit of $192,823,958. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its preclinical and clinical programs, strategic alliances and the development of its administrative organization. The Company expects the cash and cash equivalents of $31,748,686 at December 31, 2019 may not be sufficient to meet its operating and capital requirements at least 12 months from the filing of this 10-K.

Should the Company be unable to raise sufficient additional capital, the Company may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities. The Company will need to raise significant additional capital to continue to fund the clinical trials for lenabasum and CRB-4001 (see Note 4). The Company may seek to sell common or preferred equity or convertible debt securities, enter into a credit facility or another form of third-party funding, or seek other debt financing. The sale of equity and convertible debt securities may result in dilution to the Company's stockholders and certain of those securities may have rights senior to those of the Company's common shares. If the Company raises additional funds through the issuance of preferred stock, convertible debt securities or other debt financing, these securities or other debt could contain covenants that would restrict the Company's operations. Any other third-party funding arrangement could require the Company to relinquish valuable rights.

The source, timing and availability of any future financing will depend principally upon market conditions, and, more specifically, on the progress of the Company's clinical development programs. Funding may not be available when needed, at all, or on terms acceptable to the Company. Lack of necessary funds may require the Company, among other things, to delay, scale back or eliminate some or all of the Company's planned clinical trials. These factors among others cause management to conclude there is a substantial doubt about the Company's ability to continue as a going concern. There have been no adjustments made to these consolidated financial statements as a result of these uncertainties.

On February 11, 2020, the Company consummated an underwritten public offering of shares of its common stock ("February2020 Offering") (See Note 14).

3. SIGNIFICANT ACCOUNTING POLICIES

A summary of the significant accounting policies followed by the Company in the preparation of the financial statements is as follows:

Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany transactions and accounts have been eliminated in consolidation.

Use of Estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of 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 those estimates and changes in estimates may occur. The most significant estimates are related to stock-based compensation expense, the accrual of research, product development and clinical obligations, the recognition of revenue under the Investment Agreement (see Note 9) and the valuation of the CFF Warrant discussed in Note 13).

Cash and Cash Equivalents

The Company considers only those investments which are highly liquid, readily convertible to cash, and that mature within three months from date of purchase to be cash equivalents. Marketable investments are those with original maturities in excess of three months. At December 31, 2019 and 2018, cash equivalents were comprised of money market funds. The Company had no marketable investments at December 31, 2019 and 2018.

Cash and cash equivalents consists of the following:

	December 31,	
	2019	2018
Cash	$ 884,115	$ 808,943
Money market fund	30,864,571	40,939,525
Total cash and cash equivalents	$ 31,748,686	$ 41,748,468

As of December 31, 2019, all of the Company's cash and cash equivalents was held in the United States, except for approximately $466,000 of cash which was held principally in our subsidiary in the United Kingdom. As of December 31, 2018, all of the Company's cash was held in the United States, except for approximately $702,000 of cash which was held primarily in our subsidiary in the United Kingdom.

Financial Instruments

The carrying amounts reported in the consolidated balance sheet for cash and cash equivalents, receivables, accounts payable and accrued expenses approximate their fair value based on the short-term nature of these instruments. The carrying values of the notes payable approximate their fair value due to the fact that they are at market terms.

Property and Equipment

The estimated life for the Company's property and equipment is as follows: three years for computer hardware and software and three to five years for office furniture and equipment. The Company's leasehold improvements and assets under capital lease are amortized over the shorter of their useful lives or the respective leases. See Note 5 for details of property and equipment and Note 6 for operating and capital lease commitments.

Research and Development Expenses

Costs incurred for research and development are expensed as incurred.

Nonrefundable advance payments for goods or services that have the characteristics that will be used or rendered for future research and development activities pursuant to executory contractual arrangements with third party research organizations are deferred and recognized as an expense as the related goods are delivered or the related services are performed.

Accruals for Research and Development Expenses and Clinical Trials

As part of the process of preparing its financial statements, the Company is required to estimate its expenses resulting from its obligations under contracts with vendors, clinical research organizations and consultants and under clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment terms that do not match the periods over which materials or services are provided under such contracts. The Company's objective is to reflect the appropriate expenses in its financial statements by matching those expenses with the period in which services are performed and efforts are expended. The Company accounts for these expenses according to the timing of various aspects of the expenses. The Company determines the accrual estimates by taking into account discussion with applicable personnel and outside service providers as to the progress of clinical trials, or the services completed. During the course of a clinical trial, the Company adjusts its clinical expense recognition if actual results differ from its estimates. The Company makes estimates of its accrued expenses as of each balance sheet date based on the facts and circumstances known to it at that time. The Company's clinical trial accruals are dependent upon the timely and accurate reporting of contract research organizations and other third-party vendors. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in it reporting amounts that are too high or too low for any particular period. For the years ended December 31, 2019 and 2018, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets, other current liabilities and operating lease liabilities in the Company's consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. This is the rate the Company would have to pay if borrowing on a collateralized basis over a similar term to each lease. The ROU asset also includes any lease payments made and excludes lease incentives. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

Concentrations of Credit Risk

The Company has no significant off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other hedging arrangements. The Company may from time to time have cash in banks in excess of Federal Deposit Insurance Corporation insurance limits. However, the Company believes the risk of loss is minimal as these banks are large financial institutions.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, or decision-making group, in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as principally one operating segment, which is developing and commercializing therapeutics to treat rare life-threatening inflammatory and fibrotic diseases. As of December 31, 2019, all of the Company's assets were located in the United States, except for approximately $466,000 of cash, $1,606,000 of prepaid expenses and other current assets, $23,000 of other assets, and $52,000 of property and equipment, net which were held outside of the United States, principally in our subsidiary in the United Kingdom. As of December 31, 2018, all of the Company's assets were located in the United States, except for approximately $702,000 of cash, $1,183,000 of prepaid expenses and other current assets, $28,000 of other assets, and $54,000 of property and equipment, net which were held in our subsidiary in the United Kingdom.

Income Taxes

For federal and state income taxes, deferred tax assets and liabilities are recognized based upon temporary differences between the financial statement and the tax basis of assets and liabilities. Deferred income taxes are based upon prescribed rates and enacted laws applicable to periods in which differences are expected to reverse. A valuation allowance is recorded to reduce a net deferred tax benefit when it is not more likely than not that the tax benefit from the deferred tax assets will be realized. Accordingly, given the cumulative losses since inception, the Company has provided a valuation allowance equal to 100% of the deferred tax assets in order to eliminate the deferred tax assets amounts.

Tax positions taken or expected to be taken in the course of preparing the Company's tax returns are required to be evaluated to determine whether the tax positions are "more-likely-than-not" of being sustained by the applicable tax authority. Tax positions not deemed to meet a more-likely-than-not threshold, as well as accrued interest and penalties, if any, would be recorded as a tax expense in the current year. There were no uncertain tax positions that require accrual or disclosure to the financial statements as of December 31, 2019 or 2018.

Impairment of Long-lived Assets

The Company continually monitors events and changes in circumstances that could indicate that carrying amounts of long-lived assets may not be recoverable. An impairment loss is recognized when expected undiscounted cash flows of an asset are less than an asset's carrying value. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of such assets in relation to the operating performance and future undiscounted cash flows of the underlying assets. An impairment loss equal to the excess of the fair value of the asset over its carrying amount, is recorded when it is determined that the carrying value of the asset may not be recoverable. No impairment charges were recorded for the years ended December 31, 2019 and 2018.

Stock-based Payments

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees, non-employees and directors as an expense in the statement of operations over the service period based on a measurement of fair value for each stock-based award. The fair value of each option grant to employees is estimated as of the date of grant using the Black-Scholes option-pricing model, net of estimated forfeitures. The fair value is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Prior to the Company's adoption of ASU 2018-07, (see *Recent Accounting Pronouncements* section to follow), stock options granted to non-employee consultants were revalued at the end of each reporting period until vested using the Black-Scholes option-pricing model and the changes in their fair value were recorded as adjustments to expense over the related vesting period.

Net Loss Per Common Share

Basic and diluted net loss per share of the Company's common stock has been computed by dividing net loss by the weighted average number of shares outstanding during the period. For years in which there is a net loss, options and warrants are anti-dilutive and therefore excluded from diluted loss per share calculations. The following table sets forth the computation of basic and diluted earnings per share for the years ended December 31, 2019 and 2018:

	Years Ended December 31,	
	2019	2018
Basic and diluted net loss per share of common stock:		
Net loss	$ (71,453,718)	$ (55,672,139)
Weighted average shares of common stock outstanding	63,899,184	56,999,741
Net loss per share of common stock-basic and diluted	$ (1.12)	$ (0.98)

The impact of the following potentially dilutive securities outstanding as of December 31, 2019 and 2018 have been excluded from the computation of dilutive weighted average shares outstanding as the inclusion would be antidilutive.

	December 31,	
	2019	2018
Warrants	1,000,000	2,283,500
Stock options	13,245,366	9,593,990
	14,245,366	11,877,490

Recent Accounting Pronouncements

The Company considers applicability and impact of all Accounting Standard Updates ("ASUs"). ASUs not discussed below were assessed and determined to be either not applicable or are expected to have minimal impact on the Company's balance sheets or statements of operations.

Accounting for Leases

In February 2016, the FASB issued ASU No**.** 2016-02, *Leases (Topic 842),* as amended ("ASU 2016-02"). Under ASU 2016-02, a lessee is required to recognize assets and liabilities for all leases with lease terms of more than 12 months. ASU 2016-02 requires both financing and operating types of leases to be recognized on the balance sheet. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. ASU 2016-02 required a modified retrospective transition approach, which initially required application of the new guidance for all periods presented in the Company's financial statements ("comparative method"). In July 2018, the FASB released ASU 2018-11, offering a second option which provides further relief in the transition to ASC 842. Companies are allowed to follow the cumulative-effect adjustment transition approach ("effective date method"), which releases companies from presenting comparative periods and related disclosures according to ASC 842. Instead, companies electing to utilize the effective date method will recognize a one-time adjustment to retained earnings on the transition date without the additional burden of presenting the comparative periods under the new guidance. The Company adopted ASU 2016-02 using the effective date method as of January 1, 2019 and recorded an operating lease liability of approximately $3.8 million, and an operating lease right-of-use asset of approximately $2.4 million, with no operations adjustment to the accumulated deficit (See Note 6).

Nonemployee Share-Based Payment Accounting

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. Under ASU 2018-07, consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards within the scope of Topic 718 are to be measured at the grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity-classified nonemployee share-based payment awards are to be measured at the grant date. The definition of the term grant date is amended to generally state the date at which a grantor and a grantee reach a mutual understanding of the key terms and conditions of a share-based payment award. ASU 2018-07 specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in its own operations by issuing share-based payment awards. ASU 2018-07 also clarifies that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under ASC 606. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company's adoption of ASU 2018-07 on January 1, 2019 had no impact on the Company's financial statements and related disclosures.

Collaborative Arrangements

In November 2018, the FASB issued ASU 2018-08, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* ("ASU 2018-08"). ASU 2018-08 clarifies the interaction between the accounting guidance for collaborative arrangements and revenue from contracts with customers.ASU 2018-08 is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption, including adoption in any interim period, is permitted. The Company is currently evaluating the timing of the adoption of ASU 2018-08 and the expected impact it could have on the Company's financial statements and related disclosures.

Accounting for Income Taxes

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*which is intended to simplify various aspects related to accounting for income taxes. The standard is effective for fiscal years, and interim periods within those years, beginning after December 15, 2020, with early adoption permitted. The standard will be adopted upon the effective date for us beginning January 1, 2021. The Company is currently evaluating the timing of the adoption of ASU 2019-12 and the expected impact it could have on the Company's financial statements and related disclosures.

4. LICENSE AGREEMENT

The Company entered into a License Agreement (the "Jenrin Agreement") with Jenrin Discovery, LLC, a privately-held Delaware limited liability company ("Jenrin"), effective September 20, 2018. Pursuant to the Jenrin Agreement, Jenrin granted the Company exclusive worldwide rights to develop and commercialize the Licensed Products (as defined in the Jenrin Agreement) which includes the Jenrin library of over 600 compounds and multiple issued and pending patent filings. The compounds are designed to treat inflammatory and fibrotic diseases by targeting the endocannabinoid system. The lead product candidate is CRB-4001, a peripherally-restricted CB-1 inverse agonist targeting fibrotic liver, lung, heart and kidney diseases.

In consideration of the license and other rights granted by Jenrin, the Company paid Jenrin a $250,000 upfront cash payment and is obligated to pay potential milestone payments to Jenrin totaling up to $18.4 million for each compound it elects to develop based upon the achievement of specified development and regulatory milestones. In addition, Corbus is obligated to pay Jenrin royalties in the mid, single digits based on net sales of any Licensed Products, subject to specified reductions.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01") which clarifies the definition of a business and determines when an integrated set of assets and activities is not a business. ASU 2017-01 requires that if substantially all of the fair value of gross assets acquired or disposed of is concentrated in a single asset or group of similar identifiable assets, the assets would not represent a business. The Company determined that substantially all of the fair value of the Jenrin Agreement was attributable to a single in-process research and development asset, CRB-4001, which did not constitute a business. The Company concluded that it did not have any alternative future use for the acquired in-process research and development asset. Thus, the Company recorded the $250,000 upfront payment to research and development expenses in the third quarter of 2018. The Company will account for the $18.4 million of development and regulatory milestone payments in the period that the relevant milestones are achieved as either research and development expense or as an intangible asset as applicable.

5. PROPERTY AND EQUIPMENT

Property and Equipment consisted of the following:

	December 31,	
	2019	2018
Computer hardware and software	$ 711,442	$ 431,637
Office furniture and equipment	1,627,896	914,742
Leasehold improvements	4,150,488	2,025,410
Property and equipment, gross	6,489,826	3,371,789
Less: accumulated depreciation	(1,405,961)	(666,583)
Property and equipment, net	$ 5,083,865	$ 2,705,206

Depreciation expense was approximately $739,000 and $494,000 for the years ended December 31, 2019 and 2018, respectively. In the first quarter of 2018, the Company wrote off $191,244 of fully amortized leasehold improvements.

6. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitment

On August 21, 2017, the Company entered into a lease agreement ("August 2017 Lease Agreement") for commercial lease of office space, pursuant to which the Company agreed to lease 32,733 square feet of office space ("Leased Premises"). The initial term of the August 2017 Lease Agreement was for a period of seven years which began with the Company's occupancy of the Leased Premises in February 2018. The base rent for the Leased Premises ranged from approximately $470,000 for the first year to approximately $908,000 for the seventh year. Per the terms of the August 2017 Lease Agreement, the landlord agreed to reimburse the Company for $1,080,189 of leasehold improvements. The reimbursements had been deferred and were to be recognized as a reduction of rent expense over the term of the lease. Additionally, the August 2017 Lease Agreement required a standby irrevocable letter of credit of $400,000, which was to be reduced, if the Company is not in default under the August 2017 Lease Agreement, to $300,000 and $200,000 on the third and fourth anniversary of the commencement date, respectively, The Company entered into an unsecured letter of credit for $400,000 in connection with the August 2017 Lease Agreement for which it incurred interest expense of $19,025 and $7,431 for the year ended December 31, 2019 and 2018.

The Company adopted ASU 2016-02 using the effective date method as of January 1, 2019 and recorded a lease liability of approximately $3.8 million, and a right-of-use asset of approximately $2.4 million, with no operations adjustment to the accumulated deficit related to the Leased Premises. Operating leases are included in operating lease right-of-use assets, operating lease liabilities, current and operating lease liabilities, noncurrent in the Company's consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at the date of adoption based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments, which was 9%. This is the rate the Company would have to pay if borrowing on a collateralized basis over a similar term to each lease. The ROU asset also includes any lease payments made and excludes lease incentives. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

On February 26, 2019, the Company amended its lease ("February 2019 Lease Agreement") pursuant to which an additional 30,023 square feet of office space ("New Premises") will be leased by the Company in the same building for an aggregate total of 62,756 square feet of leased office space ("Total Premises"). Per ASC 842, the February 2019 Lease Agreement constitutes a modification as it extends the original lease term and increases the scope of the lease (additional space provided under the amendment), which requires evaluation of the remeasurement of the lease liability and corresponding ROU asset. Accordingly, the Company reassessed the classification of the Leased Premises and remeasured the lease liability on the basis of the extended lease term using the 20 additional monthly rent payments and the incremental borrowing rate at the effective date of the modification of 9%. The remeasurement for the modification resulted in an increase to the lease liability and the ROU asset of approximately $855,000. The Company determined that the New Premises will be treated as a new standalone operating lease under ASC 842 and recorded a lease liability and a right-of-use asset of approximately $2.7 million for this lease.

Per the terms of the February 2019 Lease Agreement, the landlord agreed to reimburse the Company for $990,759 of leasehold improvements. The reimbursements are being recognized as a reduction of rent expense over the term of the lease. Additionally, the February 2019 Lease Agreement required a standby irrevocable letter of credit of $369,900, which may be reduced, if the Company is not in default under the February 2019 Lease Agreement, to $277,425 and $184,950 on the third and fourth anniversary of the commencement date, respectively.

On October 25, 2019, the Company amended its lease ("October 2019 Lease Amendment") pursuant to which the term of the lease was extended through November 30, 2026 and the existing office space under lease was expanded by 500 square feet for an aggregate total of 63,256 square feet of leased office space ("Amended Total Premises"). Per ASC 842, the October 2019 Lease Amendment constitutes a modification as it extends the original lease term and increases the scope of the lease (additional space provided under the amendment), which requires evaluation of the remeasurement of the lease liability and corresponding ROU asset. The additional space did not result in a separate contract as the rent increase was determined not to be commensurate with the standalone price for the additional right of use. Accordingly, the Company reassessed the classification of the Amended Total Premises, which resulted in operating classification, and remeasured the lease liability on the basis of the extended lease term using the additional monthly rent payments and the incremental borrowing rate at the effective date of the modification of 8%. The remeasurement for the modification resulted in an increase to the lease liability and the ROU asset of approximately $381,000 that was recorded in the fourth quarter of 2019.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company's operating leases for the year ended December 31, 2019:

Lease cost		
Operating lease cost	$	1,025,899
Total lease cost	$	1,025,899
Other information		
Operating cash flows received for operating leases	$	338,435
Weighted average remaining lease term		6.9 years
Weighted average discount rate		8.00%

Total rent expense for the years ended December 31, 2019 and 2018 was $1,025,899 and $587,963, respectively.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at December 31, 2019, the following table summarizes the Company's maturities of operating lease liabilities as of December 31, 2019:

Year ending December 31, 2019:

2020	$	1,265,760
2021		1,605,121
2022		1,652,563
2023		1,700,005
2024		1,747,447
Thereafter		3,483,034
Total lease payments	$	11,453,929
Less: imputed interest		(2,760,957)
Total	$	8,692,973

The following disclosures as of December 31, 2018 continue to be in accordance with ASC 840. Future minimum lease payments for operating leases as of December 31, 2018 were as follows:

2019	$	623,958
2020		784,243
2021		830,600
2022		855,150
2023		879,699
Thereafter		1,055,639
Total	$	5,029,289

Capital Lease Commitment

The lease payments under the capital lease agreement for the copier machine commenced when the machine was placed in service in January 2016. The lease was for a three-year term that concluded in January 2019 and included a bargain purchase option at the end of the term.

The following disclosures as of December 31, 2018 continue to be in accordance with ASC 840. Future minimum lease payments for capital leases as of December 31, 2018 was as follows:

Total future minimum lease payments – end in 2019	$	378
Less: interest		(3)
Future capital lease obligations		375
Less: current portion		(375)
Long-term portion	$	—

For commitments under the Company's development award agreements- see Note 9.

7. NOTES PAYABLE

In November 2017, the Company entered into a loan agreement with a financing company for $415,265 to finance one of the Company's insurance policies. The terms of the loan stipulated equal monthly payments of principal and interest payments of $41,975 over a ten-month period. Interest accrued on this loan at an annual rate of 2.35%. This loan was fully repaid in August 2018.

In November 2018, the Company entered into a loan agreement with a financing company for $491,629 to finance one of the Company's insurance policies. The terms of the loan stipulated equal monthly payments of principal and interest payments of $49,857 over a ten-month period. Interest accrued on this loan at an annual rate of 3.07%. This loan was fully repaid in August 2019.

In November 2019, the Company entered into a loan agreement with a financing company for $963,514 to finance one of the Company's insurance policies. The terms of the loan stipulate equal monthly payments of principal and interest payments of $109,413 over a nine-month period. Interest accrues on this loan at an annual rate of 5.25%. Prepaid expenses as of December 31, 2019 and December 31, 2018, included $923,292 and $441,875, respectively, related to this insurance policy.

8. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	December 31,	
	2019	2018
Accrued clinical operations and trials costs	$ 14,242,669	$ 4,914,881
Accrued product development costs	3,573,231	2,222,093
Accrued compensation	3,673,111	2,253,621
Accrued other	958,928	460,596
Total	$ 22,447,939	$ 9,851,191

9. DEVELOPMENT AWARDS AND DEFERRED REVENUE

Collaboration with Kaken

On January 3, 2019, Corbus Pharmaceuticals Holdings, Inc. the Company entered into a Collaboration and License Agreement (the "Agreement") with Kaken Pharmaceutical Co., Ltd., a company organized under the laws of Japan ("Kaken"). Pursuant to the Agreement, Corbus granted Kaken an exclusive license to commercialize pharmaceutical preparations containing lenabasum (the "Licensed Products") for the prevention or treatment of dermatomyositis and systemic sclerosis (together, the "Initial Indications") in Japan (the "Territory").

Pursuant to the terms of the Agreement, Corbus will bear the cost of, and be responsible for, among other things, conducting the clinical studies and other developmental activities for the Licensed Products in the Initial Indications in the Territory, and Kaken will bear the cost of, and be responsible for, among other things, preparing and filing applications for regulatory approval in the Territory and for commercializing Licensed Products in the Territory, and will use commercially reasonable efforts to commercialize Licensed Products and obtain pricing approval for Licensed Products in the Territory.

In consideration of the license and other rights granted by Corbus, Kaken paid to Corbus in March 2019 a $27,000,000 upfront cash payment and is obligated to pay potential milestone payments to Corbus totaling up to approximately $173,000,000 for the achievement of certain development, sales and regulatory milestones, with part of the milestone payments being calculated in Japanese Yen, and therefore subject to change based on the conversion rate to U.S. Dollars in effect at the time of payment. In addition, during the Royalty Term (as defined below), Kaken is obligated to pay Corbus royalties on sales of Licensed Products in the Territory, under certain conditions, in the double digits, which royalty shall be reduced in certain circumstances. In particular, for so long as Corbus supplies Licensed Products to Kaken pursuant to a supply agreement to be entered into by the parties, royalty payments shall be payable for each unit of Licensed Product that Corbus supplies as a percentage of the Japanese National Health Insurance price of the Licensed Product. During any time in which a supply agreement is not in effect, royalty payments shall be changed to a rate to be agreed upon by the parties in good faith.

The Agreement will remain in effect on a Licensed Product-by-Licensed product basis and will expire upon the expiration of the Royalty Term for the final Licensed Product. The "Royalty Term" means the period beginning on the date of the first commercial sale of the Licensed Product in Japan and ends on the latest of (i) the expiration of the last valid claim of the royalty patents covering such Licensed Product in Japan, (ii) the expiration of regulatory exclusivity for such Licensed Product for such Initial Indication in Japan, or (iii) ten (10) years after the first commercial sale of such Licensed Product for such Initial Indication in Japan. The Agreement may be terminated by either party for material breach, upon a party's insolvency or bankruptcy or upon a challenge by one party of any patents of the other party, and Kaken may terminate in specified situations, including for a safety concern or clinical failure, or at its convenience following the second anniversary of the first commercial sale of a Licensed Product in either of the Initial Indications in the Territory, with 180 days' notice.

Pursuant to the Agreement, the parties agreed to develop a joint steering committee to provide strategic oversight of the parties' activities under the Agreement, as well as a joint development committee to coordinate the development of Licensed Products in Japan. Additionally, the parties will establish a joint commercialization committee to review and confirm commercialization activities with respect to Licensed Products in Japan upon regulatory approval of such Licensed Product.

The Agreement also contains customary representations, warranties and covenants by both parties, as well as customary provisions relating to indemnification, confidentiality and other matters.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, Kaken, is a customer. The Company identified the following material promises under the arrangement: (1) the exclusive license to commercialize lenabasum; (2) the product's initial know-how transfer; (3) election to use the product trademarks; (4) the sharing of data gathered through the execution of the Global Development Plan for the Initial Indications; and (5) Japanese Pharmaceuticals and Medical Devices Agency ("PMDA")-required supplemental studies. The Company identified two performance obligations; (1) the combined performance obligation of the License, initial know-how transfer and license to the Company's product trademarks; and (2) the sharing of data gathered through the execution of the Global Development Plan (as defined in the Agreement) for the Initial Indications. The Company determined that the license and initial know-how transfer were not distinct from another in the context of the contract, as initial know-how transfer is highly interrelated to the license and Kaken would incur significant costs to re-create the know-how of the Company. The Company determined that the election to use the product trademarks license contributes to the exclusivity of the license and, therefore, is combined with the license. The PMDA-required supplemental study is a contingent promise although not a performance obligation as the promise does not provide Kaken with a material right.

Under the Agreement, in order to evaluate the appropriate transaction price, the Company determined that the upfront amount of $27,000,000 constituted the entirety of the consideration to be included in the transaction price at the outset of the arrangement, which was allocated to the two performance obligations. The potential milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestone payments are fully constrained based on the probability of achievement. The Company will reevaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

The Company estimated the stand-alone selling price of each performance obligation using a market approach and allocated the transaction price on a relative basis. This allocation resulted in a de minimis value attributable the obligation to sharing of data gathered through the execution of the Global Development Plan for the Initial Indications and effectively all of the value to the combined license, initial know-how transfer and license to product trademarks. Therefore, the full upfront payment of $27,000,000 is allocated to the combined performance obligation of the license, initial technology transfer and license to the product trademarks.

The Company received the upfront payment of $27,000,000 in March 2019 and, as the performance obligations were not yet satisfied at that time, the payment was recorded in deferred revenue as of March 31, 2019. The Company satisfied the combined performance obligation by June 30, 2019, upon which the Company recognized the $27,000,000 upfront payment as revenue in the second quarter of 2019.

The Company was required to make a $2,700,000 royalty payment to CFF within 60 days of receipt of the upfront cash payment from Kaken pursuant to the 2018 CFF Award. This obligation was paid by the Company to CFF in May 2019.

2018 CFF Award

On January 26, 2018, the Company entered into the Cystic Fibrosis Program Related Investment Agreement with the CFF ("Investment Agreement"), a non-profit drug discovery and development corporation, pursuant to which the Company received an award for up to $25 million in funding (the "2018 CFF Award") to support a Phase 2b Clinical Trial (the "Phase 2b Clinical Trial") of lenabasum in patients with cystic fibrosis, of which the Company has received $17.5 million in the aggregate through December 31, 2019 upon the Company's achievement of milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. The Company expects that the remainder of the 2018 CFF Award will be paid incrementally upon the Company's achievement of the remaining milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement, and we expect to receive the remainder before the end of the fourth quarter of 2020.

Pursuant to the terms of the Investment Agreement, the Company is obligated to make certain royalty payments to CFF, including a royalty payment of one and one-half times the amount of the 2018 CFF Award, payable in cash within sixty days upon the first receipt of approval of lenabasum in the United States and a second royalty payment of one and one-half times the amount of the 2018 CFF Award upon approval in another major market, as set forth in the Investment Agreement (the "Approval Royalty"). At the Company's election, the Company may satisfy the first of the two Approval Royalties in registered shares of the Company's common stock.

Additionally, the Company is obligated to make (i) royalty payments to CFF of two and one-half percent of net sales from lenabasum due within sixty days after any quarter in which such net sales occur in the Field, as defined in the Investment Agreement, (ii) royalty payments to CFF of one percent of net sales of Non-Field Products, as defined in the Investment Agreement due within sixty days after any quarter in which such net sales occur, and (iii) royalty payments to CFF of ten percent of any amount the Company and its stockholders receive in connection with the license, sale, or other transfer to a third party of lenabasum, if indicated for the treatment or prevention of CF, or a change of control transaction, except that such payment shall not exceed five times the amount of the 2018 CFF Award, with such payments to be credited against any other net sales royalty payments due. Accordingly, the Company will owe to CFF a royalty payment equal to 10% of any amounts the Company receives as payment under the collaboration agreement with Kaken, provided that the total royalties that the Company will be required to pay under the Investment Agreement resulting from income from licenses or sales subject to the Investment Agreement are capped at five times the total amount of the 2018 CFF Award, and the Company may credit such royalties against any royalties on net sales otherwise owed to CFF under the Investment Agreement. Accordingly, the Company was required to pay CFF $2,700,000 in May 2019 as a result of its receipt of the $27,000,000 upfront cash payment from Kaken.

Either CFF or the Company may terminate the Investment Agreement for cause, which includes the Company's material failure to achieve certain commercialization and development milestones. The Company's payment obligations survive the termination of the Investment Agreement.

Pursuant to the terms of the Investment Agreement, the Company issued a warrant to CFF to purchase an aggregate of 1,000,000 shares of the Company's common stock (the "CFF Warrant"). The CFF Warrant is exercisable at a price equal to $13.20 per share and is immediately exercisable for 500,000 shares of the Company's common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to the Company pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 500,000 shares of the Company's common stock. The CFF Warrant expires on January 26, 2025. Any shares of the Company's common stock issued upon exercise of the CFF Warrant will be unregistered and subject to a one-year lock-up.

Under the Investment Agreement, the Company recorded $9,143,568 and $4,822,272 of revenue during the year ended December 31, 2019 and 2018. The Company assessed the 2018 CFF Award for accounting under ASC 606, which it adopted in the first quarter of 2018. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the contract counterparty, CFF, is a customer. The Company identified the following material promise under the arrangement: research and development activities and related services under the Phase 2b Clinical Trial. Based on these assessments, the Company identified one performance obligation at the outset of the Investment Agreement, which consists of: Phase 2b Clinical Trial research and development activities and related services.

To determine the transaction price, the Company included the total aggregate payments under the Investment Agreement which amount to $25 million and reduced the revenue to be recognized by the payment to the customer of $6,215,225 in the form of the CFF Warrant representing its fair value, leaving the remaining $18,784,775 as the transaction price as of the outset of the arrangement, which will be recognized as revenue over the performance period as discussed below. The $6,215,225 fair value of the warrant was also recorded as an increase to additional paid in capital. The Company billed and collected $12,500,000 in milestone payments during the year ended December 31, 2018 and 5,000,000 during the year ended December 31, 2019, which was recorded as an increase to deferred revenue. A roll forward of deferred revenue related to the Investment Agreement for the year ended December 31, 2019 is presented below.

	December 31, 2019
Beginning balance, December 31, 2018	$ 1,462,503
Billing to CFF upon achievement of milestones	5,000,000
Recognition of revenue	(9,143,568)
Reclassification to contract asset	2,681,065
Ending balance, December 31, 2019	$ —

The CFF Warrant is accounted for as a payment to the customer under ASC 606. See Note 13 for further information related to the CFF Warrant. The Company notes that the Investment Agreement contains an initial payment that was received upon contract execution and subsequent milestone payments, which are a form of variable consideration that require evaluation for constraint considerations. The Company concluded that the related performance milestones are generally within the Company's control and as result are considered probable. Revenue associated with the performance obligation is being recognized as revenue as the research and development services are provided using an input method, according to the costs incurred as related to the research and development activities on each program and the costs expected to be incurred in the future to satisfy the performance obligation. The transfer of control occurs over this time period and, in management's judgment, is the best measure of progress towards satisfying the performance obligation. The research and development services related to this performance obligation are expected to be performed over approximately 2.75 years and is expected to be completed in the third quarter of 2020. The amounts received that have not yet been recognized as revenue are recorded in deferred revenue and the amounts recognized as revenue, but not yet received or invoiced are generally recognized as contract assets on the Company's condensed consolidated balance sheet.

2015 CFFT Award

On April 20, 2015, the Company entered into an award agreement (the "2015 CFFT Award Agreement") with the Cystic Fibrosis Foundation Therapeutics, Inc ("CFFT"), a non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation ("CFF") pursuant to which the Company received a development award (the "2015 CFFT Award") for up to $5.0 million in funding. The funding from the 2015 CFFT Award supported a first-in-patient Phase 2 clinical trial of the Company's oral anti-inflammatory drug lenabasum in adults with cystic fibrosis ("CF"). The Company received $5.0 million in payments under the 2015 CFFT Award. The payments received under the 2015 CFFT Award were recorded as deferred revenue when the triggering event to receive those amounts had occurred and were amortized on a straight-line basis over the expected duration of the remaining performance period under the 2015 CFFT Award which concluded in the third quarter of 2017.

In accordance with ASC 605, the Company recorded $2,440,195 of revenue during the year ended December 31, 2017 under the 2015 CFFT Award Agreement. No revenue was recorded under the 2015 CFFT Award Agreement during the year ended December 31, 2018 as the final performance period concluded in the third quarter of 2017. Under ASC 605, milestone payments were initially recognized only in the period that the payment-triggering event occurred or was achieved. Effective January 1, 2018, ASC 605 was superseded by *Accounting Standards Codification 606 Revenue Recognition — Revenue from Contracts with Customers* ("ASC 606"). The Company adopted ASC 606 in the first quarter of 2018 using the modified retrospective method according to which the cumulative effect of initially applying ASC 606 is recognized at the date of initial application. Since the Company concluded its performance obligations and completed recognizing revenue under the 2015 CFFT Award Agreement in the third quarter of 2017, there was no cumulative effect to record at the date of the Company's adoption of ASC 606.

Pursuant to the terms of the 2015 CFFT Award Agreement, the Company is obligated to make royalty payments to CFFT contingent upon commercialization of lenabasum in the Field of Use (as defined in the 2015 CFFT Award Agreement) as follows: (i) a royalty payment equal to five times the amount the Company receives under the 2015 CFFT Award Agreement, up to $25 million, payable in three equal annual installments following the first commercial sale of lenabasum, the first of which is due within 90 days following the first commercial sale of lenabasum, (ii) a royalty payment to CFFT equal to the amount the Company receives under the 2015 CFFT Award Agreement, up to $5 million, due in the first calendar year in which the aggregate cumulative net sales of lenabasum in the Field of Use exceed $500 million, and (iii) royalty payment(s) to CFFT of up to approximately $15 million if the Company transfers, sells or licenses lenabasum in the Field of Use other than for certain clinical or development purposes, or if the Company enters into a change of control transaction, with such payment(s) to be credited against the royalty payments due upon commercialization. The Field of Use is defined in the 2015 CFFT Award as the treatment in humans of CF, asbestosis, bronchiectasis, byssinosis, chronic bronchitis/COPD hypersensitivity pneumonitis, pneumoconiosis, primary ciliary dyskinesis, sarcoidosis and silicosis.

Either CFFT or the Company may terminate the agreement for cause, which includes the Company's material failure to achieve certain commercialization and development milestones. The Company's payment obligations, if any, would survive the termination of the 2015 CFFT Award Agreement.

10. INCOME TAXES

No provision or benefit for federal or state income taxes has been recorded, as the Company has incurred a net loss for all of the periods presented, and the Company has provided a full valuation allowance against its deferred tax assets.

At December 31, 2019 and 2018, the Company had federal net operating loss carryforwards of approximately $99,754,000 and $82,545,000, respectively, of which federal carryforwards will expire in varying amounts beginning in 2029. Of the federal net operating loss carryforwards of $99,754,000, approximately $43,403,000 are from 2018 and 2019, have no expiration date, and are limited to 80% of taxable income. At December 31, 2019 and 2018, the Company had Massachusetts net operating loss carryforwards of approximately $94,884,000 and $78,152,000, respectively. Utilization of net operating losses may be subject to substantial annual limitations due to the "change in ownership" provisions of the Internal Revenue Code, and similar state provisions. The annual limitations may result in the expiration of net operating losses before utilization. The Company has not yet conducted a study to determine if any such changes have occurred that could limit the Company's ability to use the net operating losses and tax credit carryforwards. The Company also had research and development tax credit carryforwards at December 31, 2019 and 2018 of approximately $6,031,000 and $2,926,000, respectively.

In the second half of 2019, the Company received from a foreign and domestic taxing authorities, an aggregate $4.6 million of cash payments for refundable research and development tax credits that were earned on certain research and development expenses. The Company recorded the $4.6 million in other income in the accompanying statements of operations for the year ended December 31, 2019.

Significant components of the Company's net deferred tax asset are as follows:

	December 31,	
	2019	2018
NOL carryforward	$ 26,945,090	$ 22,273,661
Foreign net operating loss carryforward	10,875,395	3,616,502
Tax credits	5,844,918	2,793,247
Stock based compensation	5,373,539	3,381,969
Accrued expenses	1,120,196	660,427
Other temporary differences	962,981	186,069
Subtotal	51,122,119	32,911,875
Valuation allowance	(51,122,119)	(32,911,875)
Net deferred tax asset	$ —	$ —

The Company has maintained a full valuation allowance against its deferred tax assets in all periods presented. A valuation allowance is required to be recorded when it is not more likely than not that some portion or all of the net deferred tax assets will be realized. Since the Company cannot determine that it is more likely than not that it will generate taxable income, and thereby realize the net deferred tax assets, a full valuation allowance has been provided. The valuation allowance increased by $18,210,244 and $14,583,207 in 2019 and 2018, respectively, due to the increase in deferred tax assets, primarily due to net operating loss carryforwards. The Company has no uncertain tax positions at December 31, 2019 and 2018 that would affect its effective tax rate. Since the Company is in a loss carryforward position, the Company is generally subject to U.S. federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available.

Income tax benefits computed using the federal statutory income tax rate differs from the Company's effective tax rate primarily due to the following:

	December 31,	
	2019	2018
Tax provision at statutory rate	21.00%	21.00%
State taxes, net of federal benefit	5.25%	5.42%
Permanent differences	-2.76%	-2.00%
Foreign expected tax	21.76%	9.85%
Tax credits	8.82%	4.31%
Income tax rate change	0.07%	—%
Other	0.45%	1.14%
Increase in valuation reserve	-54.59%	-39.72%
Total	0.00%	0.00%

11. COMMON STOCK

The Company has authorized 150,000,000 shares of common stock, $0.0001 par value per share, of which 64,672,893 shares, and 57,247,496 shares were issued and outstanding as of December 31, 2019, and 2018, respectively.

On January 5, 2018, the Company entered into a sales agreement with Cantor Fitzgerald under which the Company had the ability to direct Cantor Fitzgerald as its sales agent to sell common stock up to an aggregate offering of up to $50 million under an "At the Market Offering" ("January 2018 Sales Agreement"). Sales of common stock under the January 2018 Sales Agreement were made pursuant to an effective registration statement for an aggregate offering of up to $50 million. During the first quarter of 2018, the Company sold 1,500,000 shares of its common stock to an institutional investor under the January 2018 Sales Agreement for which the Company received net proceeds of approximately $11.2 million. The Company did not sell any shares under the January 2018 Sales Agreement in remainder of 2018 and through February 8, 2019, the effective date of the Company's termination of the January 2018 Sales Agreement.

On January 30, 2019, the Company consummated an underwritten public offering of shares of its common stock pursuant to which the Company sold an aggregate of 6,198,500 shares of its common stock, including 808,500 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a purchase price of $6.50 per share with gross proceeds to the Company totaling approximately $40.3 million, less issuance costs incurred of approximately $2.6 million.

During the year ended December 31, 2019 and 2018, the Company issued 107,029 and 144,069 shares of common stock upon the exercise of stock options to purchase common stock and the Company received proceeds of $386,810 and $352,645 from these exercises, respectively.

During the year ended December 31, 2019, warrants to purchase 1,283,500 shares of stock were exercised on a cashless basis resulting in the issuance of 1,119,868 shares of common stock. During the year ended December 31, 2018, warrants to purchase 5,000 shares were exercised for proceeds of $5,000.

On February 11, 2020, the Company consummated an underwritten public offering of shares of its common stock. See Note 14.

12. STOCK OPTIONS

In April 2014, the Company adopted the Corbus Pharmaceuticals Holdings, Inc. 2014 Equity Incentive Plan (the "2014 Plan"). Pursuant to the 2014 Plan, the Company's Board of Directors may grant incentive and nonqualified stock options and restricted stock to employees, officers, directors, consultants and advisors. Pursuant to the terms of an annual evergreen provision in the 2014 Plan, the number of shares of common stock available for issuance under the 2014 Plan shall automatically increase on January 1 of each year by at least seven percent (7%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, or, pursuant to the terms of the 2014 Plan, in any year, the Board of Directors may determine that such increase will provide for a lesser number of shares. On January 1, 2019, pursuant to an annual evergreen provision contained in the 2014 Plan, the number of shares reserved for future grants was increased by 3,000,000 shares, which was less than seven percent (7%) of the outstanding shares of common stock on December 31, 2018. As of December 31, 2019, there was a total of 18,543,739 shares reserved for issuance under the 2014 Plan and there were 4,313,836 shares available for future grants. Options issued under the 2014 Plan generally vest over 4 years from the date of grant in multiple tranches and are exercisable for up to 10 years from the date of issuance.

In accordance with the terms of the 2014 Plan, effective as of January 1, 2020, the number of shares of common stock available for issuance under the 2014 Plan increased by 4,527,103 shares, which was seven percent (7%) of the outstanding shares of common stock on December 31, 2019. As of January 1, 2020, the 2014 Plan had a total reserve of 22,770,842 shares and there were 8,540,939 shares available for future grants.

Share-based Compensation

For stock options issued and outstanding for the years ended December 31, 2019 and 2018, the Company recorded non-cash, stock-based compensation expense of $11,981,655 and $7,609,508, respectively, net of estimated forfeitures.

The fair value of each option award for employees is estimated on the date of grant and for non-employees is estimated at the end of each reporting period until vested using the Black-Scholes option pricing model that uses the assumptions noted in the following table. The Company uses historical data, as well as subsequent events occurring prior to the issuance of the financial statements, to estimate option exercises and employee terminations in order to estimate its forfeiture rate. The expected term of options granted under the 2014 Plan, all of which qualify as "plain vanilla" per SEC Staff Accounting Bulletin 107, is determined based on the simplified method due to the Company's limited operating history, and is 6.25 years based on the average between the vesting period and the contractual life of the option. For non-employee options, the expected term is the contractual term. The risk-free rate is based on the yield of a U.S. Treasury security with a term consistent with the option.

The weighted average assumptions used principally in determining the fair value of options granted were as follows:

	2019	2018
Risk free interest rate	2.33%	2.53%
Expected dividend yield	0%	0%
Expected term in years	6.25	6.25
Expected volatility	86.98%	87.70%
Estimated forfeiture rate	4.85%	5.00%

A summary of option activity for years ended December 31, 2019 and 2018 is presented below:

Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Intrinsic Value
Outstanding at December 31, 2017	7,844,966	$ 3.75		
Granted	2,378,500	$ 7.58		
Exercised	(139,069)	$ 2.50		
Forfeited	(490,407)	$ 7.85		
Outstanding at December 31, 2018	9,593,990	$ 4.51		
Granted	4,125,800	$ 6.91		
Exercised	(107,029)	$ 3.61		
Forfeited	(367,395)	$ 7.10		
Outstanding at December 31, 2019	13,245,366	$ 5.19	7.02	$ 20,076,015
Exercisable at December 31, 2019	7,836,094	$ 3.83	5.78	$ 19,809,807
Vested and expected to vest at December 31, 2019	12,913,044	$ 5.15	6.97	$ 20,058,031

The weighted average grant-date fair value of options granted during the years ended December 31, 2019 and 2018 was $5.03 and $5.63 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2019 and 2018 was approximately $324,567 and $543,060, respectively. As of December 31, 2019, there was approximately $22,101,610 of total unrecognized compensation expense, related to non-vested share-based compensation arrangements. The unrecognized compensation expense is estimated to be recognized over a period of 2.60 years at December 31, 2019.

As summary of non-vested stock options for the years ended December 31, 2019 and 2018 is presented below:

Options	Shares	Weighted Average Fair Value
Non-vested at December 31, 2017	3,329,989	$ 4.61
Granted	2,378,500	$ 5.63
Vested	(1,643,772)	$ 3.98
Forfeited	(438,428)	$ 5.91
Nonvested at December 31, 2018	3,626,289	$ 5.32
Granted	4,125,800	$ 5.03
Vested	(2,038,128)	$ 4.95
Forfeited	(304,689)	$ 5.22
Non-vested at December 31, 2019	5,409,272	$ 5.21

13. WARRANTS

During the year ended December 31, 2019, warrants to purchase 1,283,500 shares of stock were exercised on a cashless basis resulting in the issuance of 1,119,868 shares of common stock.

During the year ended December 31, 2018, warrants to purchase 5,000 shares of common stock were exercised for proceeds of $5,000.

At December 31, 2019, there were warrants outstanding to purchase 1,000,000 shares of common stock with a weighted average exercise price of $13.20 and a weighted average remaining life of 5.08 years, related only to the warrant issued to CFF pursuant to the terms of the Investment Agreement (Note 9). The Company issued a warrant to CFF to purchase an aggregate of 1,000,000 shares of the Company's common stock (the "CFF Warrant"). The CFF Warrant is exercisable at a price equal to $13.20 per share and is immediately exercisable for 500,000 shares of the Company's common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to the Company pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 500,000 shares of the Company's common stock. The CFF Warrant expires on January 26, 2025. Any shares of the Company's common stock issued upon exercise of the CFF Warrant will be unregistered and subject to a one-year lock-up. The CFF Warrant is classified as equity as it meets all the conditions under GAAP for equity classification. In accordance with GAAP, the Company has calculated the fair value of the warrant for initial measurement and will reassess whether equity classification for the warrant is appropriate upon any changes to the warrants or capital structure, at each balance sheet date. The weighted average assumptions used in determining the $6,215,225 fair value of the CFF Warrant were as follows:

Risk free interest rate	2.60%
Expected dividend yield	0%
Expected term in years	7.00
Expected volatility	83.5%

14. SUBSEQUENT EVENTS

Evergreen Provision

Pursuant to the terms of an annual evergreen provision in the 2014 Plan, the number of shares of common stock available for issuance under the 2014 Plan shall automatically increase on January 1 of each year by at least seven percent (7%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year, or, pursuant to the terms of the 2014 Plan, in any year, the Board of Directors may determine that such increase will provide for a lesser number of shares. In accordance with the terms of the 2014 Plan, effective as of January 1, 2020, the number of shares of common stock available for issuance under the 2014 Plan increased by 4,527,103 shares, such amount being equal to seven percent (7%) of the outstanding shares of common stock on December 31, 2019. As of January 1, 2020, the 2014 Plan had a total reserve of 23,070,842 shares and there were 8,840,939 shares available for future grants.

Public Offering

On February 11, 2020, the Company consummated an underwritten public offering of shares of its common stock pursuant to which the Company sold an aggregate of 7,666,667 shares of its common stock, including 1,000,000 shares sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a purchase price of $6.00 per share with gross proceeds to the Company totaling $46.0 million, less estimated issuance costs incurred of approximately $3.0 million.

Exhibit 4.9

DESCRIPTION OF CAPITAL STOCK

The following is a summary of information concerning capital stock of Corbus Pharmaceuticals Holdings, Inc. ("us," "our," "we" or the "Company") and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws currently in effect. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation (the "Certificate of Incorporation") and amended and restated bylaws (the "Bylaws"), each previously filed with the Securities and Exchange Commission ("SEC") and incorporated by reference as an exhibit to the Annual Report on Form 10-K, as well as to the applicable provisions of the Delaware General Corporation Law (the "DGCL"). We encourage you to read our Certificate of Incorporation, Bylaws and the applicable portions of the DGCL carefully.

General

Our authorized capital stock consists of:

- 150,000,000 shares of common stock, par value $0.0001 per share; and
- 10,000,000 shares of preferred stock, par value $0.0001 per share, of which, as of the date of this prospectus, none of which shares have been designated.

As of December 31, 2019, 64,672,893 shares of common stock were issued and outstanding and no shares of preferred stock were issued and outstanding.

Common Stock

Voting. The holders of our common stock are entitled to one vote for each share held of record on all matters on which the holders are entitled to vote (or consent pursuant to written consent). Directors are elected by a plurality of the votes present in person or represented by proxy and entitled to vote.

Dividends. The holders of our common stock are entitled to receive, ratably, dividends only if, when and as declared by our board of directors out of funds legally available therefor and after provision is made for each class of capital stock having preference over the common stock.

Liquidation Rights. In the event of our liquidation, dissolution or winding-up, the holders of common stock are entitled to share, ratably, in all assets remaining available for distribution after payment of all liabilities and after provision is made for each class of capital stock having preference over the common stock.

Conversion Right. The holders of our common stock have no conversion rights.

Preemptive and Similar Rights. The holders of our common stock have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to the common stock. All of the outstanding shares of our common stock are fully-paid and nonassessable.

Anti-takeover Effects of Delaware Law and our Certificate of Incorporation and Bylaws

Our Certificate of Incorporation and Bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. These provisions are as follows:

- they provide that special meetings of stockholders may be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the board of directors;
- they specifically deny the ability of stockholders to take action by written consent of the stockholders in lieu of a meeting;
- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes to the our board of directors; and
- they allow us to issue, without stockholder approval, up to 10,000,000 shares of preferred stock, with such designations, rights, and preferences as may be determined from time to time by our board of directors that could adversely affect the rights and powers of the holders of the common stock, including dividend, liquidation, conversion, voting, or other rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying or preventing a change in control of our company, all without further action by our stockholders.

We are subject to the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in the following prescribed manner:

- prior to the time of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and
- on or subsequent to the time of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Generally, for purposes of Section 203, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, owned 15% or more of a corporation's outstanding voting securities.

Listing

Our common stock is listed on The Nasdaq Global Market under the symbol "CRBP."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company, LLC.

Exhibit 21.1

SUSIDIARIES OF CORBUS PHARMACEUTICALS HOLDINGS, INC.

Name of Organization	Jurisdiction
Corbus Pharmaceuticals, Inc.	Delaware
Corbus International Limited	United Kingdom
Corbus Pharmaceuticals Australia Pty Ltd	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Corbus Pharmaceuticals Holdings, Inc. and Subsidiaries on Form S-3 (No. 333-222447) and Form S-8 (Nos. 333-200350, 333-201898, 333-210428, 333-216547, and 333-223745, and 333-230219) of our report dated March 16, 2020, on our audits of the consolidated financial statements as of December 31, 2019 and 2018 and for each of the years then ended, and the effectiveness Corbus Pharmaceuticals Holdings, Inc.'s internal control over financial reporting as of December 31, 2019, which reports are included in this Annual Report on Form 10-K to be filed on or about March 16, 2020. Our report on the effectiveness of the Company's internal control over financial reporting as of December 31, 2019 expresses an adverse opinion because of material weaknesses.

/s/ EisnerAmper LLP

EISNERAMPER LLP
Philadelphia, Pennsylvania
March 16, 2020

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Yuval Cohen, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2019 of Corbus Pharmaceuticals Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) 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 financing reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) 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 functions):

    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 16, 2020

/s/ Yuval Cohen

Yuval Cohen
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sean M. Moran, certify that:

1. I have reviewed this annual report on Form 10-K for the period ended December 31, 2019 of Corbus Pharmaceuticals Holdings, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) 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 financing reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) 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 functions):

    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 16, 2020

/s/ Sean Moran

Sean Moran
Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

Certification of Chief Executive Officer Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Annual Report on Form 10-K of Corbus Pharmaceuticals Holdings, Inc. for the year ended December 31, 2019, each of the undersigned hereby certifies in his capacity as an officer of Corbus Pharmaceuticals Holdings, Inc. that to such officer's knowledge:

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

By: */s/ Yuval Cohen*
Yuval Cohen
Chief Executive Officer
(Principal Executive Officer)

Dated: March 16, 2020

Exhibit 32.2

Certification of Chief Financial Officer Pursuant to
18 U.S.C. Section 1350,
as Adopted Pursuant to
Section 906 of the Sarbanes-Oxley Act of 2002

This Certification is being filed pursuant to 18 U.S.C. Section 1350, as adopted by Section 906 of the Sarbanes-Oxley Act of 2002. This Certification is included solely for the purposes of complying with the provisions of Section 906 of the Sarbanes-Oxley Act and is not intended to be used for any other purpose. In connection with the accompanying Annual Report on Form 10-K of Corbus Pharmaceuticals Holdings, Inc. for the year ended December 31, 2019, each of the undersigned hereby certifies in his capacity as an officer of Corbus Pharmaceuticals Holdings, Inc. that to such officer's knowledge:

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

By: */s/ Sean Moran*
Sean Moran
Chief Financial Officer
(Principal Accounting and Financial Officer)

Dated: March 16, 2020