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, 2017

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

FOR THE TRANSITION PERIOD FROM _____ TO _____.

COMMISSION FILE NUMBER: 001-37348

Corbus Pharmaceuticals Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)

500 River Ridge Drive Norwood, Massachusetts (Address of principal executive offices) 46-4348039 (I.R.S. Employer Identification No.)

> 02062 (Zip Code)

(617) 963-0100

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

<u>Title of each class</u> Common Stock, par value \$0.0001 per share Name of each exchange on which registered 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No []

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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. (Check one):

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. [X]

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, 2017, 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 \$294,882,116, based on the closing price of the registrant's common stock on June 30, 2017.

As of March 6, 2018, the number of shares outstanding of the registrant's common stock, \$0.0001 par value per share, was 57,134,677.

Documents incorporated by reference

Portions of the registrant's proxy statement for the 2018 annual meeting of stockholders to be filed pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2017, 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, 2017 TABLE OF CONTENTS

| ITE | MI Contraction of the second se | Page |
|-----|---|------|
| | <u>PART I</u> | |
| 1. | Business | 1 |
| 1A. | Risk Factors | 24 |
| 1B. | Unresolved Staff Comments | 45 |
| 2. | Properties | 45 |
| 3. | Legal Proceedings | 46 |
| 4. | Mine Safety Disclosures | 46 |
| | PART II | |
| 5. | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 47 |
| 6. | Selected Financial Data | 48 |
| 7. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 49 |
| 7A. | Quantitative and Qualitative Disclosures About Market Risk | 56 |
| 8. | Financial Statements and Supplementary Data | 56 |
| 9. | Changes in and Disagreements with Accountants on Accounting and Financial Disclosure | 56 |
| 9A. | Controls and Procedures | 56 |
| 9B. | Other Information | 56 |
| | PART III | |
| 10. | Directors, Executive Officers and Corporate Governance | 57 |
| 11. | Executive Compensation | 57 |
| 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 57 |
| 13. | Certain Relationships and Related Transactions, and Director Independence | 57 |
| 14. | Principal Accounting Fees and Services | 57 |
| | | |
| | <u>PART IV</u> | |
| 15. | Exhibits, Financial Statement Schedules | 58 |
| 16. | Form 10-K Summary | 60 |
| | | |

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 forwardlooking statement made by us. These factors include, but are not limited to:

- our lack of operating history;
- 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

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.

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-mimetic drug designed to resolve chronic inflammation and halt fibrotic processes without causing immunosuppression. 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 skinpredominant DM. Lenabasum is currently being evaluated in a Phase 3 SSc study that is expected to enroll 354 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, the Company plans to consult with the FDA on the protocol design for the next clinical study, which the Company expects to commence before the end of 2018. 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, granted lenabasum Orphan Designation as well as Fast Track Status for both SSc and CF. The European Medicines Authority, or the EMA, granted lenabasum Orphan Designation for both SSc and CF.

The development status of lenabasum is summarized below:

Figure 1-: Clinical development pipeline



Clinical Development

Systemic Sclerosis (Scleroderma)

On-Going 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 the first patient was dosed in January 2018. The RESOLVE-1 study is expected to enroll approximately 354 subjects at 70 sites in North America, Europe, Israel, Japan, South Korea, and Australia. The planned duration of treatment with study drug is 52 weeks. Subjects will be 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 will be change from baseline in modified Rodnan Skin Score ("mRSS"), a measure of skin fibrosis and a standard clinical trial outcome in SSc. Secondary outcomes of the RESOLVE-1 study include patient reported outcome of Health Assessment Questionnaire-Disability Index, the American College of Rheumatology Combined Response Index in diffuse cutaneous Systemic Sclerosis ("ACR CRISS") score, a novel composite measure of clinical improvement from baseline that incorporates change from baseline in mRSS, and lung function and forced vital capacity, % predicted. These same outcomes were evaluated in the Phase 2 study as well as the ongoing open-label extension study. The Company expects to complete the study and report top-line data in the first half of 2020.

Encouraging Data from 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 modified Rodnan Skin Score (mRSS), the primary outcome for the Phase 3 study of lenabasum in SSc, improved by a mean (SD) of -8.4 in the 32 subjects who had completed 28 weeks open-label dosing at the time of data analyses, compared to baseline at the start of the Phase 2 double-blind placebo-controlled portion of the study. 75% of 36 subjects who received open-label dosing with lenabasum achieved a degree of improvement in mRSS (reduction \geq 5 points and > 25% baseline) from the study start that has been previously associated with improved survival in SSc. A third of subjects reached a mRSS \leq 10 points and 22% achieved a mRSS score \leq 5 points.

The ACR CRISS score increased over time with lenabasum open-label dosing and reached a median of 71% at 28 weeks, with 44% of subjects achieving an ACR CRISS score \geq 70%. For comparison, the median ACR CRISS score was 32% at 48 weeks in the Phase 2 study of tocilizumab in diffuse cutaneous SSc patients and 24% at 12 months in a study of cyclophosphamide in diffuse cutaneous SSc patients with interstitial lung disease. Patient-reported disability, function, skin symptoms and global assessment of health all improved from study start and start of open-label dosing. Forced vital capacity (FVC) % predicted was stable during lenabasum treatment (mean change 0.3% predicted from study start) in contrast to the natural history of a decline in FVC in the disease.

Figure 2-: mRSS Results from Phase 2 Study-Primary Outcome Measure for Phase 3 RESOLVE -1 Study

Data are shown for subjects who received lenabasum during double-blinded placebo-controlled dosing (N = 26) and during open-label dosing (N = 36 at the start of open-label dosing). The data show the change in patient mRSS scores from the study start at the beginning of the double-blinded placebo-controlled dosing period.









Safety

There have been no severe or serious adverse events (AEs) and no clinically significant laboratory abnormalities related to lenabasum in the Phase 2 study. Thirty (83%) subjects experienced AEs and 3 (8%) subjects experienced AEs related to lenabasum during open-label dosing. The AEs experienced by $\geq 10\%$ of subjects were upper respiratory tract illness in 7 (19%) subjects and urinary tract infection in 5 (14%) subjects.

Positive Data from Double-blinded Placebo-Controlled Part of Phase 2 Systemic Sclerosis Study

In October 2016, the Company reported positive results from the double-blind, randomized placebo-controlled portion of the Phase 2 study in diffuse cutaneous SSc. This part of the multi-center Phase 2 study evaluated lenabasum's clinical benefit and safety in 27 subjects who received lenabasum and 15 who received placebo. Subjects had disease duration up to 6 years and were allowed to receive stable doses of immunosuppressive drugs during this study. Subjects were randomized in a 2 to 1 overall lenabasum to placebo ratio. Subjects randomized to lenabasum received 5 mg once a day (n = 9), 20 mg once a day (n = 9), or 20 mg twice a day (n = 9) for the first four weeks, then all lenabasum subjects received 20 mg twice a day for the next 8 weeks. Subjects randomized to placebo received placebo twice a day for 12 weeks. All subjects were followed off study drug from weeks 13 through 16.

The primary efficacy objective was to evaluate clinical benefit in all subjects who received lenabasum versus subjects who received placebo using the ACR CRISS score. Lenabasum out-performed placebo in the ACR CRISS reaching 33% at week 16 (p = 0.044, 1-sided mixed model repeated measures using rank transformed data) versus 1% for placebo. Lenabasum also outperformed placebo in the mRSS, the primary outcome for the Phase 3 study, with a mean improvement (reduction) of 4.8 points in mRSS at sixteen weeks.

Figure 4-mRSS Primary Endpoint in Phase 3 RESOLVE-1 Improved from Baseline



Cystic Fibrosis

On-Going Phase 2B Study

In January 2018, the Company initiated a Phase 2b study in cystic fibrosis which is being supported by an award for up to \$25 million from the Cystic Fibrosis Foundation. The Phase 2b multicenter, double-blinded, randomized, placebo-controlled study is expected to enroll approximately 415 subjects with CF who are at least 12 years of age and at increased risk for pulmonary exacerbations. The primary outcome is the event rate of pulmonary exacerbations which is the average number of pulmonary exacerbations per subject per time period. Secondary efficacy outcomes include other measures of pulmonary exacerbations, change in Cystic Fibrosis Questionnaire-Revised Respiratory domain score and change in forced expiratory volume in 1 second (FEV1), % predicted. The study will be conducted in approximately 100 sites across North America, Europe, Israel and Australia. Subjects will be centrally 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. The Company expects to complete this study and report top line data in the first half of 2020.

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 \geq 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 pulmonary exacerbations defined as those requiring intravenous (IV) antibiotics compared to placebo. Patients in the highest dose cohort of lenabasum (20 mg orally, twice per day) had a 75% reduction in the annualized rate of pulmonary exacerbations requiring IV antibiotics compared to placebo cohort. 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 pulmonary exacerbations.

Figure 5-Lenabasum Reduced Pulmonary Exacerbations in Completed Phase 2 Study



Figure 6-Lenabasum Reduced Inflammation in the Sputum in Completed Phase 2 Study

Reduction with lenabasum 20 mg BID compared to placebo (Log₁₀)



Least squares mean difference from placebo (SE), Log₁₀

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

Positive Data from Phase 2 Dermatomyositis Study

In October 2017, the Company completed the double-blind placebo-controlled part of the Phase 2 study in skin-predominant DM and reported positive results. The mean improvement (reduction) in the primary efficacy outcome, the Cutaneous Dermatomyositis Disease Area and Severity Index ("CDASI") activity score, an outcome measure of skin disease severity, 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, the Company plans to consult with the FDA on the protocol design for the next clinical study, which the Company expects to commence before the end of 2018.

Lenabasum improved CDASI by 9.3 vs. 3.7 for placebo; p = 0.04, 2-sided MMRM

Figure 7-Lenabasum Demonstrated Clinically Meaningful Improvement in CDASI



Dermatomyositis Open Label Study

In November 2016, the Company commenced open-label dosing of subjects in Phase 2 DM clinical study. The same safety and efficacy endpoints evaluated in the double-blinded, placebo-controlled part of the Phase 2 study are continuing to be assessed throughout open-label dosing.

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. 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 at 15 sites 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. By 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 destroy the infection and/or repair 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 8) 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 8-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 profibrotic 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 twenty two 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. We believe this unique activity of lenabasum ultimately drives the inflammatory response down the pro-resolution pathway.

Figure 9- Lenabasum Increases Pro-Resolving Lipid Mediators in Humans



Figure 10- Lenabasum also Decreases Inflammatory Lipid Mediators in Humans



Motwani et al. Clin Pharmacol Ther. 2017 Dec 14. doi: 10.1002

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.

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.

In autoimmune diseases, four out of the five top selling drugs in the U.S. are anti-inflammatory biologic drugs which had total sales of \$41 billion in 2016. These drugs however suppress the immune systems and thus leave patients susceptible to serious infections. Lenabasum, on the other hand, is designed to resolve inflammation without immunosuppression and is an oral pill, which potentially positions it as a front-line, first choice for autoimmune and other serious inflammatory and fibrotic diseases.

Lenabasum Market Opportunity for Current Indications Being Developed

Autoimmune Disorders

Systemic Sclerosis

Systemic sclerosis 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 90,000 people in the United States and Europe 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 United States 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 45% of patients) and those with more restricted skin thickening (limited cutaneous SSc, about 55% 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 US, SSc is the most deadly 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 TGF β , myofibroblast accumulation, and production of collagen and other extracellular matrix proteins are all present in SSc.

Currently, there are no FDA-approved therapies specifically for SSc, although therapies have been approved for the pulmonary artery hypertension associated with this disease. Immunosuppressants with significant toxicities are commonly used to treat SSc, however, as far as we know, there is a general absence of clinical data to support their use. For example, systemic corticosteroids are used frequently in SSc patients despite concerns about toxic side effects and precipitation of renal crisis.

We believe there is general agreement in the SSc community that an effective anti-inflammatory and anti-fibrotic drug 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 is a serious and rare autoimmune idiopathic inflammatory myopathy with characteristic cutaneous findings. About 70,000 individuals in the U.S. suffer from dermatomyositis. Dermatomyositis 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.

Therapy for DM involves both general measures and specific measures to control the muscle disease and the skin disease. In addition, some patients with DM need treatment for other systemic manifestations or complications. The muscle component is treated by administering corticosteroids, typically with an immunosuppressive agent. The skin disease is treated by avoiding sun exposure and by using sunscreens and photoprotective clothing, as well as with topical corticosteroids, and antimalarial agents. Antimalarial therapy frequently is ineffective or can cause drug reactions. Antimalarial-refractory disease is then treated with systemic therapies that may additionally cause toxicity, including systemic glucocorticoids, immunosuppressive therapies such as methotrexate, mycophenolate mofetil, or intravenous immunoglobulin.

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, or 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 500,000 individuals in the U.S. and in the E.U. 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.

Drugs specifically approved by the FDA for SLE are limited to aspirin, corticosteroids, hydroxychloroquine and belimumab. Physicians commonly treat SLE disease manifestations with immunosuppressive or corticosteroid therapies that have significant toxicities.

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 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 or 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 gives 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 75,000 people in the United States 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 is consistent with inability of innate immune responses to make the transition out of the activation phase and into and through the resolution phase. Specialized Pro-Resolving 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 11.





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 specific genetic sub-populations of patients, including KalydecoTM, OrkambiTM and the recently approved SymdecoTM. 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 annual rate of 17,000 case per year and an event rate of 0.70 times per patient 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 a number of 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 buildup 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%).

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 and Orkambi.

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 Roche, Boehringer Ingelheim, Bayer, Inventiva, Bristol Myers and Sanofi, 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 area of CF therapy is the development of correctors and potentiators of CFTR. In January 2012, Vertex launched KalydecoTM, or ivacaftor, the first ever cystic fibrosis drug specifically targeting the underlying genetic defect in the CFTR ion channel. Kalydeco is a small synthetic oral molecule that helps potentiate the function of the G551D mutant CFTR protein, resulting in improved forced expiratory volume in one second (a measure of obstruction of airflow in the lungs) by approximately 10% in cystic fibrosis patients.

A combination drug from Vertex, OrkambiTM (lumacaftor/ivacaftor) combination treatment targets a larger population of homozygote Δ F508 CFTR mutation patients. Orkambi was approved by the FDA on July 2, 2015. In clinical studies, the lung function of patients taking Orkambi improved by a range of 2.6 percentage points to 3 percentage points, compared with that of patients receiving placebo.

Several other companies are developing drugs for CF targeting CFTR either as a protein or mRNA transcript. These are highlighted in the table below:

| Selected CF Products in Development | | | | | | | | |
|-------------------------------------|------------------------|--|----------|-----------------------|----------|--|--|--|
| Company | Drug | Mechanism | Delivery | Mutation | Stage | | | |
| PTC Therapeutics | Ataluren | Ribosome read thru (nonsense mutations) | Oral | Class 1, nonsense | Phase 3 | | | |
| UK CF Gene Therapy Consortium | pGM169/GL67A | Gene therapy | Inhaled | All | Phase 2b | | | |
| Novartis | QBW251 | Potentiator | Oral | Gating | Phase 2 | | | |
| Bayer | Riociguat | stimulates sGC enzyme | Oral | F508del homozygous | Phase 2 | | | |
| Flatley Discovery Lab | FDL169 | Corrector | Oral | F508del | Phase 1 | | | |
| Galapagos / AbbVie | GLPG1837 / ABBV-974 | Potentiator | Oral | Gating | Phase 1 | | | |
| ProQR | QR-010 | RNA oligonucleotide | Inhaled | F508del homozygous | Phase 2 | | | |
| Celtaxsys | Acebilustat | Anti-inflammatory- inhibits production of LTB4 | Oral | N/A | Phase 2 | | | |
| Proteostasis | PTI130 | CFTR amplifier | Oral | All | Phase 2 | | | |

Research and Development

We incurred expenses of approximately \$26,039,000, \$15,437,000 and \$5,889,000 for research and development activities for the years ended December 31, 2017, 2016 and 2015, 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.

On October 31, 2017, the Company announced that the U.S. Patent and Trademark Office ("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 to Corbus intellectual property exclusivity regarding use of lenabasum to treat inflammatory diseases in the United States to February 12, 2034.

On November 27, 2017, the Company announced that the U.S. Patent and Trademark Office ("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 to Corbus intellectual property exclusivity in the United States regarding the use of lenabasum through February 12, 2034.

Lenabasum has been granted Orphan Drug Designation for both cystic fibrosis and systemic sclerosis in the U.S. and in the European Union. We plan to seek orphan drug status for lenabasum in DM and possibly other orphan inflammatory diseases from the U.S. Food and Drug Administration and in Europe. Orphan drug status provides seven years of market exclusivity in the U.S. and ten years in Europe 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 United States

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 gather additional 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 United States

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 preclinical 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 United States, the marketing of medicinal products is subject to the granting of marketing authorizations by regulatory agencies. Also, as in the United States, 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

Medicinal Products require a marketing authorization before they may be placed on the market in the European Economic Area (EEA), comprising the member states of the European Union as well as Iceland, Liechtenstein and Norway. There are various application procedures available, depending on the type of product involved. The centralized procedure gives rise to marketing authorizations that are valid throughout the EEA. Applicants file marketing authorization applications with the European Medicines Agency (EMA) where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use (CHMP). The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. The centralized procedure is compulsory for medicinal products that (1) are derived from specified biotechnology processes, (2) contain a new active substance (not yet approved on November 20, 2005) indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions, (3) are orphan medicinal products or (4) are advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products). For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralized marketing authorization to the EMA, as long as the CHMP agrees that (i) the medicine concerned contains a new active substance (not yet approved on November 20, 2005), (ii) the medicine is a significant therapeutic, scientific, or technical innovation, or (iii) if its authorization under the centralized procedure would be in the interest of public health.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (1) a national procedure, which results in a marketing authorization in a single EEA member state; (2) the decentralized procedure, in which applications are submitted simultaneously in two or more EEA member states; and (3) the mutual recognition procedure, which must be used if the product has already been authorized in at least one other EEA member state, and in which the EEA member states are required to grant an authorization recognizing the existing authorization in the other EEA member state, unless they identify a serious risk to public health.

Marketing authorization applications must usually include the results of clinical trials. Clinical trials of medicinal products in the EEA must be conducted in accordance with EEA and national regulations and the International Conference on Harmonization guidelines on GCP. Prior to commencing a clinical trial in a particular EEA member state, the sponsor must obtain a clinical trial authorization from the competent authority and a positive opinion from an independent ethics committee.

In the EEA, companies developing a new medicinal product must agree a Paediatric Investigation Plan (PIP) with the EMA and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, e.g., because the relevant disease or condition occurs only in adults. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date.

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 United States, 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 contractors and plans that develop certain coverage policies and process claims 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 laws and regulations that govern its individual program. Each payer has its own process and standards for determining whether it will cover 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 (the "2018 Spending Law") 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 47 full time employees at December 31, 2017. 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.

Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (1) January 1, 2020, (2) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion, (3) the date on which we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter or (4) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three-year period.

For as long as we remain an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. We are choosing to "opt out" of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards, and intend to take advantage of the other reporting exemptions until we are no longer an "emerging growth company."

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, <u>www.corbuspharma.com</u>, 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. You may also read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549, and you may obtain information on the operation of the Public Reference Room by calling the SEC in the United States at 1-800-SEC-0330. In addition, the SEC maintains an Internet website, <u>www.sec.gov</u>, that contains reports, proxy and information statements and other information that we file electronically with the SEC.

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 have to 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 product 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 lenabasum;
- secure market exclusivity and/or adequate intellectual property protection for lenabasum;
- attract and retain an experienced management and advisory team;
- secure acceptance of lenabasum in the medical community and with third party payors and consumers;
- launch commercial sales of lenabasum, 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 lenabasum. We have been engaged in developing lenabasum since 2009. To date, we have not generated any revenue from lenabasum and we expect to incur significant expense to complete our clinical program for lenabasum in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of lenabasum in any indication in the United States or internationally. Even if we are able to commercialize lenabasum or any other product candidate, there can be no assurance that we will generate significant revenues or ever achieve profitability. Our net losses for the years ended December 31, 2017, 2016 and 2015 were approximately \$32,422,000, \$19,999,000 and \$8,851,000, respectively. As of December 31, 2017, we had an accumulated deficit of approximately \$65,698,000.

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 indications for the treatment of cystic fibrosis, systemic sclerosis, DM and systemic lupus erythematosus, or SLE. We may elect to pursue FDA approval for lenabasum in other indications, 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 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 the clinical trials for lenabasum. As of December 31, 2017, our consolidated cash and cash equivalents balance was approximately \$62.5 million. On January 5, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement ("January 2018 Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") pursuant to which Cantor Fitzgerald is serving as our sales agent to sell up to \$50 million of shares of our common stock through an "at the market offering," of which we have sold 1,500,000 shares for net proceeds of \$11.3 million to date. 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 \$6.25 million to date. The remainder of the 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 expect our cash and cash equivalents of approximately \$62.5 million at December 31, 2017 together with the \$11.3 million of net proceeds received to date from the January 2018 Sales Agreement and the up to \$25 million of proceeds that we expect to receive under the 2018 CFF Award, of which we have received \$6.25 million to date, to be sufficient to meet our operating and capital requirements through the end of the fourth quarter of 2019, based on current planned expenditures.

Other than the January 2018 Sales Agreement and 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 January 2018 Sales Agreement due to limiting terms contained therein and sales thereunder being subject to market conditions and 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 lenabasum 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 lenabasum 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 entirely on the success of lenabasum. If we are unable to generate revenues from lenabasum, our ability to create stockholder value will be limited.

Our only product candidate currently is lenabasum, for which we have completed Phase 1 safety studies and 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. 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 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 entirely on the successful development, regulatory approval and commercialization of lenabasum, which may never occur.

If we are not able to obtain any required regulatory approvals for lenabasum, we will not be able to commercialize our only product candidate 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 lenabasum's safety and efficacy, before a New Drug Application, or NDA, can be filed with the FDA for marketing approval of lenabasum.

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 lenabasum. 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 lenabasum as a prescription pharmaceutical product in the United States until we receive approval of an NDA from the FDA or comparable regulatory agencies for sales in foreign markets until we receive the requisite approval from 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 comparable applications to other regulatory authorities. If our development efforts for lenabasum, including regulatory approval, are not successful for its planned indications, or if adequate demand for lenabasum 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 lenabasum's safety and efficacy;

• 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, European Medicines Agency, or EMA, or other comparable foreign regulatory authorities for marketing approval;

- the dosing of lenabasum 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 lenabasum;

• 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 thirdparty manufacturers with which we contract for clinical and commercial supplies; and

• 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.

Failure to obtain regulatory approval for lenabasum for the foregoing or any other reasons will prevent us from commercializing this product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with 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 preclinical 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. Lenabasum 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 the 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 lenabasum in any indication will prevent us from commercializing the product candidate, 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 lenabasum 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 lenabasum may not be successful.

In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for lenabasum. 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.

Lenabasum is our only product candidate in development. If we fail to successfully commercialize lenabasum, we may need to acquire additional product candidates and our business will be adversely affected.

We have never commercialized any product candidates and do not have any other compounds in pre-clinical testing, lead optimization or lead identification stages beyond lenabasum. We cannot be certain that lenabasum will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize lenabasum as a treatment for cystic fibrosis, systemic sclerosis, DM, SLE or any other indication, whether as a stand-alone therapy or in combination with other treatments, our business would be adversely affected.

Even if we receive regulatory approval for lenabasum, we still may not be able to successfully commercialize this product, and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of lenabasum will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of lenabasum 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 lenabasum and of the target patient population to try new therapies;
- safety, tolerability and efficacy of lenabasum compared to competing products;

• the introduction of any new products that may in the future become available to treat indications for which lenabasum may be approved;

• new procedures or methods of treatment that may reduce the incidences of any of the indications in which lenabasum may show utility

- pricing and cost-effectiveness;
- the inclusion or omission of lenabasum 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 lenabasum is approved, but does 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 lenabasum 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 lenabasum 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 lenabasum not commercially viable. For example, regulatory authorities may approve lenabasum for fewer or more limited indications than we request, may not approve the price we intend to charge for lenabasum, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve lenabasum with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that 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 lenabasum. 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 lenabasum.

Even if we obtain marketing approval for lenabasum, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, lenabasum 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 lenabasum.

Even if we obtain United States regulatory approval of lenabasum for an indication, the FDA may still impose significant restrictions on its 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. Lenabasum 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 lenabasum is 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 lenabasum, physicians may nevertheless legally prescribe our 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 lenabasum 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.

We currently have no 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 lenabasum.

At present, we have no sales or marketing personnel. In order to commercialize products that are approved for commercial sales, we must either collaborate with third parties that have such commercial infrastructure or 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 lenabasum, 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 lenabasum 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 lenabasum;

• 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 lenabasum 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 competitors to lenabasum. 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 lenabasum 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 lenabasum, restrict or regulate post-approval activities and affect our ability to profitably sell lenabasum. 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 lenabasum, 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 through 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." Under the 2018 Spending Law, the discount will increase to 70% in 2019. 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 lenabasum 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 penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize lenabasum in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize lenabasum in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for lenabasum in foreign markets;
- 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.

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

If we market lenabasum 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 lenabasum, and our commercialization of lenabasum 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 lenabasum 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 ingredient, or the finished lenabasum drug product in tablet form, for use in our clinical trials or for commercial product, if any. As a result, we will be obligated to rely on contract manufactures if and when lenabasum is approved for commercialization.

The facilities used by our contract manufacturers to manufacture lenabasum must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to lenabasum. 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 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 lenabasum, 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 lenabasum, 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 lenabasum.

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 lenabasum product or should cease doing business with us, we could experience significant interruptions in the supply of lenabasum or may not be able to create a supply of lenabasum at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of lenabasum 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 lenabasum 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 lenabasum if we decided to transfer the manufacture of lenabasum 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 lenabasum, 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 lenabasum at commercial scale on a cost-effective basis. If the commercial-scale manufacturing costs of lenabasum 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.

Our 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 product candidate, lenabasum, is currently classified as a 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, 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.

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

The import and export of lenabasum requires import and export licenses. However, 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 lenabasum 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 lenabasum.

We expect that we will rely on third parties to assist us in conducting clinical trials for lenabasum. 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 lenabasum 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 lenabasum 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 lenabasum in consultation with CROs, we expect that the CROs will manage all of 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 lenabasum for the subject indication 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 lenabasum. 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 lenabasum. As a result, our financial results and the commercial prospects for lenabasum 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 lenabasum 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 lenabasum 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 lenabasum, 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 lenabasum 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, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of lenabasum, its 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 lenabasum. 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 lenabasum 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 cystic fibrosis and systemic sclerosis. We also intend to seek orphan drug status for lenabasum for the treatment of 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 lenabasum for DM or any other 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 the 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 lenabasum for the treatment of DM, or other inflammatory disease indications, if we elect to seek such applications.

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 candidate 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 lenabasum 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 lenabasum is 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 lenabasum 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.

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.

Lenabasum 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 future product candidate. 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, 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 lenabasum from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to lenabasum 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 future 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 future 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 a future 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 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, 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.

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.

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, 2017, we had 47 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 lenabasum and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

39

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, Mark Tepper, our President and Chief Scientific Officer, Barbara White, our Chief Medical 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 lenabasum. 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. In connection with the merger in April 2014 with Corbus Pharmaceuticals, Inc., our wholly-owned subsidiary, we 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, Mark Tepper, Ph.D., our President and Chief Scientific Officer, Barbara White, M.D., our Chief Medical 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 lenabasum.

We face a potential risk of product liability as a result of the clinical testing of lenabasum and will face an even greater risk if we commercialize lenabasum or any other future product. For example, we may be sued if any product we develop, including lenabasum, 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 lenabasum. 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 lenabasum or any future products that we may develop;
- 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 lenabasum; 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 19.6% of our outstanding shares of common stock as of December 31, 2017. 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.

As of December 31, 2017, we had outstanding options to purchase an aggregate of 7,844,966 shares of our common stock at a weighted average exercise price of \$3.75 per share and warrants to purchase an aggregate of 1,288,500 shares of our common stock at a weighted average exercise price of \$1.00 per share.

On January 26, 2018, pursuant to the terms of the Investment Agreement, we issued a warrant to CFF to purchase an aggregate of 1,000,000 shares of our common stock (the "CFF Warrant"). The CFF Warrant is exercisable at a price equal to \$13.20 per share and was immediately exercisable for 500,000 shares of our common stock. Upon completion of the final milestone set forth in the Investment Agreement and receipt of the final payment from CFF to us pursuant to the Investment Agreement, the CFF Warrant will be exercisable for the remaining 500,000 shares of our common stock. The CFF Warrant expires on January 26, 2025. Any shares of our common stock issued upon exercise of the CFF Warrant will be unregistered and subject to a one-year lock-up.

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 are an "emerging growth company," and will be able take advantage of reduced disclosure requirements applicable to "emerging growth companies," which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, for as long as we continue to be an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (1) January 1, 2020, (2) the last day of the first fiscal year in which our annual gross revenues exceed \$1.07 billion, (3) the date on which we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, which would occur if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter or (4) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three-year period.

We intend to take advantage of these reporting exemptions described above until we are no longer an "emerging growth company." Under the JOBS Act, "emerging growth companies" can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

We cannot predict if investors will find our common stock less attractive if we choose to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

43

We incur significantly increased costs and devote substantial management time as a result of operating as a public company, , and we expect these 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 that we did not incur as a private company. 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, after we are no longer qualify as an "emerging growth company," we expect to incur additional management time and cost to comply with the more stringent reporting requirements of Section 404 of the Sarbanes-Oxley Act. In 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.

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. As of December 31, 2017, we had 47 full-time employees, which results in a lack of segregation of duties, and we may be unable to effectively establish such systems, especially in light of the fact that we expect to operate as a publicly reporting company. This would leave us without the ability to reliably assimilate and compile financial information about our company and significantly impair our ability to prevent error and detect fraud, all of which would have a negative impact on our company from many perspectives.

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.

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 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 includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting.

We may not be able to complete our evaluation, testing 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 recently passed 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 ending after 2017 and elimination of net operating loss carrybacks for net operating losses generated in tax years ending after 2017; one-time taxation of offshore earnings at reduced rates 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. On August 21, 2017, we entered into a lease agreement ("the August 2017 Lease Agreement") with the same landlord, pursuant to which we agreed to lease 32,733 square feet of office space. The initial term of the August 2017 Lease Agreement is for a period of seven years and commenced in February 2018. The base rent pursuant to the August 2017 Lease Agreement ranges from approximately \$470,000 for the first year to approximately \$908,000 for the seventh year. We believe our facilities are adequate for our foreseeable needs.

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

The following table contains information about the range of high and low sale prices for our common stock for each quarter during the last two years. The source of these high and low sales prices was the Nasdaq Global Market and the Nasdaq Capital Market.

| Fiscal Year Ended December 31, 2017 | Hi | gh Sales Price | | w Sales Price |
|--|----|-------------------|----|------------------|
| First Quarter, | \$ | 10.50 | \$ | 6.15 |
| Second Quarter | \$ | 8.45 | \$ | 5.30 |
| Third Quarter | \$ | 7.90 | \$ | 5.60 |
| Fourth Quarter | \$ | 8.75 | \$ | 6.40 |
| | | - h C - h - r | T. | w Sales |
| | H | gh Sales | LO | w baits |
| Fiscal Year Ended December 31, 2016 | | gn Sales Price | | Price |
| Fiscal Year Ended December 31, 2016 First Quarter | | 8 | | |
| , | | Price | | Price |
| First Quarter | \$ | Price 1.95 | \$ | Price 1.01 |

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 6, 2018, there are approximately 91 record holders of shares of common stock.

Shareholder Return Performance Graph.

The graph below compares the cumulative total return of holders of our common stock with the cumulative total returns of the Russell 2000 (the "RUT Index"), and the S&P Biotechnology Select Industry Index (the "S&P Index").

The graph tracks the performance of a \$100 investment in our common stock, in the RUT Index, and the S&P Index (with the reinvestment of all dividends) from November 25, 2014, the date which we first registered under the Securities Exchange Act, to December 31, 2017.

47



Item 6. SELECTED FINANCIAL DATA

| Consolidated Statements of Operations Data | For the Years Ended December 31, | | | | | | | |
|--|----------------------------------|-----------------|-----------------|-------------|-------------|--|--|--|
| | 2017 | 2016 | 2015 | 2014 | 2013 | | | |
| Revenue from awards | \$ 2,440,195 | \$ 1,911,424 | 648,382 | | | | | |
| Operating expenses: | | | | | | | | |
| Research and development | 26,038,965 | 15,436,735 | 5,888,659 | 1,255,535 | 210,670 | | | |
| General and administrative | 8,964,046 | 6,459,747 | 3,613,416 | 1,391,638 | 346,606 | | | |
| Total operating expenses | 35,003,011 | 21,896,482 | 9,502,075 | 2,647,173 | 557,276 | | | |
| Operating loss | (32,562,816) | (19,985,058) | (8,853,693) | (2,647,173) | (557,276) | | | |
| Other income (expense): | | | | | | | | |
| Interest income (expense), net | 183,112 | 477 | 977 | (21,906) | (44,360) | | | |
| Foreign currency exchange gain (loss) | (41,908) | (14,094) | 1,977 | 4,570 | (2,692) | | | |
| Change in fair value of warrant liability | | _ | | (28,448) | 1,978 | | | |
| Forgiveness of interest on note payable | | | — | 7,466 | | | | |
| Gain on settlement of debt | | | | 145,006 | | | | |
| Other income (expense), net | 141,204 | (13,617) | 2,954 | 106,688 | (45,074) | | | |
| Net loss | \$ (32,421,612) | \$ (19,998,675) | (8,850,739) | (2,540,485) | (602,350) | | | |
| Net loss per share, basic and diluted | \$ (0.65) | \$ (0.49) | (0.28) | (0.13) | (0.09) | | | |
| Weighted average number of common shares | | | | | | | | |
| outstanding, basic and diluted | 50,176,953 | 41,137,518 | 31,350,145 | 20,159,861 | 6,964,788 | | | |
| Consolidated Balance Sheet Data | | A | At December 31, | | | | | |
| | 2017 | 2016 | 2015 | 2014 | 2013 | | | |
| Working capital (deficit) | \$ 57,300,055 | \$ 8,504,340 | 9,084,757 | 5,794,961 | (343,346) | | | |
| Total Assets | 66,978,161 | 17,888,182 | 12,875,303 | 6,600,773 | 305,520 | | | |
| Total Long-Term Liabilities | 989,925 | 70,356 | 260,260 | | 331,243 | | | |
| Total Stockholders' Equity (Deficit) | 57,783,561 | 8,919,235 | 8,985,010 | 5,862,733 | (1,783,198) | | | |
| | 4 | 48 | | | | | | |

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-mimetic drug designed to resolve chronic inflammation and halt fibrotic processes without causing immunosuppression. 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 skinpredominant DM. Lenabasum is currently being evaluated in a Phase 3 SSc study that is expected to enroll 354 patients, a Phase 2b CF study that is expected to enroll 415 patients (that is being supported by a development award (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") grant. In DM, the Company plans to consult with the FDA on the protocol design for the next clinical study, which the Company expects to commence before the end of 2018. 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, granted lenabasum Orphan Designation as well as Fast Track Status for both SSc and CF. The European Medicines Authority, or the EMA, granted lenabasum Orphan Designation for both SSc and CF.

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. Three of the four clinical programs for lenabasum have been supported, by non-dilutive awards and grants. The National Institutes of Health, or NIH, is funding the majority of the clinical development costs for the DM and SLE Phase 2 clinical trials, and the Phase 2 clinical trial in cystic fibrosis has been supported by a \$5 million award from the Cystic Fibrosis Foundation Therapeutics, Inc., or CFFT, a non-profit drug discovery and development affiliate of the Cystic Fibrosis Foundation.

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, 2017, we had an accumulated deficit of approximately \$65.7 million. Our net losses for the years ended December 31, 2017, 2016 and 2015 were approximately \$32,422,000, \$19,999,000 and \$8,851,000, 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 2018 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.

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 \$2,440,195, \$1,911,424 and \$648,382 of revenue from awards in the years ended December 31, 2017, 2016 and December 31, 2015, respectively, related to an award agreement (the "2015 CFFT Award Agreement) we entered into in fiscal 2015 with the CFFT, pursuant to which we received a development award (the "2015 CFFT Award") for up to \$5 million in funding. We received a total of \$5 million in payments under the 2015 CFFT Award as outlined below. The payments received under the 2015 CFFT Award were recorded as deferred revenue when the triggering event to receive those amounts 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.

Upon the execution of the 2015 CFFT Award Agreement, we received a payment of \$1,250,000 in May 2015. In November 2015, we received a second payment of \$1,250,000 upon the achievement of a milestone for dosing the first patient. In August 2016, we received a third payment from the CFFT in the amount of \$1,000,000 for achieving a milestone in July 2016 related to dosing the median clinical trial patient. In January 2017, we received a fourth payment from the CFFT in the amount of \$1,000,000 for achieving a milestone in December 2016 related to completing the final visit for the final patient. In November 2017, we received the fifth and final payment from the CFFT in the amount of \$500,000 for achieving a milestone in September 2017 related to completing the final integrated statistical report related to the Phase 2 CF clinical trial.

Pursuant to the terms of the 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 CFFT Award Agreement) as follows: (i) a royalty payment equal to five times the amount we receive under the 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 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 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 CFFT Award Agreement.

On January 26, 2018, we entered 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 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. We will assess this agreement for accounting under ASC 606 in the first quarter of 2018, including if this agreement falls under the scope of such standard. We have not yet determined the potential effect the new standard will have on our consolidated financial statements.

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 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.

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 2018 and in the future 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 (Expense), Net

Other income (expense), net consists primarily of interest income we earn on interest-bearing accounts, interest expense incurred on our outstanding debt, and foreign currency exchange transaction losses and gains.

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 and accrued research and development 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.

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 and stock options granted to non-employee consultants are revalued at the end of each reporting period until vested and changes in their fair value are recorded as adjustments to expense over the related vesting period. 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, 2017, 2016 and 2015 is as follows:

| | 2017 | 2016 | 2015 |
|---------------------------|--------|--------|--------|
| Risk free interest rate | 2.17% | 1.70% | 1.85% |
| Expected dividend yield | 0% | 0% | 0% |
| Expected term in years | 7.00 | 6.66 | 6.73 |
| Expected volatility | 86.36% | 90.39% | 90.68% |
| Estimated forfeiture rate | 5.00% | 5.00% | 4.83% |

Emerging Growth Company Status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Results of Operations

Comparison of Year Ended 2017 to 2016

Revenue from Awards. We have recognized approximately \$2,440,000 and \$1,911,000 of revenue from awards in the years ended December 31, 2017 and December 31, 2016, respectively, related to the funding from the 2015 CFFT Award. We have received a total of \$5 million in payments since the inception of the 2015 CFFT Award as outlined below. The payments received under the 2015 CFFT Award were recorded as deferred revenue when the triggering event to receive those amounts 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.

Upon the execution of the 2015 CFFT Award Agreement, we received a payment of \$1,250,000 in May 2015. In November 2015, we received a second payment of \$1,250,000 upon the achievement of a milestone for dosing the first patient. In August 2016, we received a third payment from the CFFT in the amount of \$1,000,000 for achieving a milestone in July 2016 related to dosing the median clinical trial patient. In January 2017, we received a fourth payment from the CFFT in the amount of \$1,000,000 for achieving a milestone in December 2016 related to completing the final visit for the final patient. In November 2017, we received the fifth and final payment from the CFFT in the amount of \$500,000 for achieving a milestone in September 2017 related to completing the final integrated statistical report related to the Phase 2 CF clinical trial.

Research and Development. Research and Development expenses for the year ended December 31, 2017 totaled approximately \$26,039,000, an increase of \$10,602,000 over the \$15,437,000 recorded for the year ended December 31, 2016. The increase in fiscal 2017 as compared to fiscal 2016 was primarily attributable to increases of approximately \$6,577,000 in clinical trial costs, \$2,646,000 in compensation costs, and \$1,379,000 in stock-based compensation expense.

General and Administrative. General and Administrative expense for the year ended December 31, 2017 totaled approximately \$8,964,000, an increase of \$2,504,000 over the \$6,460,000 recorded for year ended December 31, 2016. The increase in fiscal 2017 as compared to fiscal 2016 was primarily attributable to increases of approximately \$1,152,000 in stock-based compensation expense, \$429,000 in compensation costs, \$289,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in company costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in recruiting costs, \$150,000 in investor relations and public company costs, \$260,000 in consulting expenses.

Other Income (Expense), Net. Other income, net for fiscal 2017 was approximately \$141,000 as compared to other expense, net of approximately \$14,000 recorded for fiscal 2016 and was primarily attributable to an increase in net interest income of approximately \$183,000 due to increased cash balances in 2017 as compared to 2016, offset partially by increases in foreign currency exchange transaction losses of approximately \$28,000.



Comparison of Year Ended 2016 to 2015

Revenue from Awards. We have recognized approximately \$1,911,000 and \$648,000 of revenue related to the 2015 CFFT Award in the years ended December 31, 2016 and December 31, 2015, respectively. As of December 31, 2016, we had billed and received a total of \$4.5 million in payments since the inception of the 2015 CFFT Award as outlined below The payments received under the 2015 CFFT Award were recorded as deferred revenue when the triggering event to receive those amounts occurred and were amortized on a straight-line basis over the expected duration of the remaining performance period under the 2015 CFFT Award.

Upon the execution of the 2015 CFFT Award Agreement, we received a payment of \$1,250,000 in May 2015. In November 2015, we received a second payment of \$1,250,000 upon the achievement of a milestone for dosing the first patient. In August 2016, we received a third payment from the CFFT in the amount of \$1,000,000 for achieving a milestone in July 2016 related to dosing the median clinical trial patient. In January 2017, we received a fourth payment from the CFFT in the amount of \$1,000,000 for achieving a milestone in December 2016 related to completing the final visit for the final patient. In November 2017, we received the fifth and final payment from the CFFT in the amount of \$500,000 for achieving a milestone in September 2017 related to completing the final integrated statistical report related to the Phase 2 CF clinical trial.

Research and Development. Research and Development expenses for the year ended December 31, 2016 totaled approximately \$15,437,000, an increase of \$9,548,000 over the \$5,889,000 recorded for the year ended December 31, 2015. The increase in fiscal 2016 as compared to fiscal 2015 was primarily attributable to increases of \$7,132,000 in clinical trial costs, \$1,447,000 in compensation costs, and \$969,000 in stock-based compensation expense.

General and Administrative. General and Administrative expense for the year ended December 31, 2016 totaled approximately \$6,460,000, an increase of \$2,847,000 over the \$3,613,000 recorded for year ended December 31, 2015. The increase in fiscal 2016 as compared to fiscal 2015 was primarily attributable to increases of approximately \$1,251,000 in stock-based compensation expense, \$997,000 in compensation costs, \$375,000 in investor relations costs, and \$213,000 in legal costs.

Other Income (Expense), Net. Other expense, net for fiscal 2016 was approximately \$14,000 as compared to other income, net of approximately \$3,000 recorded for fiscal 2015 and was primarily attributable to an increase in foreign currency exchange transaction losses recorded during fiscal 2016.

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 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, 2017, our accumulated deficit since inception was approximately \$65,698,000.

At December 31, 2017, we had total current assets of approximately \$65,505,000 and current liabilities of approximately \$8,205,000 resulting in working capital of approximately \$57,300,000. Net cash used in operating activities for the year ended December 31, 2017 was approximately \$27,797,000, which includes a net loss of approximately \$32,422,000, adjusted for non-cash expenses of approximately \$6,855,000 principally related to stock-based compensation expense of \$5,694,000 and deferred rent of \$914,000, and for approximately \$2,230,000 of cash used by net working capital items.

Cash used in investing activities for the year ended December 31, 2017 totaled approximately \$707,000, which was principally related to construction costs in the fourth quarter of 2017 to build out our office space that we began occupying in February 2018.

Cash provided by financing activities for the year ended December 31, 2017 totaled approximately \$76,008,000. On February 28, 2017, we entered into a securities purchase agreement providing for the issuance and sale of 3,887,815 shares of our common stock in a registered direct offering to institutional and accredited investors at a purchase price of \$7.00 per share with net proceeds to us totaling \$27,177,102. In November 2016, we entered into a Controlled Equity OfferingSM Sales Agreement ("2016 Sales Agreement") with Cantor Fitzgerald pursuant to which Cantor Fitzgerald served as our sales agent to sell up to \$35 million of shares of our common stock through an "at the market offering." During the year ended December 31, 2017, we received net proceeds of approximately \$13,404,000 from sales of our common stock pursuant to the 2016 Sales Agreement, net of 3% commission paid to Cantor Fitzgerald. All sales of common stock under the 2016 Sales Agreement occurred in the first quarter of 2017, and we did not sell any shares of our common stock under the 2016 Sales Agreement during the remainder of 2017. The 2016 Sales Agreement was terminated in connection with the October 2017 Offering discussed below.

On October 26, 2017, we consummated an underwritten public offering of shares of our common stock pursuant to which we sold an aggregate of 5,347,500 shares of our common stock to institutional investors at a purchase price of \$7.00 per share with net proceeds to us totaling approximately \$35,181,000 ("October 2017 Offering").

During the year ended December 31, 2017, we also received proceeds of approximately \$189,490 from the issuance of 272,734 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, 2017 included proceeds from issuances of notes payable of \$415,265, partially offset by principal payments on notes payable of \$354,161 in connection with our loan agreements with financing companies. The terms of the loan that we entered into in November 2017 stipulate equal monthly payments of principal and interest payments of \$41,975 over a ten-month period. Interest accrues on this loan at an annual rate of 2.35%.

On January 5, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement ("January 2018 Sales Agreement") with Cantor Fitzgerald pursuant to which Cantor Fitzgerald is serving as our sales agent to sell up to \$50 million of shares of our common stock through an "at the market offering," of which we have sold 1,500,000 shares for net proceeds of \$11.3 million to date.

We expect our cash and cash equivalents of approximately \$62.5 million at December 31, 2017 together with the \$11.3 million of net proceeds received from the January 2018 Sales Agreement and the up to \$25 million of proceeds that we expect to receive under the 2018 CFF Award, of which we have received \$6.25 million to date, to be sufficient to meet our operating and capital requirements through the end of the fourth quarter of 2019, based on current planned expenditures. The 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. We may seek to sell common stock, including sales under our January 2018 Sales Agreement, 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, 2017. 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 2018 Fiscal 2019-2020 Fiscal 2021-2022 After Fiscal 2 | | | | | | | | fter Fiscal 2022 | |
| Operating lease obligations (1) | \$ | 5,474,623 | \$ | 445,333 | \$ | 1,408,201 | \$ | 1,685,750 | \$ | 1,935,339 |
| Capital lease obligations (2) | | 4,922 | | 4,543 | | 379 | | — | | — |
| Total | \$ | 5,479,545 | \$ | 449,876 | \$ | 1,408,580 | \$ | 1,685,750 | \$ | 1,935,339 |

- (1) On August 21, 2017, we entered into a lease agreement ("the August 2017 Lease Agreement") with the initial term of a period of seven years which commenced in February 2018. The base rent pursuant to the August 2017 Lease Agreement ranges from approximately \$470,000 for the first year to approximately \$908,000 for the seventh year. The September 2016 Amendment was terminated upon the commencement date of the August 2017 Lease Agreement. Additionally, the August 2017 Lease Agreement required us to provide a standby irrevocable letter of credit of \$400,000, which may be reduced, if we are 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, We entered into an unsecured letter of credit with a commercial bank for \$400,000 in connection with the August 2017 Lease Agreement.
- (2) On December 30, 2015, we entered into a lease agreement for a copier machine. The machine was placed in service in January 2016. The lease is for a three-year term and includes a bargain purchase option at the end of the term.

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, 2017, 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.

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 any foreign currency or other derivative financial instruments.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See pages F-1 through F-20 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 Rule 13(a)-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2017, our disclosure controls and procedures were effective.

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 effective as of December 31, 2017.

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.

This Annual Report does not include an attestation report of our independent registered public accounting firm because we are an "emerging growth company," and may take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

Changes in Internal Controls over Financial Reporting

During the year ended December 31, 2017, there have been no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal controls over financial reporting. From time to time, we make changes to our internal control over financial reporting that are intended to enhance its effectiveness and which do not have a material effect on our overall 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 2018 Annual Meeting of Stockholders.

Item 11. EXECUTIVE COMPENSATION

Information required by this item is incorporated herein by reference to our Proxy Statement for the 2018 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 2018 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 2018 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 2018 Annual Meeting of Stockholders.

57

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-19 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* |
| 10.1 | Placement Agency Agreement, dated March 27, 2014, between the Company and Aegis Capital Corporation (incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). |
| 10.2 | Consulting Agreement, dated March 21, 2014, between the Company and Orchestra Medical Ventures (incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). |

| Exhibit No. | Description |
|-------------|--|
| 10.3 | Form of Subscription Agreement for the Company's 2014 Private Placement (incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). |
| 10.4 | Form of Voting Agreement, dated April 11, 2014, by and among the Company and the stockholders named therein (incorporated by reference to Exhibit 10.4 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). |
| 10.5 | 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). † |
| 10.6 | 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). † |
| 10.7 | 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). † |
| 10.8 | 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). † |
| 10.9 | Employment Agreement, dated April 11, 2014, between the Company and Yuval Cohen (incorporated by reference to Exhibit 10.9 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). † |
| 10.10 | Employment Agreement, dated April 11, 2014, between the Company and Mark Tepper (incorporated by reference to Exhibit 10.10 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). † |
| 10.11 | Amended and Restated Employment Agreement, dated June 19, 2014, between the Company and Sean Moran (incorporated by reference to Exhibit 10.11 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). † |
| 10.12 | Agreement and Plan of Merger, dated March 27, 2014, by and among the Company, Corbus Pharmaceuticals Acquisition, Inc. and JB Therapeutics, Inc. (incorporated by reference to Exhibit 10.12 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). |
| 10.13 | Subscription Agreement, dated April 2009, between Sumner Burstein and JB Therapeutics, Inc. (which is now known as Corbus Pharmaceuticals, Inc.) (incorporated by reference to Exhibit 10.13 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). |
| 10.14 | Letter Agreement, dated April 29, 2009, between JB Therapeutics, Inc. (which is now known as Corbus Pharmaceuticals, Inc.) and Sumner Burstein (incorporated by reference to Exhibit 10.14 of the Company's Registration Statement on Form S- 1 filed with the SEC on September 3, 2014). |
| 10.15 | 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). † |
| 10.16 | Letter Agreement, dated August 18, 2014, between the Company and Barbara White (incorporated herein by reference to Exhibit 10.15 of the Company's Post-Effective Amendment No. 1 to Form S-1 filed with the SEC on March 31, 2015). † |
| 10.17 | 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).# |
| 10.18 | Amendment No.1 to Employment Agreement, dated April 11, 2016, between the Company and Yuval Cohen (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on April 15, 2016). † |
| 10.19 | Amendment No.1 to Employment Agreement, dated April 11, 2016, between the Company and Mark Tepper (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on April 15, 2016). † |
| 10.20 | Amendment No.1 to Amended and Restated Employment Agreement, dated April 11, 2016, between the Company and Sean Moran (incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed with the SEC on April 15, 2016). † |
| | 59 |

| Exhibit No. | Description |
|-------------|--|
| 10.21 | Employment Agreement, dated April 11, 2016, between the Company and Barbara White (incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed with the SEC on April 15, 2016). † |
| 10.22 | Securities Purchase Agreement, dated June 10, 2016, between Company and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on June 10, 2016). |
| 10.23 | 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). |
| 10.24 | 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). |
| 10.25 | 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). |
| 10.26 | 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). |
| 10.27 | 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). |
| 10.28 | <u>Controlled Equity Offering^{S M} Sales Agreement, dated November 23, 2016, by and between Corbus Pharmaceuticals</u> <u>Holdings, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 of the Company's Current Report on</u> <u>Form 8-K filed with the SEC on November 23, 2016.)</u> |
| 10.29 | Securities Purchase Agreement, dated February 28, 2017, between Company and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on February 28, 2017). |
| 10.30 | 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). |
| 10.31 | 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). |
| 10.32 | <u>Controlled Equity OfferingSM Sales Agreement, dated January 5, 2018, by and between Corbus Pharmaceuticals Holdings.</u> <u>Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 of the Company's Registration Statement on Form S-3 filed with the SEC on January 5, 2018).</u> |
| 10.33 | Cystic Fibrosis Program Related Investment Agreement, dated January 26, 2018, between Cystic Fibrosis Foundation Therapeutics, Inc. and the Company.#* |
| 21.1 | List of Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 of the Company's Registration Statement on Form S-1 filed with the SEC on September 3, 2014). |
| 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.
- # 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 12, 2018

| 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 12, 2018 |
| /s/ SEAN MORAN Sean Moran | Chief Financial Officer (Principal Financial and Accounting Officer) | March 12, 2018 |
| /s/ ALAN HOLMER Alan Holmer | Director | March 12, 2018 |
| /s/ DAVID HOCHMAN David Hochman | Director | March 12, 2018 |
| /s/ RENU GUPTA Renu Gupta | Director | March 12, 2018 |
| /s/ AVERY CATLIN Avery Catlin | Director | March 12, 2018 |
| /s/ PARIS PANAYIOTOPOULOS Paris Panayiotopoulos | Director | March 12, 2018 |
| | 61 | |

INDEX TO FINANCIAL STATEMENTS

| | Page Number |
|--|----------------|
| Report of Independent Registered Public Accounting Firm | F-2 |
| <u>Corbus Pharmaceuticals Holdings, Inc. Financial Statements-December 31, 2017:</u> | |
| Consolidated Balance Sheets as of December 31, 2017 and December 31, 2016 | F-3 |
| Consolidated Statements of Operations for the Years Ended December 31, 2017, 2016 and 2015 | F-4 |
| Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2017, 2016 and 2015 | F-5 |
| Consolidated Statements of Cash Flows for the Years Ended December 31, 2017, 2016 and 2015 | F-6 |
| Notes to Consolidated Financial Statements | F-7 |
| | |

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Corbus Pharmaceuticals Holdings, Inc. and Subsidiary (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2017, 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, 2017 and 2016, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 Iselin, New Jersey March 12, 2018

Corbus Pharmaceuticals Holdings, Inc. Consolidated Balance Sheets

| | December 31, | | | |
|--|--------------|--------------|----|--------------|
| | | 2017 | | 2016 |
| ASSETS | | | | |
| Current assets: | | | | |
| Cash and cash equivalents | \$ | 62,537,495 | \$ | 14,992,257 |
| Restricted cash | | 158,991 | | 150,000 |
| Grants receivable | | — | | 1,000,000 |
| Stock subscriptions receivable | | | | 330,413 |
| Prepaid expenses and other current assets | | 2,808,244 | | 930,261 |
| Total current assets | _ | 65,504,730 | | 17,402,931 |
| Restricted cash | | _ | | 50,000 |
| Property and equipment, net | | 1,432,655 | | 435,251 |
| Other assets | | 40,776 | | _ |
| Total assets | \$ | 66,978,161 | \$ | 17,888,182 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | | |
| Current liabilities: | | | | |
| Notes payable | \$ | 332,861 | \$ | 271,757 |
| Accounts payable | | 3,130,295 | | 3,419,921 |
| Accrued expenses | | 4,741,519 | | 3,256,455 |
| Deferred revenue, current | | | | 1,940,195 |
| Deferred rent, current | _ | | | 10,263 |
| Total current liabilities | | 8,204,675 | | 8,898,591 |
| Deferred rent, noncurrent | | 989,550 | | 65,724 |
| Other liabilities | | 375 | | 4,632 |
| Total liabilities | | 9,194,600 | | 8,968,947 |
| Commitments and Contingencies | | | | |
| Stockholders' equity | | | | |
| Preferred Stock \$0.0001 par value:10,000,000 shares authorized, no shares issued and | | | | |
| outstanding at December 31, 2017 and 2016 | | | | — |
| Common stock, \$0.0001 par value; 150,000,000 shares authorized at December 31, 2017 and | | | | |
| 2016, 55,603,427 and 44,681,745 shares issued and outstanding at December 31, 2017 and | | 5.5(0) | | 4.460 |
| 2016, respectively | | 5,560 | | 4,468 |
| Additional paid-in capital | | 123,476,102 | | 42,191,256 |
| Accumulated deficit | | (65,698,101) | | (33,276,489) |
| Total stockholders' equity | | 57,783,561 | | 8,919,235 |
| Total liabilities and stockholders' equity | \$ | 66,978,161 | \$ | 17,888,182 |

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, | | | |
|---|----|--------------|----|----------------------------------|----|-------------|--|
| | | 2017 | | 2016 | | 2015 | |
| Revenue from awards | \$ | 2,440,195 | \$ | 1,911,424 | \$ | 648,382 | |
| Operating expenses: | | | | | | | |
| Research and development | | 26,038,965 | | 15,436,735 | | 5,888,659 | |
| General and administrative | | 8,964,046 | | 6,459,747 | | 3,613,416 | |
| Total operating expenses | | 35,003,011 | _ | 21,896,482 | | 9,502,075 | |
| Operating loss | | (32,562,816) | _ | (19,985,058) | | (8,853,693) | |
| Other income (expense): | | | | | | | |
| Interest income, net | | 183,112 | | 477 | | 977 | |
| Foreign currency exchange gain (loss) | | (41,908) | | (14,094) | | 1,977 | |
| Other income (expense), net | | 141,204 | _ | (13,617) | | 2,954 | |
| Net loss | \$ | (32,421,612) | \$ | (19,998,675) | \$ | (8,850,739) | |
| Net loss per share, basic and diluted | \$ | (0.65) | \$ | (0.49) | \$ | (0.28) | |
| Weighted average number of common shares outstanding, basic and diluted | | 50,176,953 | | 41,137,518 | | 31,350,145 | |

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

Corbus Pharmaceuticals Holdings, Inc. Statements of Stockholders' Equity

| | Common Stock | | | Additional Paid-in | Total Stockholders' | | |
|---|--------------|----|-------|-----------------------|------------------------|--------------|----|
| | | | | | Accumulated | | |
| | Shares | | mount | Capital | Deficit | Equity | _ |
| Balance at December 31, 2014 | 25,938,332 | \$ | 2,594 | \$ 10,287,214 | \$ (4,427,075) | \$ 5,862,73 | 3 |
| Stock-based compensation expense | | | | 1,153,302 | | 1,153,30 | 2 |
| Issuance of common stock upon exercise of warrants, net | | | | | | | |
| of issuance costs of \$509,215 | 11,615,674 | | 1,162 | 10,812,963 | | 10,814,12 | 5 |
| Issuance of common stock upon exercise of stock options | 51,128 | | 5 | 5,584 | | 5,58 | 9 |
| Net Loss | | - | | | (8,850,739) | (8,850,73 | 9) |
| | | | | | | ()) | / |
| Balance at December 31, 2015 | 37,605,134 | \$ | 3,761 | \$ 22,259,063 | \$ (13,277,814) | \$ 8,985,01 | 0 |
| Stock-based compensation expense | | | | 3,163,534 | | 3,163,53 | 4 |
| Issuance of common stock, net of issuance costs of | | | | | | | |
| \$260,179 | 6,148,695 | | 615 | 16,300,309 | | 16,300,92 | 4 |
| | | | | | | | |
| Issuance of common stock upon exercise of warrants | 601,030 | | 60 | 1,190 | | 1,25 | 0 |
| Issuance of common stock upon exercise of stock options | 326,886 | | 32 | 467,160 | | 467,19 | 2 |
| Net Loss | | | | | (19,998,675) | (19,998,67 | |
| Balance at December 31, 2016 | 44,681,745 | \$ | 4,468 | \$ 42,191,256 | \$ (33,276,489) | | |
| Stock-based compensation expense | | | | 5,694,489 | | 5,694,48 | 9 |
| Issuance of common stock, net of issuance costs of | | | | | | | |
| \$2,969,837 | 10,648,948 | | 1,065 | 75,400,894 | | 75,401,95 | 9 |
| | | | | | | | |
| Issuance of common stock upon exercise of stock options | 272,734 | | 27 | 189,463 | | 189,49 | 0 |
| Net Loss | | | | | (32,421,612) | (32,421,61 | 2) |
| Balance at December 31, 2017 | 55,603,427 | \$ | 5,560 | \$123,476,102 | \$ (65,698,101) | \$ 57,783,56 | 1 |

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

Corbus Pharmaceuticals Holdings, Inc. Consolidated Statements of Cash Flows

| | Year Ended December 31, | | | | | |
|---|-------------------------|--------------|--------------|----|-------------|--|
| | | 2017 | 2016 | | 2015 | |
| Cash flows from operating activities: | | | | | | |
| Net loss | \$ | (32,421,612) | (19,998,675) | \$ | (8,850,739) | |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | | | |
| Stock-based compensation expense | | 5,694,489 | 3,163,534 | | 1,153,302 | |
| Depreciation and amortization | | 255,652 | 87,664 | | 43,943 | |
| (Gain) loss on foreign exchange | | (8,490) | 14,094 | | (1,977) | |
| Deferred rent | | 913,563 | 75,987 | | | |
| Changes in operating assets and liabilities: | | | | | | |
| Decrease (increase) in grants receivable | | 1,000,000 | (1,000,000) | | — | |
| Increase in prepaid expenses and other current assets | | (1,877,983) | (553,745) | | (105,959) | |
| Increase in other assets | | (40,776) | — | | | |
| (Decrease) increase in accounts payable | | (885,797) | 1,890,876 | | 972,194 | |
| Increase in accrued expenses | | 1,514,521 | 2,660,461 | | 312,788 | |
| (Decrease) increase in deferred revenue | | (1,940,195) | 88,577 | | 1,851,618 | |
| Net cash used in operating activities | | (27,796,628) | (13,571,227) | _ | (4,624,830) | |
| Cash flows from investing activities: | | | | | · | |
| Purchases of property and equipment | | (707,429) | (353,032) | | (114,037) | |
| Net cash used in investing activities | | (707,429) | (353,032) | | (114,037) | |
| Cash flows from financing activities: | _ | | | | | |
| Proceeds from issuance of notes payable | | 415,265 | 348,750 | | 207,750 | |
| Principal payments on notes payable | | (354,161) | (239,012) | | (190,120) | |
| Proceeds from issuance of common stock | | 78,891,699 | 16,699,133 | | 11,328,929 | |
| Issuance costs paid for common stock financings | | (2,940,685) | (63,830) | | (509,215) | |
| Principal payments under capital lease obligations | | (3,832) | (3,175) | | _ | |
| Net cash provided by financing activities | | 76,008,286 | 16,741,866 | | 10,837,344 | |
| Net increase in cash, cash equivalents, and restricted cash | | 47,504,229 | 2,817,607 | | 6,098,477 | |
| Cash, cash equivalents, and restricted cash at beginning of the year | | 15,192,257 | 12,374,650 | | 6,276,173 | |
| Cash, cash equivalents, and restricted cash at end of the year | \$ | 62,696,486 | 15,192,257 | \$ | 12,374,650 | |
| Supplemental disclosure of cash flow information and non cash transactions: | | | | | | |
| Cash paid during the period for interest | \$ | 12,377 | 5,586 | \$ | | |
| Assets acquired under capital lease obligation | \$ | | 11,638 | \$ | | |
| Purchases of property and equipment included in accounts payable or | _ | | | - | | |
| accrued expenses | \$ | 579,734 | 34,107 | \$ | | |
| Unpaid stock issuance costs | * | 225,501 | 196,349 | \$ | | |
| onpara stock issuance costs | _ | 223,301 | 190,549 | Э | | |

The accompanying notes are an integral part of these Consolidated Financial Statements.
Corbus Pharmaceuticals Holdings, Inc. Notes to Consolidated Financial Statements

1. NATURE OF OPERATIONS

Business

Corbus Pharmaceuticals Holdings, Inc. ("CPHI" or "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

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 has incurred recurring losses since inception and as of December 31, 2017, had an accumulated deficit of \$65,698,101.

On January 5, 2018, the Company entered into a Controlled Equity OfferingSM Sales Agreement ("January 2018 Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor Fitzgerald") pursuant to which Cantor Fitzgerald is serving as the Company's sales agent to sell up to \$50 million of shares of the Company's common stock through an "at the market offering," of which 1,500,000 shares have been sold for net proceeds of \$11.3 million to date. (See Note 15).

On January 26, 2018, the Company entered 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 the Company 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 the Company has received \$6.25 million to date. The Company expects the remainder of the 2018 CFF Award will be paid to the Company 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. (See Note 15).

The Company expects the cash on hand of \$62,537,495 at December 31, 2017 together with the \$11.3 million of net proceeds received from the January 2018 Sales Agreement and the \$6.25 million that the Company has received to date under the 2018 CFF Award, to 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. 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.



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:

Use of Estimates

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America 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, and the expected performance period under the 2015 CFFT Award (See Note 8).

Prior to the registration of its common stock and the subsequent public listing of the common stock, the Company had granted stock options at exercise prices not less than the fair value of its common stock as determined by the board of directors, with input from management. The Company's board of directors determined the estimated fair value of the common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the historic prices at which the Company sold shares of preferred stock.

Cash, Cash Equivalents, and Restricted Cash

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, 2017 and 2016, cash equivalents were comprised of money market funds. The Company had no marketable investments at December 31, 2017 and 2016.

Restricted cash as of December 31, 2017 and 2016 included a collateral account for the Company's corporate credit cards and is classified in current assets in the amount of \$108,991 and \$150,000, respectively. Additionally, as of December 31, 2017 and 2016 restricted cash included a stand-by letter of credit issued in favor of a landlord for \$50,000 which was classified in current assets as of December 31, 2017 (see Note 5).

Cash, cash equivalents, and restricted cash consists of the following:

| | December 31, | | | 31, |
|---|--------------|------------|----|------------|
| | | 2017 | | 2016 |
| Cash | \$ | 206,510 | \$ | 1,127,530 |
| Money market fund | | 62,330,985 | | 13,864,727 |
| Cash and cash equivalents | | 62,537,495 | | 14,992,257 |
| | | | | |
| Restricted cash, current | | 158,991 | | 150,000 |
| Restricted cash, noncurrent | | | | 50,000 |
| Restricted cash | | 158,991 | | 200,000 |
| Total cash, cash equivalents, and restricted cash shown in the statement of | | | | |
| cash flows | \$ | 62,696,486 | \$ | 15,192,257 |

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 4 for details of property and equipment and Note 5 for operating and capital lease commitments.

Research and Development Expenses and Development Award Agreements

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.

For amounts received under the development award received from the CFFT (See Note 8), the Company recognized those amounts when the triggering event to receive those payments occurred, with those amounts being amortized on a straight-line basis over the expected duration of the remaining performance period of the development program under the award, which concluded in the third quarter of 2017.

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 determines 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, 2017, 2016 and 2015, there were no material adjustments to the Company's prior period estimates of accrued expenses for clinical trials.

Leases and Deferred Rent

The Company leases its office space. Leases are evaluated and classified as operating or capital leases for financial reporting purposes. The Company's office space leases qualify as operating leases. For operating leases that contain rent escalations and rent holidays, the Company records the total rent payable during the lease term on a straight-line basis over the term of the lease and records the difference between the rents paid and the straight-line rent as deferred rent. Additionally, any tenant improvement allowances received from the lessor are recorded as a reduction to rent expense over the term of the lease.

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, 2017 and 2016, all of the Company's assets were located in the United States.

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 asset 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, 2017 or 2016.

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, 2017, 2016 and 2015.

Share-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. 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. Stock options granted to non-employee consultants are revalued at the end of each reporting period until vested using the Black-Scholes option-pricing model and the changes in their fair value are recorded as adjustments to expense over the related vesting period.

On March 30, 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 simplifies several aspects of the accounting for employee share-based payment transactions including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as well as classification in the statement of cash flows. ASU 2016-09 took effect for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. In the first quarter of 2017, when the Company adopted ASU 2016-09 it did not elect to account for forfeitures as they occur but rather to continue to estimate forfeitures at grant date. As a result, the adoption of ASU 2016-09 did not have an impact on the Company's consolidated financial statements. ASU 2016-09 also removed the requirement to recognize the excess tax benefits in respect of share based payments only when realized (See Note 9).

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, 2017, 2016 and 2015:

| | | Years Ended December 31, | | |
|---|--------------|--------------------------|----------------|--|
| | 2017 | 2016 | 2015 | |
| Basic and diluted net loss per share of common stock: | | | | |
| Net loss | (32,421,612) | (19,998,675) | \$ (8,850,739) | |
| Weighted average shares of common stock outstanding | 50,176,953 | 41,137,518 | 31,350,145 | |
| Net loss per share of common stock-basic and diluted | \$ (0.65) | \$ (0.49) | \$ (0.28) | |

The impact of the following potentially dilutive securities for the years ended December 31, 2017, 2016 and 2015 have been excluded from the computation of dilutive weighted average shares outstanding as the inclusion would be antidilutive.

| | | December 31, | | | |
|---------------|--------------|--------------|-----------|--|--|
| | 2017 2016 20 | | | | |
| Warrants | 1,288,500 | 1,288,500 | 1,969,250 | | |
| Stock options | 7,844,966 | 6,610,179 | 3,982,065 | | |
| | 9,133,466 | 7,898,679 | 5,951,315 | | |

Recent Accounting Pronouncements

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, and is effective for public companies for annual and interim periods beginning after December 15, 2017. Specifically, the new standard differs from the current accounting standard in many respects, such as in the accounting for variable consideration received, including milestone payments or contingent payments. Under the Company's 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 (See Note 8). 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. 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 has concluded its performance obligations and has completed recognizing revenue under the agreement with CFFT in the third quarter of 2017 (See Note 8), there was no cumulative effect to record at the date of the Company's adoption of ASC 606. The Company will assess any new agreements it enters into, including the 2018 CFF Award, (See Note 15) under ASC 606, including if such agreements fall under the scope of such standard.

Accounting for Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). Under ASU 2016-02, a lessee will be required to recognize assets and liabilities for all leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily will depend on its classification as a finance or operating lease. However, unlike current GAAP, which requires only capital leases to be recognized on the balance sheet, ASU 2016-02 will require both types of leases to be recognized on the balance sheet. ASU 2016-02 will take effect for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018, with early application permitted. The adoption of ASU 2016-02 will have an impact on the Company's financial position as the Company has operating lease commitments for office space as of December 31, 2017 with future non-cancelable lease payments amounting to \$5,474,623 (see Note 5) for which ASU 2016-02 would apply.

4. PROPERTY AND EQUIPMENT

Property and Equipment consisted of the following:

| | December 31, | | |
|--------------------------------|------------------|----|------------|
| | 2017 | | 2016 |
| Computer hardware and software | \$ 136,522 | \$ | 96,131 |
| Office furniture and equipment | 287,048 | | 259,138 |
| Leasehold improvements | 191,244 | | 188,219 |
| Construction in progress | 1,181,730 | | — |
| Property and equipment, gross | 1,796,544 | | 543,488 |
| Less: accumulated depreciation | (363,889) | | (108, 237) |
| Property and equipment, net | \$ 1,432,655 | \$ | 435,251 |

Depreciation expense was approximately \$256,000, \$88,000 and \$44,000 for the years ended December 31, 2017, 2016 and 2015, respectively. At December 31, 2017, construction in progress consisted of purchased property and equipment not placed in service until the Company's relocation into 32,733 square feet of office space in February 2018 (See Note 5).

On December 30, 2015, the Company entered into a lease agreement for a copier machine. The cost of the machine was approximately \$12,000 and is included in office furniture and equipment category in the table above. The lease payments commenced when the machine was placed in service in January 2016. The machine is being amortized over the life of the lease, which is for a three-year term and includes a bargain purchase option at the end of the term. See Note 5 for details of this capital lease commitment.

5. COMMITMENTS AND CONTINGENCIES

Operating Lease Commitment

In September 2016, the Company amended its commercial lease for office space to expand into an additional 4,088 square feet of office space within the same building for an aggregate total of 10,414 square feet of leased office space ("September 2016 Amendment"). The Company began occupying this space in early November 2016 and the final lease payment was to be due in January 2021. The September 2016 Amendment required an increase in the standby letter of credit to \$50,000 (See Note 3). The September 2016 Amendment was terminated upon the commencement date of the August 2017 Lease Agreement discussed below.

On August 21, 2017, the Company entered into a lease agreement ("August 2017 Lease Agreement") with the same landlord, 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 is 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 ranges 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 have been deferred and will 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 may 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 \$9,743 in year ended December 31, 2017.

The Company records the total rent payable during the lease term on a straight-line basis over the term of the lease and records the difference between the rents paid and the straight-line rent as deferred rent, which is classified in deferred rent, current and deferred rent, noncurrent in the Company's balance sheet as of December 31, 2017 and 2016.

Pursuant to the terms of the Company's non-cancelable lease agreements in effect at December 31, 2017, the future minimum rent commitments are as follows:

| 2018 | \$ 445,333 |
|------------|--------------|
| 2019 | 623,958 |
| 2020 | 784,243 |
| 2021 | 830,600 |
| 2022 | 855,150 |
| Thereafter | 1,935,339 |
| Total | \$ 5,474,623 |

Total rent expense for the years ended December 31, 2017, 2016 and 2015 was \$356,547, \$229,705 and \$55,496, respectively.

Capital Lease Commitment

The lease payments commenced when the machine was placed in service in January 2016. The lease is for a three-year term and includes a bargain purchase option at the end of the term. In the accompanying balance sheet as of December 31, 2017 and 2016, the current portion of this capital lease obligation is classified in accrued expenses and the long-term portion of the capital lease obligation is classified in other long-term liabilities. Pursuant to the terms of this capital lease agreement, the future minimum capital lease commitments are as follows as of December 31, 2017:

| 2018 | \$ 4,543 |
|-------------------------------------|-------------|
| 2019 | 379 |
| Total future minimum lease payments | 4,922 |
| Less: interest | (291) |
| Future capital lease obligations | 4,631 |
| Less: current portion | (4,256) |
| Long-term portion | \$ 375 |

Interest expense for this capital lease obligation for the years ended December 31, 2017, 2016 and 2015 was \$712, \$1,286 and \$0, respectively.

For commitments under the Company's development award agreements- see Note 8.

6. NOTES PAYABLE

In November 2015, the Company entered into a loan agreement with a financing company for \$207,750 to finance one of the Company's insurance policies. The terms of the loan stipulated equal monthly payments of principal and interest payments of \$23,397 over a nine month period. Interest on this loan was accrued at an annual rate of 3.25%. This loan was fully repaid in July 2016.

In October 2016, the Company entered into a loan agreement with a financing company for \$348,750 to finance one of the Company's insurance policies. The terms of the loan stipulate equal monthly payments of principal and interest payments of \$39,114 over a nine-month period. Interest on this loan was accrued at an annual rate of 2.25%. This loan was fully repaid in July 2017.

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 stipulate equal monthly payments of principal and interest payments of \$41,975 over a ten-month period. Interest accrues on this loan at an annual rate of 2.35%.

Prepaid expenses and other current assets as of December 31, 2017 and 2016 included \$368,976 and \$378,750, respectively, related to these insurance policies.

Interest expense for notes payable for the years ended December 31, 2017, 2016 and 2015 totaled \$3,632, \$3,115 and \$2,440, respectively.

7. ACCRUED EXPENSES

Accrued expenses consisted of the following:

| | December 31, | | |
|--|------------------|----|-----------|
| | 2017 | | 2016 |
| Accrued clinical operations and trials costs | \$ 2,003,799 | \$ | 1,647,490 |
| Accrued product development costs | 1,255,439 | | 713,426 |
| Accrued compensation | 1,335,672 | | 778,250 |
| Accrued other | 146,609 | | 117,289 |
| Total | \$ 4,741,519 | \$ | 3,256,455 |

8. DEVELOPMENT AWARD AND DEFERRED REVENUE

On April 20, 2015, the Company entered into an award agreement (the "2015 CFFT Award Agreement ") with the CFFT pursuant to which it received a development award (the "2015 CFFT Award") for up to \$5 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 has received \$5.0 million in payments since the inception of the 2015 CFFT Award as outlined below. 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.

Upon the execution of the 2015 CFFT Award Agreement, the Company received a payment of \$1,250,000 in May 2015. In November 2015, the Company received a second payment of \$1,250,000 upon the achievement of a milestone for dosing the first patient. In August 2016, the Company received a third payment from the CFFT in the amount of \$1,000,000 for achieving a milestone in July 2016 related to dosing the median clinical trial patient. In January 2017, the Company received a fourth payment from the CFFT in the amount of \$1,000,000 for achieving a milestone in December 2016 related to completing the final visit for the final patient, which was billed by the Company to CFFT in December 2016 and was classified in grants receivable as of December 31, 2016. The Company received the final payment from CFFT in the amount of \$500,000 in November 2017 for achieving the final milestone in September 2017 related to the issuance to CFFT of the final integrated statistical report for to the Phase 2 CF clinical trial. At that time the Company had completed all its performance obligations under the contract and therefore the performance period had concluded.



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. For the years ended December 31, 2017, 2016 and 2015, in respect of the 2015 CFFT Award Agreement, the Company recognized revenue of \$2,440,195, \$1,911,424 and \$648,382, respectively. Deferred revenue consisted of the following:

| | Decem | ber 31, |
|-----------------------|---|--------------|
| | 2017 | 2016 |
| Deferred revenue | <u>\$ </u> | \$ 1,940,195 |
| Less: current portion | | (1,940,195) |
| Long term portion | \$ | \$ |

See Note 15 for the Investment Agreement entered into by the Company after the balance sheet date.

9. 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, 2017 and 2016, the Company had federal net operating loss carryforwards of approximately \$56,536,000 and \$28,644,000, respectively, of which federal carryforwards will expire in varying amounts beginning in 2029. At December 31, 2017 and 2016, the Company had Massachusetts net operating loss carryforwards of approximately \$53,110,000 and \$26,573,000, respectively. In the first quarter of 2017, the Company adopted ASU 2016-09, which removed the requirement to recognize the deferred tax assets on excess tax benefits in respect of share based payments only when realized. As such, during the year ended December 31, 2017, the Company's gross deferred tax assets and corresponding valuation allowance each included a one-time increase in respect of an additional federal and state net operating losses of \$1,432,000. The adoption of ASU 2016-09 did not have an impact on the Company's balance sheet, results of operations, cash flows or statement of stockholders' equity because the Company has a full valuation allowance on its deferred tax assets. 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, 2017 and 2016 of approximately \$1,283,000 and \$736,000, respectively.

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

| | December 31, | | | |
|-----------------------------|---------------|---------------|--|--|
| | 2017 | 2016 | | |
| NOL carryforward | \$ 15,229,127 | \$ 10,860,828 | | |
| Tax credits | 1,213,347 | 673,690 | | |
| Stock based compensation | 1,724,248 | 1,177,650 | | |
| Accrued expenses | 45,654 | 302,943 | | |
| Other temporary differences | 116,292 | 225,214 | | |
| Subtotal | 18,328,668 | 13,240,325 | | |
| Valuation allowance | (18,328,668) | (13,240,325) | | |
| 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 \$5,088,343 and \$7,860,985 in 2017 and 2016, 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, 2017 and 2016 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, | | |
|-------------------------------------|---------|--------------|---------|--|
| | 2017 | 2016 | 2015 | |
| Tax provision at statutory rate | 34.00% | 34.00% | 34.00% | |
| State taxes, net of federal benefit | 5.66% | 4.76% | 4.76% | |
| Permanent differences | -2.05% | -0.65% | -0.62% | |
| Tax credits | 1.59% | 1.33% | 2.67% | |
| Income tax rate change | -24.11% | % | | |
| Other | 0.60% | -0.13% | 0.04% | |
| Increase in valuation reserve | -15.69% | -39.31% | -40.85% | |
| Total | 0.00% | 0.00% | 0.00% | |

The Tax Cut and Jobs Act of 2017

On December 22, 2017, the Tax Cut and Jobs Act (the "Tax Act") was enacted into law. 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. As of December 31, 2017, we have made a reasonable estimate of the effects of the Tax Act on our existing deferred taxes and related disclosures by reducing our net federal and state deferred tax assets by \$7,815,832 for the reduction in corporate tax rate. This adjustment to our deferred tax assets is offset against the valuation allowance.

Additionally, the SEC staff has issued SAB 118, which allows to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Act. Because the Company is still in the process of analyzing certain provisions of the Tax Act, the Company has determined that the adjustment to its deferred taxes was a provisional amount as permitted under SAB 118.

10. COMMON STOCK

The Company has authorized 150,000,000 shares of common stock, \$0.0001 par value per share, of which 55,603,427 shares, 44,681,745 shares, and 37,605,134 shares were issued and outstanding as of December 31, 2017, 2016, and 2015, respectively.

During the year ended December 31, 2015, the Company issued 11,666,802 shares of common stock upon the exercise of warrants and stock options to purchase common stock and the Company received net proceeds of \$10,819,714 from these exercises.

In June 2016, the Company completed a sale of shares of its common stock pursuant to the terms of a securities purchase agreement under which the Company sold an aggregate of 5,960,000 shares of its common stock in a registered direct offering to investors at a purchase price of \$2.50 per share with gross proceeds to the Company totaling approximately \$14,900,000 less issuance costs of \$25,222. On February 28, 2017, the Company entered in a securities purchase agreement providing for the issuance and sale by the Company of 3,887,815 shares of its common stock in a registered direct offering to institutional and accredited investors at a purchase price of \$7.00 per share with gross proceeds to the Company totaling \$27,214,705 less issuance costs of \$36,291.

In November 2016, the Company entered into a sales agreement with Cantor Fitzgerald under which the Company could direct Cantor Fitzgerald as its sales agent to sell common stock under an "At the Market Offering" ("Sales Agreement"). Sales of common stock under the Sales Agreement were made pursuant to an effective registration statement for an aggregate offering of up to \$35 million. Under the Sales Agreement, the Company was obligated to pay Cantor a 3% commission on gross proceeds. In 2016, the Company sold 188,695 shares of our common stock under the Sales Agreement at an average selling price of approximately \$8.54 per share (net of 3% commission paid to Cantor Fitzgerald) which resulted in proceeds of approximately \$1,621,182 and net proceeds of approximately \$1,426,145 net of incurred issuance costs. Approximately \$330,413 of these proceeds were classified in stock subscriptions receivable as of December 31, 2016 because the Company sold 1,413,633 shares of its common stock under the Sales Agreement at an average selling price of \$13,724,591 and net proceeds of \$13,268,208. The Company did not sell any shares of its common stock under the Sales Agreement in connection with the October 2017 Offering discussed below. The aggregate amount sold under the Sales Agreement as described above was approximately \$15.4 million.

See Note 15 for the January 2018 Sales Agreement entered into by the Company and Cantor Fitzgerald after the balance sheet date.

On October 26, 2017, the Company consummated an underwritten public offering of shares of its common stock pursuant to which the Company sold an aggregate of 4,650,000 shares of its common stock to institutional investors at a purchase price of \$7.00 per share with gross proceeds to the Company totaling \$32,550,000, less estimated issuance costs incurred of approximately \$2,184,000. The Company also granted the underwriters a 30-day option to purchase up to an additional 697,500 shares of common stock on the same terms as the underwriters were purchasing the base number of shares, which they exercised in November 2017 with net proceeds to us totaling \$4,589,550.

During the year ended December 31, 2017, the Company issued 272,734 shares of common stock upon the exercise of stock options and warrants to purchase common stock and the Company received net proceeds of \$189,490 from these exercises. During the year ended December 31, 2016, the Company issued 927,916 shares of common stock upon the exercise of stock options and warrants to purchase common stock and the Company received net proceeds of \$468,442 from these exercises.

11. 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. On January 1, 2017, pursuant to an annual evergreen provision contained in the 2014 Plan, the number of shares reserved for future grants was increased by 3,127,722 shares. As of December 31, 2017, there was a total of 13,043,739 shares reserved for issuance under the 2014 Plan and there were 4,460,334 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.

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, 2018, the number of shares of common stock available for issuance under the 2014 Plan increased by 2,500,000 shares, which was less than seven percent (7%) of the outstanding shares of common stock on December 31, 2017. As of January 1, 2018, the 2014 Plan had a total reserve of 15,543,739 shares and there were 6,960,334 shares available for future grants.

Share-based Compensation

For stock options issued and outstanding for the years ended December 31, 2017, 2016 and 2015, the Company recorded non-cash, stock-based compensation expense of \$5,694,489 (\$4,640,646 for employees and \$1,053,843 for non-employees), \$3,163,534 (\$2,104,939 for employees and \$1,058,595 for non-employees) and \$1,153,302 (\$672,071 for employees and \$481,231 for non-employees), 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 using the Black-Scholes option pricing model that uses the assumptions noted in the following table. Due to its limited operating history, the Company estimated its volatility in consideration of a number of factors, including the volatility of comparable public companies and, commencing in 2015, the Company also included the volatility of its own common stock, taking into account the expected life of the option. 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 based on the average between the vesting period and the contractual life of the options which is 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.

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

| | 2017 | 2016 | 2015 |
|---------------------------|--------|--------|--------|
| Risk free interest rate | 2.12% | 1.70% | 1.85% |
| Expected dividend yield | 0% | 0% | 0% |
| Expected term in years | 6.25 | 6.66 | 6.73 |
| Expected volatility | 86.01% | 90.39% | 90.68% |
| Estimated forfeiture rate | 5.00% | 5.00% | 4.83% |

For the year ended December 31, 2017, the assumptions used in determining the fair value of options granted to nonemployees included risk free interest rate ranging from 2.12%-2.38%, no expected dividend yield, expected term ranging from 4.91 years to 9.91 years, expected volatility ranging from 85.58% to 89.58%, and estimated forfeiture rate of 5%.

A summary of option activity for years ended December 31, 2017 and 2016 is presented below:

| Options | Shares | А | Veighted Verage Xercise Price | Weighted Average Remaining Contractual Term in Years | Intrinsic Value |
|----------------------------------|-----------|----|--|---|--------------------|
| Outstanding at December 31, 2015 | 3,982,065 | \$ | 1.03 | Tears | value |
| Granted | 3,020,000 | \$ | 4.42 | | |
| Exercised | (326,886) | \$ | 1.43 | | |
| Forfeited | (65,000) | \$ | 2.44 | | |
| Outstanding at December 31, 2016 | 6,610,179 | \$ | 2.54 | | |
| Granted | 1,681,500 | \$ | 8.28 | | |
| Exercised | (272,734) | \$ | 0.67 | | |
| Forfeited | (173,979) | \$ | 6.53 | | |
| Outstanding at December 31, 2017 | 7,844,966 | \$ | 3.75 | 7.72 | \$ 29,433,877 |
| Vested at December 31, 2017 | 4,514,977 | \$ | 1.98 | 7.02 | \$ 23,444,225 |

The weighted average grant-date fair value of options granted during the years ended December 31, 2017, 2016 and 2015 was \$6.22, \$3.81 and \$1.41 per share, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2017, 2016 and 2015 was approximately \$2,092,964. \$1,004,321 and \$152,531, respectively. As of December 31, 2017 there was approximately \$12,542,918 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 2.87 years at December 31, 2017.

As summary of non-vested stock options for the years ended December 31, 2017 and 2016 is presented below:

| Options | Shares | Weighted Average Fair Value |
|---------------------------------|-------------|--------------------------------------|
| Non-vested at December 31, 2015 | 2,035,254 | \$ 0.85 |
| Granted | 3,020,000 | \$ 3.69 |
| Vested | (1,194,600) | \$ 1.57 |
| Forfeited | (34,380) | \$ 1.77 |
| Nonvested at December 31, 2016 | 3,826,274 | \$ 2.86 |
| Granted | 1,681,500 | \$ 6.22 |
| Vested | (2,003,806) | \$ 2.60 |
| Forfeited | (173,979) | \$ 5.03 |
| Non-vested at December 31, 2017 | 3,329,989 | \$ 4.61 |



12. WARRANTS

At December 31, 2017, there were warrants outstanding to purchase 1,288,500 shares of common stock with a weighted average exercise price of \$1.00 and a weighted average remaining life of 1.41 years. No warrants were exercised during the year ended December 31, 2017. During the year ended December 31, 2016, warrants to purchase 679,500 shares of common stock were exercised on a cashless basis resulting in the issuance of 599,780 shares and 1,250 shares of common stock were exercised on a for cash basis. There were no warrants issued or cancelled during the year ended December 31, 2017 or 2016

For warrant issued to CFF after the balance sheet date - see Note 15.

13. RELATED PARTY TRANSACTIONS

On September 20, 2016, the Company entered into a consulting agreement (the "2016 Consulting Agreement") with Orchestra Medical Ventures, LLC ("Orchestra"), of which a member of the Company's Board of Directors, David Hochman, is Managing Partner. Under this agreement, Orchestra rendered a variety of consulting and advisory services relating principally to identifying and evaluating strategic relationships, licensing opportunities, and business strategies. The term of the 2016 Consulting Agreement, the Company paid to Orchestra cash compensation in an aggregate amount of \$100,000. In connection with this agreement, the Company granted an equity incentive award to Mr. Hochman consisting of options to purchase 50,000 shares ("Option Shares") of common stock (the "Option Award") pursuant to the Company's 2014 Equity Compensation Plan, of which fifty percent (50%) vested on the three (3) month anniversary of the date of grant of the Option Award and the remainder of the Option Shares vested on the six (6) month anniversary of the date of grant of the Option Award. The Option Shares were granted with an exercise price of \$7.14 per share. The Company recorded stock-based compensation expense of approximately \$222,000 during the year ended December 31, 2016 and \$171,000 during the first quarter of 2017 in respect of the Option Award. No stock-based compensation expense was recorded after the first quarter of 2017 related to the Option Shares as they were fully vested in March 2017.

14. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

| | Quarters Ended | | | | |
|---|----------------|-------|---------------|--------------------|-------------------|
| | March 31, 2017 | | June 30, 2017 | September 30, 2017 | December 31, 2017 |
| Revenue from awards | \$ 1,293,69 | 7 \$ | 350,186 | \$ 796,312 | \$ — |
| Operating expenses: | | | | | |
| Research and development | 6,366,11 | 2 | 5,763,660 | 5,622,511 | 8,286,682 |
| General and administrative | 2,380,12 | 5 | 1,878,090 | 2,130,587 | 2,575,244 |
| Total operating expenses | 8,746,23 | 7 | 7,641,750 | 7,753,098 | 10,861,926 |
| Operating loss | (7,452,54 | 0) | (7,291,564) | (6,956,786) | (10,861,926) |
| Other income (expense): | | | | | |
| Interest income (expense), net | 1,36 | 6 | 5,271 | 43,402 | 133,073 |
| Foreign currency exchange gain | | | | | |
| (loss) | (14,26 | 5) | (10,594) | (52,212) | 35,163 |
| Other income (expense), net | (12,89 | 9) | (5,323) | (8,810) | 168,236 |
| Net loss | \$ (7,465,43 | 9) \$ | (7,296,887) | \$ (6,965,596) | (10,693,690) |
| Net loss per share, basic and diluted | \$ (0.1 | 6) \$ | (0.15) | \$ (0.14) | (0.20) |
| Weighted average number of common shares outstanding, basic and diluted | 46,381,48 | | 50,193,726 | 50 221 507 | 53,828,680 |
| | 40,381,48 | 2 | 50,195,720 | 50,221,597 | 55,828,080 |

F-18

| | Quarters Ended | | | | | | |
|---|----------------|----------------|----|---------------|---|--------------------|-------------------|
| | | March 31, 2016 | | June 30, 2016 | | September 30, 2016 | December 31, 2016 |
| Revenue from awards | \$ | 396,598 | \$ | 396,598 | | \$ 742,558 | \$ 375,670 |
| Operating expenses: | | | | | | | |
| Research and development | | 2,173,933 | | 3,567,003 | | 4,315,632 | 5,380,167 |
| General and administrative | | 1,109,889 | | 1,021,225 | | 1,760,696 | 2,567,937 |
| Total operating expenses | | 3,283,822 | | 4,588,228 | | 6,076,328 | 7,948,104 |
| Operating loss | | (2,887,224) | | (4,191,630) | | (5,333,770) | (7,572,434) |
| Other income (expense): | | | | | | | |
| Interest income (expense), net | | (5,360) | | 4,049 | | 1,731 | 57 |
| Foreign currency exchange gain | | | | | | | |
| (loss) | | 343 | | (1,810) | | (14,729) | 2,102 |
| Other income (expense), net | | (5,017) | | 2,239 | | (12,998) | 2,159 |
| Net loss | \$ | (2,892,241) | \$ | (4,189,391) | | \$ (5,346,768) | (7,570,275) |
| Net loss per share, basic and diluted | \$ | (0.08) | \$ | (0.11) | | \$ (0.12) | (0.17) |
| Weighted average number of common shares outstanding, basic and diluted | | 27 (05 210 | | 20 740 452 | - | 42 792 504 | 44.249.542 |
| and unuted | _ | 37,605,210 | _ | 38,748,452 | | 43,783,504 | 44,348,543 |

15. 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, 2018, the number of shares of common stock available for issuance under the 2014 Plan increased by 2,500,000 shares, such amount being less than seven percent (7%) of the outstanding shares of common stock on December 31, 2017. As of January 1, 2018, the 2014 Plan had a total reserve of 15,543,739 shares and there were 6,960,334 shares available for future grants.

At the Market Offering

On January 5, 2018, the Company entered into a sales agreement with Cantor Fitzgerald under which the Company may 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. In February 2018, the Company sold 1,500,000 shares of its common stock to an institutional investor under the January 2018 Sales Agreement for which it received net proceeds of \$11,349,000.

Cystic Fibrosis Program Related Investment Agreement

On January 26, 2018, the Company entered into the Cystic Fibrosis Program Related Investment Agreement with the Cystic Fibrosis Foundation ("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 \$6.25 million to date. 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.

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. 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.

Warrant Certificate No. F-1

NEITHER THE SECURITIES REPRESENTED BY THIS CERTIFICATE NOR THE SECURITIES ISSUABLE UPON THE EXERCISE OF THIS WARRANT HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS, AND NEITHER SUCH SECURITIES NOR ANY INTEREST THEREIN MAY BE OFFERED, SOLD, ASSIGNED OR OTHERWISE TRANSFERRED UNLESS (1) A REGISTRATION STATEMENT WITH RESPECT THERETO IS EFFECTIVE UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS, OR (2) AN EXEMPTION FROM SUCH REGISTRATION EXISTS AND THE COMPANY RECEIVES AN OPINION OF COUNSEL TO THE HOLDER OF SUCH SECURITIES, WHICH COUNSEL AND OPINION ARE SATISFACTORY TO THE COMPANY, THAT SUCH SECURITIES MAY BE OFFERED, SOLD, PLEDGED, ASSIGNED OR TRANSFERRED IN THE MANNER CONTEMPLATED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR APPLICABLE STATE SECURITIES LAWS.

Effective Date: January 26, 2018

Void After: January 26, 2025

CORBUS PHARMACEUTICALS HOLDINGS, INC.

WARRANT TO PURCHASE COMMON STOCK

Corbus Pharmaceuticals Holdings, Inc., a Delaware corporation (the "**Company**"), for value received on January 26, 2018 (the "**Effective Date**"), hereby issues to The Cystic Fibrosis Foundation (the "**Holder**") this warrant (the "**Warrant**") to purchase, 1,000,000 shares (each such share as from time to time adjusted as hereinafter provided being a "**Warrant Share**" and all such shares being the "**Warrant Shares**") of the Company's Common Stock (as defined below), at the Exercise Price (as defined below), as adjusted from time to time as provided herein, on or before January 26, 2025 (the "**Expiration Date**"), all subject to the following terms and conditions.

As used in this Warrant, (i) "**Business Day**" means any day other than Saturday, Sunday or any other day on which commercial banks in the City of New York, New York, are authorized or required by law or executive order to close; (ii) "**Common Stock**" means the common stock of the Company, par value \$0.0001 per share, including any securities issued or issuable with respect thereto or into which or for which such shares may be exchanged for, or converted into, pursuant to any stock dividend, stock split, stock combination, recapitalization, reclassification, reorganization or other similar event; (iii) "**Exercise Price**" means \$13.20 per share of Common Stock, subject to adjustment as provided herein; (iv) "**Trading Day**" means any day on which the Common Stock is traded (or available for trading) on its principal Trading Market (as defined below); and (v) "**Affiliate**" means any person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, a person, as such terms are used and construed in Rule 144 promulgated under the Securities Act of 1933, as amended (the "**Securities Act**"). For purposes hereof, "**Trading Market**" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Select Market, the NASDAQ Global Market, the NASDAQ Capital Market, or any other national securities exchange, as well as the OTC Bulletin Board or any tier of the OTC Markets.

1. DURATION AND EXERCISE OF WARRANTS

(a) <u>Exercise Period</u>. Commencing on the Effective Date of this Warrant, the Holder may exercise this Warrant for up to 500,000 shares of Common Stock (the "**Initial Exercise Amount**"). Upon the Completion of the CF Trial (as defined below), the Holder may exercise this Warrant for the remaining 500,000 shares of Common Stock (the "**Additional Exercise Amount**") issuable pursuant to the terms of this Warrant. At no point in time, may the Holder exercise this Warrant for more than 1,000,000 shares of Common Stock in the aggregate. The Holder may exercise this Warrant, in whole or in part (in accordance with the limitations set forth in this Section 1(a)), on any Business Day on or before 5:00 P.M., Eastern Time, on the Expiration Date, at which time this Warrant shall become void and of no value. For purposes of this Warrant, the term "**Completion of the CF Trial**" shall mean completion of the final Milestone by the Company and receipt of the final Milestone Payment by the Company from Cystic Fibrosis Foundation as set forth in Exhibit B to the Cystic Fibrosis Program Related Investment Agreement by and between Corbus Pharmaceuticals, Inc. and Cystic Fibrosis Foundation dated January 26, 2018.

(b) Exercise Procedures.

(i) While this Warrant remains outstanding and exercisable in accordance with Section 1(a), the Holder may exercise this Warrant in whole or in part at any time and from time to time by:

(A) delivery to the Company of a duly executed copy of the Notice of Exercise attached as Exhibit A;

(B) surrender of this Warrant to the Secretary of the Company at its principal offices or at such other office or agency as the Company may specify in writing to the Holder; and

(C) payment of the then-applicable Exercise Price per share multiplied by the number of Warrant Shares being purchased upon exercise of the Warrant (such amount, the "Aggregate Exercise Price") made in the form of cash, or by certified check, bank draft or money order payable in lawful money of the United States of America.

(ii) Upon the exercise of this Warrant in compliance with the provisions of Section 1(a) and this Section 1(b), the Company shall promptly issue and cause to be delivered to the Holder a certificate for the Warrant Shares purchased by the Holder. Each exercise of this Warrant shall be effective immediately prior to the close of business on the date (the "Date of Exercise") that the conditions set forth in this Section 1(b) have been satisfied, as the case may be. On the first Business Day following the date on which the Company has received each of the Notice of Exercise and the Aggregate Exercise Price (the "Exercise Delivery Documents"), the Company shall transmit an acknowledgment of receipt of the Exercise Delivery Documents to the Company's transfer agent (the "Transfer Agent"). On or before the second Business Day following the date on which the Company has received all of the Exercise Delivery Documents (the "Share Delivery Date"), the Company shall (X) provided that the Transfer Agent is participating in The Depository Trust Company ("DTC") Fast Automated Securities Transfer Program, upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit Withdrawal Agent Commission system, or (Y) if the Transfer Agent is not participating in the DTC Fast Automated Securities Transfer Program, issue and dispatch by overnight courier to the address as specified in the Notice of Exercise, a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. Upon delivery of the Exercise Delivery Documents, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the certificates evidencing such Warrant Shares.

(c) <u>Partial Exercise</u>. This Warrant shall be exercisable, either in its entirety or, from time to time, for part only of the number of Warrant Shares referenced by this Warrant for which the Warrant is then currently exercisable. If this Warrant is submitted in connection with any exercise pursuant to Section 1 and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the actual number of Warrant Shares being acquired upon such an exercise, then the Company shall as soon as practicable after any exercise and at its own expense, issue a new Warrant of like tenor representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, less the number of Warrant Shares with respect to which this Warrant is exercised.

(d) <u>Disputes</u>. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed and resolve such dispute in accordance with Section 16.

-2-

2. ISSUANCE OF WARRANT SHARES

(a) The Company covenants that all Warrant Shares will, upon issuance in accordance with the terms of this Warrant, be (i) duly authorized, fully paid and non-assessable, and (ii) free from all liens, charges and security interests, with the exception of claims arising through the acts or omissions of any Holder and except as arising from applicable Federal and state securities laws.

(b) The Company shall register this Warrant upon records to be maintained by the Company for that purpose in the name of the record holder of such Warrant from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner thereof for the purpose of any exercise thereof, any distribution to the Holder thereof and for all other purposes.

(c) The Company will not, by amendment of its certificate of incorporation, by-laws or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at all times in good faith assist in the carrying out of all the provisions of this Warrant and in the taking of all action necessary or appropriate in order to protect the rights of the Holder to exercise this Warrant, or against impairment of such rights.

3. ADJUSTMENTS OF EXERCISE PRICE, NUMBER AND TYPE OF WARRANT SHARES

(a) The Exercise Price and the number of shares purchasable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the occurrence of certain events described in this Section 3; <u>provided</u>, that notwithstanding the provisions of this Section 3, the Company shall not be required to make any adjustment if and to the extent that such adjustment would require the Company to issue a number of shares of Common Stock in excess of its authorized but unissued shares of Common Stock, less all amounts of Common Stock that have been reserved for issue upon the conversion of all outstanding securities convertible into shares of Common Stock and the exercise of all outstanding options, warrants and other rights exercisable for shares of Common Stock. If the Company does not have the requisite number of authorized but unissued shares of Common Stock to make any adjustment, the Company shall use its commercially reasonable efforts to obtain the necessary stockholder consent to increase the authorized number of shares of Common Stock to make such an adjustment pursuant to this Section 3.

(i) <u>Subdivision or Combination of Stock</u>. In case the Company shall at any time subdivide (whether by way of stock dividend, stock split or otherwise) its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision shall be proportionately reduced and the number of Warrant Shares, the Initial Exercise Amount and the Additional Exercise Amount shall be proportionately increased, and conversely, in case the outstanding shares of Common Stock of the Company shall be combined (whether by way of stock combination, reverse stock split or otherwise) into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased and the number of Warrant Shares, the Initial Exercise Amount and the Additional Exercise Amount and the Additional Exercise Amount shall be proportionately decreased. The Exercise Price, the Warrant Shares, the Initial Exercise Amount and the Additional Exercise Amount, as so adjusted, shall be readjusted in the same manner upon the happening of any successive event or events described in this Section 3(a)(i).

(ii) <u>Dividends in Stock, Property, Reclassification</u>. If at any time, or from time to time, all of the holders of Common Stock (or any shares of stock or other securities at the time receivable upon the exercise of this Warrant) shall have received or become entitled to receive, without payment therefore:

(A) any shares of stock or other securities that are at any time directly or indirectly convertible into or exchangeable for Common Stock, or any rights or options to subscribe for, purchase or otherwise acquire any of the foregoing by way of dividend or other distribution, or

(B) additional stock or other securities or property (including cash) by way of spin-off, split-up, reclassification, combination of shares or similar corporate rearrangement (other than shares of Common Stock issued as a stock split or adjustments in respect of which shall be covered by the terms of Section 3(a)(i) above), then and in each such case, the Exercise Price and the number of Warrant Shares to be obtained upon exercise of this Warrant shall be adjusted proportionately, and the Holder hereof shall, upon the exercise of this Warrant, be entitled to receive, in addition to the number of shares of Common Stock receivable thereupon, and without payment of any additional consideration therefor, the amount of stock and other securities and property (including cash in the cases referred to above) that such Holder would hold on the date of such exercise had such Holder been the holder of record of such Common Stock as of the date on which holders of Common Stock received or became entitled to receive such shares or all other additional stock and other securities and property. The Exercise Price and the Warrant Shares, as so adjusted, shall be readjusted in the same manner upon the happening of any successive event or events described in this Section 3(a)(i).



(iii) Reorganization, Reclassification, Consolidation, Merger or Sale. If any recapitalization, reclassification or reorganization of the capital stock of the Company, or any consolidation or merger of the Company with another corporation, or the sale of all or substantially all of its assets or other transaction shall be effected in such a way that holders of Common Stock shall be entitled to receive stock, securities, or other assets or property (an "Organic Change"), then, as a condition of such Organic Change, lawful and adequate provisions shall be made by the Company whereby the Holder hereof shall thereafter have the right to purchase and receive (in lieu of the shares of the Common Stock of the Company immediately theretofore purchasable and receivable upon the exercise of the rights represented by this Warrant) such shares of stock, securities or other assets or property as may be issued or payable with respect to or in exchange for a number of outstanding shares of such Common Stock equal to the number of shares of such stock immediately theretofore purchasable and receivable assuming the full exercise of the rights represented by this Warrant. In the event of any Organic Change, appropriate provision shall be made by the Company with respect to the rights and interests of the Holder to the end that the provisions hereof (including, without limitation, provisions for adjustments of the Exercise Price and of the number of shares purchasable and receivable upon the exercise of this Warrant) shall thereafter be applicable, in relation to any shares of stock, securities or assets thereafter deliverable upon the exercise hereof. The Company will not affect any such consolidation, merger or sale unless, prior to the consummation thereof, the successor corporation (if other than the Company) resulting from such consolidation or merger or the corporation purchasing such assets shall assume by written instrument reasonably satisfactory in form and substance to the Holder executed and mailed or delivered to the registered Holder hereof at the last address of such Holder appearing on the books of the Company, the obligation to deliver to such Holder such shares of stock, securities or assets as, in accordance with the foregoing provisions, such Holder may be entitled to purchase. If there is an Organic Change, then the Company shall cause to be mailed to the Holder at its last address as it shall appear on the books and records of the Company, at least 10 calendar days before the effective date of the Organic Change, a notice stating the date on which such Organic Change is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares for securities, cash, or other property delivered upon such Organic Change; provided, that the failure to mail such notice or any defect therein or in the mailing thereof shall not affect the validity of the corporate action required to be specified in such notice. The Holder is entitled to exercise this Warrant during the 10-day period for the amount of shares of Common Stock for which this Warrant is then currently exercisable commencing on the date of such notice to the effective date of the event triggering such notice. In any event, the successor corporation (if other than the Company) resulting from such consolidation or merger or the corporation purchasing such assets shall be deemed to assume such obligation to deliver to such Holder such shares of stock, securities or assets even in the absence of a written instrument assuming such obligation to the extent such assumption occurs by operation of law.

(b) <u>Certificate as to Adjustments</u>. Upon the occurrence of each adjustment or readjustment pursuant to this Section 3, the Company at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and furnish to each Holder a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based. The Company shall promptly furnish or cause to be furnished to such Holder a like certificate setting forth: (i) such adjustments and readjustments; and (ii) the number of shares and the amount, if any, of other property which at the time would be received upon the exercise of the Warrant.

(c) <u>Certain Events</u>. If any event occurs as to which the other provisions of this Section 3 are not strictly applicable but the lack of any adjustment would not fairly protect the purchase rights of the Holder under this Warrant in accordance with the basic intent and principles of such provisions, or if strictly applicable would not fairly protect the purchase rights of the Holder under this Warrant in accordance with the basic intent and principles of such provisions, then the Company's Board of Directors will, in good faith, make an appropriate adjustment to protect the rights of the Holder; <u>provided</u>, that no such adjustment pursuant to this Section 3(c) will increase the Exercise Price or decrease the number of Warrant Shares as otherwise determined pursuant to this Section 3.

4-

4. RESERVED

5. TRANSFERS AND EXCHANGES OF WARRANT AND WARRANT SHARES

(a) <u>Registration of Transfers and Exchanges</u>. Subject to Section 5(c), upon the Holder's surrender of this Warrant, with a duly executed copy of the Form of Assignment attached as **Exhibit B**, to the Secretary of the Company at its principal offices or at such other office or agency as the Company may specify in writing to the Holder, the Company shall register the transfer of all or any portion of this Warrant. Upon such registration of transfer, the Company shall issue a new Warrant, in substantially the form of this Warrant, evidencing the acquisition rights transferred to the transfere and a new Warrant, in similar form, evidencing the remaining acquisition rights not transferred, to the Holder requesting the transfer.

(b) <u>Warrant Exchangeable for Different Denominations</u>. The Holder may exchange this Warrant for a new Warrant or Warrants, in substantially the form of this Warrant, evidencing in the aggregate the right to purchase the number of Warrant Shares which may then be purchased hereunder, each of such new Warrants to be dated the date of such exchange and to represent the right to purchase such number of Warrant Shares as shall be designated by the Holder. The Holder shall surrender this Warrant with duly executed instructions regarding such re-certification of this Warrant to the Secretary of the Company at its principal offices or at such other office or agency as the Company may specify in writing to the Holder.

(c) <u>Restrictions on Transfers</u>. This Warrant may not be transferred at any time without: (i) registration under the Securities Act; or (ii) an exemption from such registration and a written opinion of legal counsel addressed to the Company that the proposed transfer of the Warrant may be effected without registration under the Securities Act, which opinion will be in form and from counsel reasonably satisfactory to the Company.

(d) <u>Permitted Transfers and Assignments</u>. Notwithstanding any provision to the contrary in this Section 5, the Holder may transfer, with or without consideration, this Warrant or any of the Warrant Shares (or a portion thereof) to the Holder's Affiliates without obtaining the opinion from counsel that may be required by Section 5(c)(ii), <u>provided</u>, that the Holder delivers to the Company and its counsel certification, documentation, and other assurances reasonably required by the Company's counsel to enable the Company's counsel to render an opinion to the Company's Transfer Agent that such transfer does not violate applicable securities laws.

6. MUTILATED OR MISSING WARRANT CERTIFICATE

If this Warrant is mutilated, lost, stolen or destroyed, upon request by the Holder, the Company will, at its expense, issue, in exchange for and upon cancellation of the mutilated Warrant, or in substitution for the lost, stolen or destroyed Warrant, a new Warrant, in substantially the form of this Warrant, representing the right to acquire the equivalent number of Warrant Shares; <u>provided</u>, that, as a prerequisite to the issuance of a substitute Warrant, the Company may require satisfactory evidence of loss, theft or destruction as well as an indemnity from the Holder of a lost, stolen or destroyed Warrant.

7. PAYMENT OF TAXES

The Company will pay all transfer and stock issuance taxes attributable to the preparation, issuance and delivery of this Warrant and the Warrant Shares (and replacement Warrants) including, without limitation, all documentary and stamp taxes; <u>provided</u>, <u>however</u>, that the Company shall not be required to pay any tax in respect of the transfer of this Warrant, or the issuance or delivery of certificates for Warrant Shares or other securities in respect of the Warrant Shares to any person or entity other than to the Holder.

-5-

8. FRACTIONAL WARRANT SHARES

No fractional Warrant Shares shall be issued upon exercise of this Warrant. The Company, in lieu of issuing any fractional Warrant Share, shall round up the number of Warrant Shares issuable to nearest whole share.

9. NO STOCK RIGHTS AND LEGEND

No holder of this Warrant, as such, shall be entitled to vote or be deemed the holder of any other securities of the Company that may at any time be issuable on the exercise hereof, nor shall anything contained herein be construed to confer upon the holder of this Warrant, as such, the rights of a stockholder of the Company or the right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or give or withhold consent to any corporate action or to receive notice of meetings or other actions affecting stockholders (except as provided herein), or to receive dividends or subscription rights or otherwise (except as provide herein).

Each certificate for Warrant Shares initially issued upon the exercise of this Warrant, and each certificate for Warrant Shares issued to any subsequent transferee of any such certificate, shall be stamped or otherwise imprinted with a legend in substantially the following form:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS, AND NEITHER SUCH SECURITIES NOR ANY INTEREST THEREIN MAY BE OFFERED, SOLD, PLEDGED, ASSIGNED OR OTHERWISE TRANSFERRED UNLESS (1) A REGISTRATION STATEMENT WITH RESPECT THERETO IS EFFECTIVE UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS, OR (2) AN EXEMPTION FROM SUCH REGISTRATION EXISTS AND THE COMPANY RECEIVES AN OPINION OF COUNSEL TO THE HOLDER OF SUCH SECURITIES, WHICH COUNSEL AND OPINION ARE REASONABLY SATISFACTORY TO THE COMPANY, THAT SUCH SECURITIES MAY BE OFFERED, SOLD, PLEDGED, ASSIGNED OR TRANSFERRED IN THE MANNER CONTEMPLATED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR APPLICABLE STATE SECURITIES LAWS."

10. LOCK-UP

Any Warrant Shares acquired pursuant to an exercise of this Warrant must not be transferred, sold, hypothecated or otherwise disposed for a period of one year from the date on which the Share Delivery Date .

11. NOTICES

All notices, consents, waivers, and other communications under this Warrant must be in writing and will be deemed given to a party when (a) delivered to the appropriate address by hand or by nationally recognized overnight courier service (costs prepaid); (b) sent by facsimile or e-mail with confirmation of transmission by the transmitting equipment; (c) received or rejected by the addressee, if sent by certified mail, return receipt requested, if to the registered Holder hereof; or (d) seven (7) days after the placement of the notice into the mails (first class postage prepaid), to the Holder at the address, facsimile number, or e-mail address furnished by the registered Holder to the Company in accordance with the Subscription Agreement by and between the Company and the Holder, or if to the Company, to it at One Kendall Square, Bldg 200, Cambridge, MA 02139, Attn: Yuval Cohen, CEO (or to such other address, facsimile number, or e-mail address as the Holder or the Company as a party may designate by notice the other party).

12. SEVERABILITY

If a court of competent jurisdiction holds any provision of this Warrant invalid or unenforceable, the other provisions of this Warrant will remain in full force and effect. Any provision of this Warrant held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

-6-

13. BINDING EFFECT

This Warrant shall be binding upon and inure to the sole and exclusive benefit of the Company, its successors and assigns, the registered Holder or Holders from time to time of this Warrant and the Warrant Shares.

14. SURVIVAL OF RIGHTS AND DUTIES

This Warrant shall terminate and be of no further force and effect on the earlier of 5:00 P.M., Eastern Time, on the Expiration Date or the date on which this Warrant has been exercised in full.

15. GOVERNING LAW

This Warrant will be governed by and construed under the laws of the State of New York without regard to conflicts of laws principles that would require the application of any other law.

16. DISPUTE RESOLUTION

In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall submit the disputed determinations or arithmetic calculations via facsimile within two (2) Business Days of receipt of the Notice of Exercise giving rise to such dispute, as the case may be, to the Holder. If the Holder and the Company are unable to agree upon such determination or calculation of the Exercise Price or the Warrant Shares within three Business Days of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall, within two Business Days, submit via facsimile (a) the disputed determination of the Exercise Price to an independent, reputable investment bank selected by the Company and approved by the Holder or (b) the disputed arithmetic calculation of the Warrant Shares to the Company's independent, outside accountant. The Company shall cause at its expense the investment bank or the accountant, as the case may be, to perform the determinations or calculations and notify the Company and the Holder of the results no later than ten (10) Business Days from the time it receives the disputed determinations or calculations. Such investment bank's or accountant's determination or calculation, as the case may be, shall be binding upon all parties absent demonstrable error.

17. NOTICES OF RECORD DATE

Upon (a) any establishment by the Company of a record date of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any dividend or other distribution, or right or option to acquire securities of the Company, or any other right; or (b) any capital reorganization, reclassification, recapitalization, merger or consolidation of the Company with or into any other corporation, any transfer of all or substantially all the assets of the Company, or any voluntary or involuntary dissolution, liquidation or winding up of the Company, or the sale, in a single transaction, of a majority of the Company shall mail to the Holder at least ten (10) Business Days, or such longer period as may be required by law, prior to the record date specified therein, a notice specifying; (i) the date established as the record date for the purpose of such dividend, distribution, option or right and a description of such dividend, option or right; (ii) the date on which any such reorganization, reclassification, transfer, consolidation, merger, dissolution, liquidation or winding up, or sale is expected to become effective;and (iii) the date, if any, fixed as to when the holders of record of Common Stock shall be entitled to exchange their shares of Common Stock for securities or other property deliverable upon such reorganization, reclassification, transfer, consolation, merger, dissolution, reclassification, transfer, consolation, merger, dissolution, reclassification, transfer, consolation frecord of Common Stock shall be entitled to exchange their shares of Common Stock for securities or other property deliverable upon such reorganization, reclassification, transfer, consolation, merger, dissolution, ilquidation or winding up.

18. RESERVATION OF SHARES

The Company shall reserve and keep available out of its authorized but unissued shares of Common Stock for issuance upon the exercise of this Warrant, free from pre-emptive rights, such number of shares of Common Stock for which this Warrant shall from time to time be exercisable. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation. Without limiting the generality of the foregoing, the Company covenants that it will use commercially reasonable efforts to take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and use commercially reasonable efforts to obtain all such authorizations, exemptions or consents, including but not limited to consents from the Company's stockholders or Board of Directors or any public regulatory body, as may be necessary to enable the Company to perform its obligations under this Warrant.

19. NO THIRD PARTY RIGHTS

This Warrant is not intended, and will not be construed, to create any rights in any parties other than the Company and the Holder, and no person or entity may assert any rights as third-party beneficiary hereunder.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed as of the date first set forth above.

CORBUS PHARMACEUTICALS HOLDINGS, INC.

By: <u>/s/ Yuval Cohen</u> Name: Yuval Cohen Title: Chief Executive Officer

EXHIBIT A NOTICE

OF EXERCISE

(To be executed by the Holder of Warrant if such Holder desires to exercise Warrant)

To Corbus Pharmaceuticals Holdings, Inc.:

The undersigned hereby irrevocably elects to exercise this Warrant and to purchase thereunder, [] full shares of Corbus Pharmaceuticals Holdings, Inc. Common Stock issuable upon exercise of the Warrant and delivery of:

[] (in cash as provided for in the foregoing Warrant) and any applicable taxes payable by the undersigned pursuant to such Warrant.

The undersigned requests that certificates for such shares be issued in the name of:

(Please print name, address and social security or federal employer identification number (if applicable))

If the shares issuable upon this exercise of the Warrant are not all of the Warrant Shares which the Holder is entitled to acquire upon the exercise of the Warrant, the undersigned requests that a new Warrant evidencing the rights not so exercised be issued in the name of and delivered to:

(Please print name, address and social security or federal employer identification number (if applicable))

Name of Holder (print): (Signature): (By:) (Title:) Dated:

-9-

EXHIBIT B

FORM OF ASSIGNMENT

] hereby sells, assigns and transfers to each assignee set forth below all of the rights of the FOR VALUE RECEIVED, [undersigned under the Warrant (as defined in and evidenced by the attached Warrant) to acquire the number of Warrant Shares set opposite the name of such assignee below and in and to the foregoing Warrant with respect to said acquisition rights and the shares issuable upon exercise of the Warrant:

| Name of Assignee | Address | Number of Shares | | | | | |
|--|---|------------------|--|--|--|--|--|
| If the total of the Warrant Shares are not all of the Warrant Shares evidenced by the foregoing Warrant, the undersigned requests that a Warrant evidencing the right to acquire the Warrant Shares not so assigned be issued in the name of and delivered to the undersigned. | | | | | | | |
| | Name of Holder (print): (Signature): | | | | | | |

(By:)

-10-

| (Title:) | |
|----------|--|
| Dated: | |
| | |

CONFIDENTIAL TREATMENT

CONFIDENTIAL TREATMENT HAS BEEN REQUESTED AS TO CERTAIN PORTIONS OF THIS DOCUMENT. EACH SUCH PORTION, WHICH HAS BEEN OMITTED HEREIN AND REPLACED WITH AN ASTERISK [*], HAS BEEN FILED SEPERATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Execution Copy

CYSTIC FIBROSIS PROGRAM RELATED INVESTMENT AGREEMENT

by and between

Corbus Pharmaceuticals, Inc.

and

Cystic Fibrosis Foundation

Cystic Fibrosis Program Related Investment Agreement

| ARTICL | E I – DEFINITIONS | 2 |
|--------|--|----|
| ARTICL | E II – DEVELOPMENT PLAN | 10 |
| | | |
| 2.1 | Commencement; Objective | 10 |
| 2.2 | Duration of the Development Plan | 10 |
| 2.3 | Development Diligence | 10 |
| 2.4 | Project Advisory Group | 11 |
| 2.5 | Delivery of Information to the PAG | 12 |
| | | |
| ARTICL | <u>E III – AWARD PAYMENTS; RECORDS</u> | 13 |
| 3.2 | Records; Reporting Obligations; Audits | 15 |
| 5.2 | Keeling Obigations, Audits | 15 |
| ARTICL | <u>E IV – COMMERCIALIZATION; ROYALTIES</u> | 17 |
| | | |
| 4.1 | Development and Commercialization of a Product | 17 |
| 4.2 | Royalties | 17 |
| 4.3 | <u>Warrants</u> | 19 |
| 4.4 | Sales Reports | 19 |
| 4.5 | Transferee Liability | 20 |
| | | |
| ARTICL | <u>E V – CONFIDENTIALITY</u> | 21 |
| | | |
| 5.1 | <u>Confidentiality</u> | 21 |
| 5.2 | Publicity; Use of Name | 23 |
| ADTICL | | 24 |
| ARTICL | <u>E VI – PUBLICATION</u> | 24 |
| ADTICU | E VII INDEMNIEICATION AND INCLIDANCE | 25 |
| AKTICL | <u>E VII – INDEMNIFICATION AND INSURANCE</u> | 25 |
| 7.1 | Indemnification by Corbus | 25 |
| 7.1 | <u>Claims Procedures</u> | 25 |
| 7.2 | Participation; Assuming Control of the Defense | 25 |
| 7.3 | Insurance | 26 |
| 7.5 | Limitation of Liability | 20 |
| 1.5 | <u>Elimitation of Elability</u> | 21 |
| ARTICL | E VIII – PATENTABLE INVENTIONS | 27 |
| minice | | 21 |
| 8.1 | Ownership | 27 |
| 8.2 | Exclusive License Grant | 27 |
| 8.3 | Preparation | 28 |
| 8.4 | Costs | 28 |
| 8.5 | Abandonment | 28 |
| 8.6 | <u>No License</u> | 28 |
| 0.0 | | 20 |
| ARTICL | <u>E IX – TERM AND TERMINATION</u> | 29 |
| | | |
| 9.1 | Term | 29 |
| 9.2 | Termination by CFF For Cause | 29 |
| 9.3 | Termination for CFF Breach | 30 |
| 9.4 | General Effect of Termination; Survival | 30 |
| 9.5 | Prior Agreement | 30 |
| | | |

- i -

| ARTICLE | X – REPRESENTATIONS AND WARRANTIES | 31 |
|---------|--|----|
| | | |
| 10.1 | Representations and Warranties of Corbus | 31 |
| 10.2 | Representations and Warranties of CFF | 31 |
| | | |
| ARTICLE | XI – MISCELLANEOUS PROVISIONS | 31 |
| | | |
| 11.1 | Governing Law | 31 |
| 11.2 | Dispute Resolution | 32 |
| 11.3 | Waiver | 32 |
| 11.4 | Force Majeure | 32 |
| 11.5 | <u>Severability</u> | 33 |
| 11.6 | Assignment | 33 |
| 11.7 | Counterparts | 34 |
| 11.8 | No Agency | 34 |
| 11.9 | Notice | 34 |
| 11.10 | Headings | 36 |
| 11.11 | Entire Agreement | 36 |
| 11.12 | No Impairment | 36 |
| | | |

Exhibit A – Development Plan

Exhibit B – Budget and Milestone Payments

Exhibit C - CFF Patents

 $\underline{Exhibit \ D} - \underline{Warrants \ to \ CFF}$

- ii -

<u>Exhibits</u>

PROGRAM RELATED INVESTMENT AGREEMENT

This Agreement (this "<u>Agreement</u>") is made on this 26th day of January, 2018 (the "<u>Effective Date</u>") by and between Corbus Pharmaceuticals, Inc. ("Corbus"), a Delaware corporation, with its principal office at 100 River Ridge Drive, Norwood, MA 02062, and Cystic Fibrosis Foundation ("<u>CFF</u>"), a nonprofit corporation with its principal offices at 4550 Montgomery Ave, Bethesda, Maryland, 20814. Corbus and CFF are each a "<u>Party</u>," and, collectively, the "<u>Parties</u>."

WHEREAS, CFF's principal charitable mission is the discovery and development of drugs to cure or mitigate Cystic Fibrosis, to which CFF brings significant scientific, human resources and financial support; and

WHEREAS, Corbus is developing Lenabasum for the treatment of rare, chronic and serious inflammatory and fibrotic diseases including (i) systemic sclerosis (ii) Cystic Fibrosis (iii) dermatomyositis and (iv) systemic lupus erythematosus; and

WHEREAS, Corbus desires to prepare for and conduct a Phase 2 Clinical Trial for Lenabasum in cystic fibrosis patients; and

WHEREAS, CFF desires to provide an Award to fund the Phase 2 Clinical Trial on the terms and conditions set forth in this Agreement and Corbus desires to accept the Award;

NOW, THEREFORE, in consideration of the mutual covenants set forth in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE I – DEFINITIONS

For purposes of this Agreement, the terms defined in this Article 1 shall have the following meanings whether used in their singular or plural forms. Use of the singular shall include the plural and vice versa, unless the context requires otherwise:

1.1 "Affiliate" shall mean, with respect to any Person, any other Person which directly or indirectly, by itself or through one or more intermediaries, controls, or is controlled by, or is under direct or indirect common control with, such Person. The term "control" as used in this Section 1.1 means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise. Control will be presumed if one Person owns, either of record or beneficially, more than fifty percent (50%) of the voting stock of any other Person.

1.2 "Agreement" means this agreement, together with all appendices, exhibits and schedules hereto, and as the same may be amended or supplemented from time to time hereafter by a written agreement duly executed by authorized representatives of each Party hereto.

1.3 "Applicable Laws" shall mean the applicable laws of any jurisdiction which are applicable to any of the Parties or their respective Affiliates in carrying out activities hereunder or to which any of the Parties or their respective Affiliates in carrying out the activities hereunder is subject, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, policies, directions, directives and orders of any statutory authority, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions.

1.4 "Approval" shall mean all approvals from the relevant Regulatory Authority in a given country necessary to market and sell a pharmaceutical product in such country, including pricing and reimbursement approvals if required for marketing or sale of such product in such country.

1.5 "Approval Date" shall mean the date on which an Approval is granted by a relevant Regulatory Authority for the Product.

-2-

1.6 "Award" shall mean the total amount of funding CFF provides to Corbus pursuant to this Agreement, provided that the Award shall not exceed Twenty-Five Million Dollars (\$25 million).

1.7 "Budget" shall mean the total amount of monies estimated and agreed to by the Parties for the costs and expenses of the Phase 2 Clinical Trial as set forth in the Development Plan as shown on <u>Exhibit B</u>, which (a) may be amended from time to time solely upon the mutual written agreement of the Parties, and (b) shall detail the projected allocation and use of: the funds to be paid by CFF to Corbus with respect of the Award.

1.8 "CFF" shall have the meaning set forth in the preamble of this Agreement.

1.9 "CFF Designees" shall have the meaning set forth in Section 2.4.1.

1.10 "CFF Indemnitee" shall have the meaning set forth in Section 7.1.

1.11 "CFF Patents" shall mean any Patents Controlled by CFF or its Affiliates relating to the Phase 2 Clinical Trial and directed to a CFF Sole Invention which CFF Patents are set forth on <u>Exhibit C</u>.

1.12 "CFF Sole Invention" shall have the meaning set forth in Section 8.1.

1.13 "Change of Control" shall mean the consummation of a transaction, whether in a single transaction or in a series of related and substantially contemporaneous transactions, constituting (i) a merger, share exchange or other reorganization, (ii) the sale by one or more stockholders of a majority of the voting power of Corbus, or (iii) a sale of all or substantially all of the assets of Corbus (or that portion of its assets related to the subject matter of this Agreement), in which the stockholders of Corbus immediately prior to such transaction do not own a majority of the voting power of the acquiring, surviving or successor entity, as the case may be, provided that a Change of Control shall not include a bona fide financing transaction for the benefit of Corbus (i.e. in which Corbus raises capital for general working or business purposes) in which voting control of Corbus transfers to one or more persons who acquire shares of Corbus and the existing Corbus shareholders receive no consideration directly or indirectly in connection with the transaction.

-3-

1.14 "Commercially Reasonable Efforts" shall mean the level of effort, expertise and resources that is substantially and materially consistent with industry standards for companies of similar size and financial resources to develop and commercialize the Product, provided such effort is technically and commercially feasible, devoting the degree of attention and diligence to such efforts that are substantially and materially consistent with industry standards for a product at a comparable stage of development with similar market potential, and taking into account, with limitation issues of safety and efficacy, proprietary position, the regulatory environment, and other relevant scientific and commercial factors for companies of similar size and financial resources.

1.15 "Confidential Information" shall have the meaning set forth in Section 5.1.1.

1.16 "Controlled" (except in the context of Section 1.1) shall mean the legal authority or right of a Party hereto to grant a license or sublicense of intellectual property rights to another party, without breaching the terms of any agreement with a Third Party.

1.17 "Corbus Designees" shall have the meaning set forth in Section 2.4.1.

1.18 "Corbus Patents" shall mean any Patents Controlled by Corbus or its Affiliates claiming Corbus Development Plan Technology and directed to a Corbus Sole Invention.

1.19 "Corbus Sole Invention" shall have the meaning set forth in Section 8.1.

1.20 "Cystic Fibrosis" or "CF" shall mean any one and/or all of the human diseases commonly known as cystic fibrosis.

1.21 "Default" shall have the meaning set forth in Section 9.2.

1.22 "Development Plan" shall mean the Development Plan attached hereto in <u>Exhibit A</u>, which shall cover the work performed under the Agreement until the Development Plan Completion Date.

-4-

1.23 "Development Plan Technology" shall mean all intellectual property, data, technical information, know-how, inventions (whether or not patented), trade secrets, laboratory notebooks, processes and methods at any time discovered or developed in the performance of the Development Plan under this Agreement.

1.24 "Development Plan Completion Date" shall mean the date on which the last milestone specified in Exhibit B has been completed.

1.25 "Discloser" shall have the meaning set forth in Section 5.1.2.

1.26 "Disposition Royalty" shall have the meaning set forth in Section 4.2.3.

1.27 "Disposition Transaction" shall have the meaning set forth in Section 4.2.3.

1.28 "Dispute" shall have the meaning set forth in Section 11.2.1.

1.29 "Dollars" shall have the meaning set forth in Section 3.1.1.

1.30 "Effective Date" shall mean the date set forth in the first paragraph of this Agreement.

1.31 "FDA" shall mean the United States Food and Drug Administration, or any successor agency having regulatory jurisdiction over the manufacture, distribution and sale of drugs in the United States, and its territories and possessions.

1.32 "Field" shall mean the use of the Product for the treatment or prevention of Cystic Fibrosis, asbestosis, bronchiectasis, byssinosis, chronic bronchitis/COPD hypersensitivity pneumonitis, pneumoconiosis, primary ciliary dyskinesia, sarcoidosis and silicosis.

1.33 "First Commercial Sale" shall mean the first sale of a Product by Corbus or an Affiliate, licensee, sublicensee, transferee or successor of Corbus in a country in the Territory following Approval of the Product in that country or, if no such Approval or similar marketing approval is required, the date upon which a Product is first commercially sold in that country in an arms-length transaction. For clarity, the supply of a Product as part of a compassionate use or sampling program shall not constitute a First Commercial Sale.

-5-

1.34 "GAAP" shall mean generally accepted accounting principles consistently applied.

1.35 "IND" shall mean the investigational new drug application filed with respect to a Product with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto.

1.36 "Interest" shall mean the Prime Rate plus five (5) percentage points.

1.37 "Joint Invention" shall have the meaning set forth in Section 8.1.

1.38 "Joint Patents" shall mean any Patents Controlled by Corbus and CFF or their respective Affiliates claiming Development Plan Technology and directed to a Joint Invention.

1.39 "Losses" shall have the meaning set forth in Section 7.1.

1.40 "Major Market" shall mean Canada, Israel, any member country of the European Union, and the United Kingdom (if it ceases to be a member of the European Union).

1.41 "Net Sales" shall mean the gross amounts invoiced for sales or other dispositions of the Product to Third Parties (excluding, for the avoidance of doubt, any sales to Related Parties for resale), less the following deductions actually incurred, allowed, paid, accrued or otherwise specifically allocated to sales of Product in the Field and for Non-Field Indications (as applicable) less: (a) customary trade discounts, including trade, cash and quantity discounts or rebates credits or refunds, actually allowed or taken; (b) credits or allowances actually granted or made for rejection of or return of previously sold Products in the Field or Non-Field Products (as applicable), including recalls, or for retroactive price reductions and billing errors or for stocking allowances; (c) governmental and other rebates (or credits or other equivalents thereof) actually granted to managed health care organizations, commercial insurance companies, pharmacy benefit managers (or equivalents thereof), distributors, national, state/provincial, local, and other governments, their agencies and purchasers, and reimbursers, or to trade customers; (d) reasonable fees paid to wholesalers, distributors, selling agents (excluding sales representatives of the Selling Party), group purchasing organizations, Third Party payors, other contractees and managed care entities, in each case with respect to the Product in the Field or Non-Field Indications (as applicable); (e) charges separately invoiced for freight, insurance, transportation, postage and handling; (f) taxes, custom duties or other governmental charges (including any tax such as a value added or similar tax or government charge but excluding what is commonly known as income tax) levied on or measured by the billing amount for Products in the Field or Non-Field Indications (as applicable), as adjusted for rebates and refunds; (g) bad debts or provision for bad debts deductions actually written off during the applicable accounting period; and (h) any other specifically identifiable amounts included in the Product's gross invoice price that should be credited for reasons substantially equivalent to those listed above; all as determined in accordance with the selling Party's usual and customary accounting methods, which are in accordance with GAAP. In no event shall any particular amount identified above be deducted more than once in calculating Net Sales (i.e., no "double counting" of deductions).

-6-

In the case of any sale or other disposal for value, such as barter or counter-trade, of any Product, or part thereof, other than in an arm's length transaction exclusively for money, Net Sales shall be calculated as above on the value of the consideration received.

1.42 "Non-Field Product" shall mean any pharmaceutical composition or preparation (in any and all dosage forms) in final form containing Lenabasum or any derivative thereof that is approved or being developed for a Non-Field Indication. For clarity, different formulations or dosage strengths of a given Non-Field Product shall be considered the same Non-Field Product for purposes of this Agreement. In addition, the Parties acknowledge that the same product may be both a Product for use in the Field and a Non-Field Product (i.e., where such product has more than one indication such that it is for use in the Field and for Non-Field Indications).
1.43 "Non-Field Indication" shall mean the treatment or prevention of any disease in humans other than those in the Field.

1.44 "Non-Publishing Party" shall have the meaning set forth in Section 6.

1.45 "Party(ies)" shall have the meaning set forth in the preamble of this Agreement.

1.46 "Patents" means all existing patents and patent applications and all patent applications hereafter filed, including any continuation, continuation-in-part, division, provisional, priority, or any substitute applications, any patent issued with respect to any such patent applications, any reissue, reexamination, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all foreign counterparts of any of the foregoing.

1.47 "Person" means any individual, corporation, partnership, association, joint-stock company, trust, unincorporated organization or government or political subdivision thereof.

1.48 "Phase 2 Clinical Trial" shall mean a multicenter, randomized, double blind, placebo-controlled Phase 2 clinical trial to evaluate the efficacy and safety of Lenabasum in the treatment of cystic fibrosis which shall be conducted pursuant to the Development Plan.

1.49 "Prime Rate" shall mean the average prime rate published in the *Wall Street Journal* during the relevant period (calculated by dividing (a) the sum of the prime rates for each of the days during the relevant period, by (b) the number of days in the relevant period).

1.50 "Prior Agreement" shall mean the agreement of April 9, 2015 entered into by the Parties.

1.51 "Product" means Lenabasum in any form, dosage or preparation in finished form, and any derivative thereof.

-8-

1.52 "Project Advisory Group" or "PAG" shall have the meaning set forth in Section 2.4.1.

1.53 "Publishing Party" shall have the meaning set forth in Article VI.

1.54 "Recipient" shall have the meaning set forth in Section 5.1.2.

1.55 "Recipient Notice Requirement" shall have the meaning set forth in Section 5.1.3.

1.56 "Regulatory Authority" shall mean any country, federal, supranational, state or local regulatory agency, department, bureau or other governmental or regulatory authority having the administrative authority to regulate the development or marketing of pharmaceutical products in any country or other jurisdiction.

1.57 "Results" shall have the meaning set forth in Article VI.

1.58 "Securities Regulatory Authority" shall have the meaning set forth in Section 5.1.3.

1.59 "Share Election" shall have the meaning set forth in Section 4.2.1.

1.60 "Territory" shall mean worldwide.

1.61 "Third Party" shall mean any Person which is not a Party or an Affiliate of any Party to this Agreement.

1.62 "Trading Day" shall mean any day in which the stock exchange on which Corbus shares are regularly traded is open.

-9-

ARTICLE II – DEVELOPMENT PLAN

2.1 Commencement; Objective. The objective of the Phase 2 Clinical Trial will be to establish clinical proof of principal and to obtain sufficient information of the Product's safety and efficacy in the Field to permit the design of further clinical studies and that would satisfy the requirements of 21 CFR 312.21(b). Corbus shall be solely responsible for the conduct of the Phase 2 Clinical Trial as set forth in the Development Plan. CFF shall provide the financial support hereinafter specified, consultation and advice as provided herein through its participation on the PAG as provided below.

2.2 Duration of the Development Plan. The Development Plan shall commence on the Effective Date and shall conclude on the Development Plan Completion Date, unless extended by mutual agreement of the Parties, or unless earlier terminated in accordance with the provisions of Article IX hereof.

2.3 Development Diligence.

2.3.1 <u>Generally</u>. Corbus shall use Commercially Reasonable Efforts to conduct the Phase 2 Clinical Trial pursuant to the Development Plan. In furtherance of the foregoing, and in accordance with the terms and conditions of this Agreement (including, without limitation, Section 2.3.2 below), Corbus shall commit (i) the level of staffing required by the Development Plan, with such staff that possess the necessary experience, training and scientific expertise in order for Corbus to fulfill its obligations hereunder, and (ii) the infrastructure (e.g., laboratories, offices, equipment and facilities) required by the Development Plan.

2.3.2 <u>Obligations of Corbus</u>. Subject to the terms and conditions of this Agreement, and without limiting the generality of Section 2.3.1 above, Corbus shall be solely responsible for the sponsorship, conduct and oversight of the Phase 2 Clinical Trial as set forth in the Development Plan, which such responsibilities shall include, without limitation, utilizing Commercially Reasonable Efforts to perform its obligations hereunder and complete the Phase 2 Clinical Trial in a timely fashion so as to enable the possibility of further development and commercialization of the Product in the Field in accordance with Section 4.1; and responding to all reasonable requests and inquiries of CFF for information in possession of Corbus regarding any of the subject matter hereof.

-10-

2.4 Project Advisory Group.

2.4.1 <u>Composition and Purposes</u>. During the term of the Development Plan, a Program Advisory Group ("<u>PAG</u>") shall facilitate communication between the Parties, and make recommendations, with respect to the Development Plan. The PAG shall consist of four (4) members, two (2) of whom shall be designated by Corbus (the "<u>Corbus Designees</u>"), and two (2) of whom shall be designated by CFF (the "<u>CFF Designees</u>"). Each Party (i) shall select a Program Coordinator from among its designees to the PAG (who may be changed at any time or from time to time by such Party), and (ii) may change any of its designees to the PAG at any time or from time to time. The Program Coordinator of Corbus shall serve as the Chairperson of the PAG.

Without limiting the generality of the foregoing, the PAG shall:

(a) consider, review, reevaluate and discuss the Development Plan, evaluate any proposed revisions or modifications by either Party to the Development Plan, and give its recommendations regarding any proposed amendments to the Development Plan;

(b) monitor the progress of the Development Plan, and make recommendations to Corbus's team as needed on next steps to implement the Development Plan; and

(c) determine that the Award has been used as set forth in the Development Plan.

The PAG shall terminate on the First Commercial Sale of a Product in the Field or in the event Corbus determines to discontinue development of the Product for use in the Field.

-11-

2.4.2 <u>Meetings</u>. The PAG shall meet no less frequently than once in each three (3) month period; <u>provided</u>, <u>however</u>, that the PAG may meet more or less frequently upon mutual agreement of the Program Coordinators. The first meeting of the PAG shall be held within ninety (90) days of the Effective Date. Meetings of the PAG shall be held at such times and locations as may be mutually agreed by the Program Coordinators, which times and locations shall be communicated in writing (including, without limitation, by email) to the other members of the PAG with reasonable advance notice of the meeting. At least one (1) Corbus Designee and one (1) CFF Designee shall be required to participate in a meeting for such meeting to be deemed a quorum. So long as a quorum is present at a meeting, the PAG may make, or decide to make, recommendations to Corbus, or take, or decide to take, such actions as are within the scope of the PAG's authority hereunder. Members of the PAG may attend each meeting either in person or by means of telephone or other telecommunications device that allows all participants to hear and speak at such meeting simultaneously. At least ten (10) business days prior to each meeting of the PAG. Within twenty (20) days after the date of each meeting, the Corbus Designees shall prepare and deliver (including by email) to the CFF Designees written minutes of such meeting setting forth in detail all discussions and/or recommendations of the PAG made at such meeting, which such minutes shall be subject to the prior approval of CFF's Program Coordinator.

2.4.3 <u>Discussions/Recommendations</u>. As a general matter, and except as otherwise provided for herein, the PAG shall discuss the items set forth in Section 2.4.1, make unanimous, non-binding recommendations to Corbus as a result of such discussions, and facilitate communication between the Parties with respect to the Development Plan.

2.4.4 <u>Expenses</u>. Each Party shall pay its own expenses (including travel and lodging expenses) incurred in connection with its participation on the PAG.

2.5 Delivery of Information to the PAG. Corbus shall deliver to each PAG member such information and other data as soon as practicable following its availability as is necessary to facilitate mutual understanding of the status of, and developments relating to, the Development Plan.

-12-

ARTICLE III – AWARD PAYMENTS; RECORDS

3.1.1 <u>Award Grant and Payments</u>. In accordance with the terms, and subject to the conditions, set forth in this Agreement, CFF hereby grants the Award to Corbus and Corbus accepts such Award. Corbus shall send invoices in United States Dollars ("<u>Dollars</u>") to CFF for payment of the Award in accordance with the milestones set forth in <u>Exhibit B</u>. CFF shall pay amounts invoiced by Corbus within [*] days of the receipt of the invoice for amounts expended in accordance with the Budget and milestone schedule. Except as expressly provided in Sections 4.2.1 (a) and (b), all payments to be made hereunder (including, without limitation, pursuant to Article IV) shall be made in Dollars and, at the option and direction of the receiving party, shall be made by cashier's or certified check or by wire transfer of immediately available funds.

3.1.2 Limitations. Notwithstanding Section 3.1.1 above or any contrary provision contained herein, CFF shall not be required to make any payment or additional payment in respect of the Award:

(a) To the extent amounts paid hereunder would exceed of Twenty-Five Million Dollars (\$25 million);

Laws;

(b) unless at the time such payment is due, the Development Plan is in material compliance with all Applicable

(c) upon the occurrence and/or during the continuance of any uncured default and/or any material breach by Corbus of any of its covenants or obligations under this Agreement (including, without limitation, Corbus's obligations under Sections 3.1.3 and 3.1.4 below);

-13-

(d) if a case or proceeding (i) under the bankruptcy laws of the United States, or relevant non-U.S. law, now or hereafter in effect is filed against Corbus or all or substantially all of its assets and such petition or application is not dismissed within sixty (60) days after the date of its filing or Corbus shall file any answer admitting and not contesting such petition, or (ii) under the bankruptcy laws of the United States, or relevant non-U.S. law, now or hereafter in effect or under any insolvency, reorganization, receivership, dissolution or liquidation law or statute of any jurisdiction now or hereafter in effect (whether at law or equity) is filed by Corbus for all or substantially all of its assets; and/or

(e) if this Agreement is terminated by either Party in accordance with Article IX.

3.1.3 <u>Budget</u>. Corbus hereby covenants and agrees to use the Award funds provided by CFF to Corbus hereunder to fund the Phase 2 Clinical Trial in accordance with the Budget (including, without limitation, making applicable payments to subcontractors and vendors) and Development.

3.1.4 <u>Competition</u>. Corbus hereby agrees and acknowledges that nothing contained herein shall restrict or prevent CFF's ability to provide funding to, or take any other action with respect to, any Person that competes with a Product, the business, operations, and/or Development Plan of Corbus; and Corbus hereby waives any claim against CFF with respect to any such competing activities; provided, however, that CFF shall use Corbus Confidential Information only in accordance with the provisions of this Agreement, and Corbus does not waive any claims relating to use or misuse of Corbus Confidential Information not in accordance with this Agreement.

-14-

3.2 Records; Reporting Obligations; Audits.

3.2.1 <u>Records</u>. Corbus shall prepare and maintain complete and accurate books and records in connection with the Development Plan in accordance with GAAP (including financial records of expenditures under the Award) and the development and commercialization of any Product, and shall keep all such books and records in a manner that is consistent with its document retention policy. CFF shall have the right to inspect such books and records at the offices of Corbus during normal business hours.

3.2.2 <u>Response to Inquiries</u>. Corbus personnel (including, without limitation, licensees, sublicensees, transferees, successors and subcontractors) shall be available to discuss (whether in person or via telephone) with CFF the books and records and/or reports delivered by Corbus to CFF at such time or times as CFF may reasonably request.

3.2.3 <u>Audit</u>. At the request of CFF, from time to time prior to the first anniversary of the Development Plan Completion Date, Corbus shall permit agents of an independent, certified public accounting firm appointed by CFF, upon reasonable notice, but not more often than once a year, to audit and examine such books and records of Corbus as may be necessary for verifying Corbus's compliance with the terms and conditions hereunder. Any and all records audited and examined by agents of such accounting firm shall be deemed Corbus's Confidential Information. CFF shall pay the costs of such audit and examination of the books and records of Corbus, provided, however, that, if such audit and examination reveal a material breach of this Agreement or a material discrepancy with respect to other information previously provided by Corbus to CFF, then the costs of such audit and examination shall be borne by Corbus and Corbus shall reimburse CFF for all of the costs and expenses incurred by CFF in connection with such audit and examination.

-15-

3.2.4 Reports; Notices. Corbus shall furnish to CFF the following reports and/or notices:

(a) As soon as practicable, and in any event within sixty (60) days after the end of each calendar quarter (including the calendar quarter ending December 31), financial reports which describe the use of the Award funds (including, without limitation, a detailed breakdown of the actual costs of the Development Plan and how such Award funds have been allocated and in fact used in respect of the Development Plan), the progress made toward achieving the purposes of the Development Plan, and the development of any Product, and any other information in possession of Corbus that CFF reasonably requests.

(b) As soon as practicable after the Development Plan Completion Date, a closing report customary for a Development Plan at such stage of development which shall (i) be prepared by Corbus or a Corbus-approved Third Party, (ii) be reasonably satisfactory to CFF, and (iii) set forth Corbus's final analysis, summary tables, data listings, results and conclusions from the Development Plan and such other information and materials as CFF may reasonably request.

(c) As soon as practicable, and in any event within sixty (60) days after January 1 and June 1 of each fiscal year following the Development Plan Completion Date, progress reports and status updates on Corbus's activities with respect to the Development Plan Technology and/or a Product including, without limitation, the development and/or commercialization of any Products, Corbus's compliance with the terms of this Agreement, and any other information that CFF reasonably requests. Corbus shall include the requirements of this Section 3.2.4(c) in any agreements with sublicensees relating to the development and/or commercialization of any Products.

-16-

ARTICLE IV – COMMERCIALIZATION; ROYALTIES

4.1 Development and Commercialization of a Product

4.1.1 <u>Development and Commercialization of a Product</u>. Corbus shall use Commercially Reasonable Efforts to develop and commercialize the Product in the United States and in one of the other Major Markets; provided however that nothing contained herein shall require Corbus to initiate any other clinical trials (other than the Phase 2 Clinical Trial described herein) for the Product in the Field.

4.1.2 <u>Commercialization of Product</u>. Corbus and/or its Affiliates, licensees, sublicensees, transferees and successors shall have the exclusive rights to develop, commercialize, market, sell and distribute any or all Products throughout the Territory.

4.2 Royalties. Corbus shall make the following payments to CFF:

4.2.1 <u>Approval Royalties</u>. Corbus shall make the following royalty payments to CFF in the event of the following Approvals:

(a) A royalty payment equal to one and one-half (1.5) times the amount of the Award, such royalty to be paid by Corbus to CFF within sixty (60) days of the first Approval of the Product in the United States; and

(b) A royalty payment equal to one and one-half (1.5) times the amount of the Award such royalty to be paid by Corbus to CFF within sixty (60) days of the first Approval of the Product in a Major Market.

-17-

The first milestone payment due under Section 4.2.1(a) or (b), as the case may be, may be made in cash or, at Corbus's election, made by notice to CFF within ten (10) days after such Approval, in Corbus shares (the "Share Election"), provided, however, that the Share Election shall no longer be applicable after a Change of Control. If Corbus makes the Share Election: (i) such payment shall be made to the extent available in registered Corbus common shares that can be sold by CFF on the stock exchange on which Corbus is customarily traded immediately following such transfer of shares to CFF or (ii) if such registered shares are not available, Corbus shall register such shares within sixty (60) days of the Share Election. The Corbus shares transferred to CFF as a result of the Share Election shall be determined in accordance with the following sentence to be of equal value to the cash payment otherwise due. If Corbus makes the Share Election, the number of shares transferred to CFF shall be determined by (A) dividing an amount equal to 1.5 times the Award by (B) the average share price of Corbus shares determined by adding the closing prices of Corbus shares on each of the five (5) Trading Days prior to the relevant Approval plus the closing prices of Corbus shares on the Approval date and each of the four (4) Trading Days thereafter, and dividing such sum by ten 10; provided that, if the Approval date is not a Trading Day, the fifth (5th) Trading Day after the Approval date shall be used for purposes of the foregoing calculation; and further provided, if Corbus must register the Shares after the Share Election, and if the shares on the effective date of their registration have a lower market value on the date such shares are registered than the average price calculated in accordance with (B) above, Corbus shall transfer such additional registered shares to CFF on the effective date of such registration as are necessary to provide CFF with a payment equal to such average.

4.2.2 Royalty on Net Sales. Corbus shall pay to CFF:

(a) A royalty equal to two and one-half percent (2.5%) of Net Sales of the Product in the Field within sixty (60) days after any quarter in which such Net Sales occur; and

(b) A royalty equal to one percent (1.0%) of the Net Sales of Non-Field Products within sixty (60) days after any quarter in which such Net Sales occur.

-18-

4.2.3 <u>Disposition Payment</u>. A royalty equal to ten percent (10%) of any amount Corbus and its shareholders receive in connection with the license, sale, or other transfer to a Third Party of the Product and/or Development Plan Technology (a "<u>Disposition Royalty</u>") and a Change of Control (collectively, a "<u>Disposition Transaction</u>"), whether such amounts are received by Corbus upfront, in subsequent milestone payments, or other payment prior to the First Commercial Sale, <u>provided</u>, <u>however</u>, that the Disposition Royalty shall not exceed five (5) times the amount of the Award, and shall be credited against the royalties on Net Sales otherwise due under Section 4.2.2 until the full amount of the Disposition Payment has been offset against such royalties . The Disposition Payment[s] shall be made to CFF with sixty (60) days after Corbus receives any amount attributable to a Disposition Transaction. Corbus shall notify CFF promptly of any Disposition Transaction.

4.3 Warrants. In addition to the royalties specified in Section 4.2, Corbus Pharmaceuticals Holdings, Inc. hereby awards to CFF warrants entitling CFF upon exercise to one-million (1,000,000) Corbus common shares. Such warrants shall be subject to the terms specified in Exhibit D to this Agreement.

4.4 Sales Reports.

4.4.1 <u>Reports</u>. Commencing upon Approval of a Product and ending upon the last payment of all royalties under Section 4.2.2, within sixty (60) days after the end of each quarter, Corbus shall furnish or cause to be furnished to CFF a written sales report or reports covering the relevant period setting forth in detail the Net Sales of Product during such period divided into sales inside the Field and for Non-Field Indications. With respect to sales of Products invoiced in Dollars, the Net Sales amounts and the amounts due to CFF hereunder shall be expressed in Dollars. With respect to sales of Products invoiced in a currency other than Dollars, the Net Sales and amounts due to CFF hereunder shall be expressed in the domestic currency of the party making the sale, together with the Dollar equivalent of the amount payable to CFF, calculated by translating foreign currency sales into Dollars in accordance with Corbus's accounting policies. If any licensee or sublicensee makes any sales invoiced in a currency other than its domestic currency, the Net Sales shall be converted to its domestic currency in accordance with the licensee's or sublicensee's normal accounting principles. Corbus shall keep accurate records in sufficient detail to enable the amounts due hereunder to be determined and to be verified by CFF.

-19-

4.4.2 <u>Independent Accountant</u>. Upon the written request of CFF, at CFF's expense and not more than one time in the twelve (12) month period following the receipt by CFF of the report required under Section 4.4.1, Corbus shall permit an independent accountant selected by CFF to have access during normal business hours to those records of Corbus as may be reasonably necessary to verify the accuracy of the report furnished by Corbus pursuant to this Section 4.4. CFF shall pay the cost of any such examination, <u>provided</u>, <u>however</u>, that if such examination determines that actual Net Sales were five percent (5%) or greater than the amount reported by Corbus to CFF, in addition to promptly paying CFF for any additional royalty then due, Corbus shall reimburse CFF for its reasonable and documented expenses associated with such examination.

4.4.3 <u>Interest</u>. In case of any delay in payment by Corbus to CFF not occasioned by force majeure in accordance with Section 11.4, Interest shall be calculated from the tenth (10^{th}) day after the date upon which the applicable payment first becomes due from Corbus.

4.5 Transferee Liability. In the event of a license, sale or other transfer of the Product and/or Development Plan Technology, Corbus shall cause the licensee, buyer or other transferee to agree to be jointly and severally liable with Corbus for the royalties specified in Section 4.1 and 4.2, and failing that, such license, sale or other transfer shall be null and void.

-20-

ARTICLE V - CONFIDENTIALITY

5.1 Confidentiality.

5.1.1 <u>Definition of Confidential Information</u>. For purposes of this Agreement, "<u>Confidential Information</u>" shall mean all information Recipient received from the Discloser in connection with this Agreement, including (a) the financial terms of this Agreement and any other terms of this Agreement that a Party believes disclosure of which would be harmful to it, and (b) any other trade secrets, confidential or proprietary information, or any other knowledge, information, data, reports, documents or materials, owned, developed or possessed by Discloser(as defined below) whether in tangible or intangible form, the confidentiality of which Discloser takes reasonable measures to protect. "<u>Confidential Information</u>" shall not, however, include any information of Discloser that: (a) is already known to Recipient (as defined below) at the time of its disclosure; (b) becomes publicly known through no wrongful act of Recipient; (c) is received from a Third Party free to disclose it to Recipient and without any obligations to Discloser to keep confidential; (d) is independently developed by Recipient without use of the Confidential Information; or (e) is communicated to a Third Party without confidentiality requirements with express written consent of Discloser.

5.1.2 <u>Non-Disclosure</u>. During the term of this Agreement and for a period of five (5) years thereafter, each Party ("<u>Recipient</u>") shall hold all Confidential Information it receives or received from the other Party ("<u>Discloser</u>") in strict confidence, and, other than as provided herein or without first obtaining the prior written consent of Discloser, Recipient shall not disclose any Confidential Information of Discloser to any Person, except to directors, officers, employees, consultants, committee members, volunteers, contractors, subcontractors, licensees, sublicensees, accountants or counsel of Recipient who have a need to know, who are subject to terms of confidentiality that are no less stringent than such confidentiality terms under this Agreement and who have been informed of the confidential nature of the information. Recipient shall use not less than a reasonable degree of care to protect such Confidential Information of Discloser.

-21-

5.1.3 <u>Required Disclosure</u>. Notwithstanding Section 5.1.2 above, Recipient's disclosure of Confidential Information shall not be prohibited if such disclosure is required by a legally binding requirement; <u>provided</u>, <u>however</u>, that, Recipient shall have first given prompt notice to Discloser of any possible requirement and Discloser shall have been afforded a reasonable opportunity to prevent or limit such disclosure (the "<u>Recipient Notice Requirement</u>"); <u>provided</u>, <u>further</u>, that the Recipient Notice Requirement shall not apply to proceedings which, by applicable law, are of a nature that the existence of such proceedings may not be discloser of made public in which case Recipient shall take all legally available measures to minimize or avoid the public disclosure of Discloser Confidential Information. In the event that Recipient discloser and Exchange Commission or other body regulating Corbus's or its Affiliates' securities (<u>Securities Regulatory Authority</u>"), Corbus shall exercise good faith efforts to give confidential treatment of the information described in Section 5.1.1, and Corbus shall provide CFF with contemporaneous copies of the requests for confidential treatment filed with such Securities Regulatory Authority.

5.1.4 <u>No Use of Confidential Information</u>. Recipient hereby agrees and acknowledges that, other than as provided herein or without first obtaining Discloser's prior written consent, Recipient shall not use any of Discloser's Confidential Information.

-22-

5.2 Publicity; Use of Name.

5.2.1 <u>Mutual Agreement</u>. The Parties shall mutually agree upon the timing and content of any initial press release or other public announcement relating to this Agreement and the transactions contemplated herein.

5.2.2 <u>Prior Written Consent</u>. Except to the extent already disclosed in the initial press release or other public announcement referenced in Section 5.2.1 above, and except as may be otherwise provided herein, neither Party shall issue any press release or make any public announcement concerning the terms of this Agreement or the transactions described herein without the prior written consent of the other Party, which such consent shall not be unreasonably withheld, conditioned or delayed; <u>provided</u>, <u>however</u>, that it shall not be unreasonable for any Party to withhold consent with respect to any press release or public announcement containing any of such Party's Confidential Information; and, <u>provided</u>, <u>further</u>, that this Section 5.2.2 shall not preclude any Party from issuing any such press release or making any such public announcement if such Party reasonably believes that any such release or announcement is (a) legally required by Applicable Laws, or (b) required by the rules of any stock exchange on which such Party's (or such Party's Affiliates') securities are listed.

5.2.3 <u>Advanced Written Copy</u>. In each instance, the Party desiring to issue any press release or to make any public announcement shall provide the other Party with a written copy of the proposed release or announcement in sufficient time prior to public release to allow such other Party to comment upon such release or announcement prior to its public release. In addition, each press release and/or public announcement issued or made pursuant to this Section 5.2 shall include CFF-approved language acknowledging CFF's funding of the Development Plan.

5.2.4 <u>Trademark and Logos</u>. Except as may be otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logos of the other Party for any purpose.

-23-

5.2.5 <u>Permitted Use of Name and Logo</u>. Notwithstanding the foregoing or any contrary provision contained herein, in connection with: (a) any description by CFF of its portfolio and of its industry discovery and Development Plan, and/or (b) CFF's fundraising activities, marketing materials and/or reporting requirements, CFF shall be entitled to use and/or disclose, and Corbus hereby pre-approves CFF's use and/or disclosure of: (i) the mark "Corbus," Corbus's logo and a general description of Corbus, (ii) the existence and a general description of the nature of this Agreement (excluding financial terms), and (iii) a general description of the nature of the Development Plan consistent with the confidentiality terms herein; *provided, however*, CFF shall properly use any and all Corbus trademarks in a manner so as to not diminish its goodwill. Notwithstanding the foregoing or any contrary provision contained herein, in connection with: any description by Corbus or its Affiliates of its portfolio and of its industry discovery and Development Plan, Corbus shall be entitled to use and/or disclose, and CFF hereby pre-approves Corbus's use and/or disclosure of: (i) a general description of CFF, (ii) the existence and a general description of the nature of this Agreement (excluding financial terms), and (iii) a general description of CFF, (ii) the existence and a general description of the nature of this Agreement (excluding financial terms), and (iii) a general description of CFF, (ii) the existence and a general description of the nature of this Agreement (excluding financial terms), and (iii) a general description of CFF, (ii) the existence and a general description of the nature of this Agreement (excluding financial terms), and (iii) a general description of the nature of the confidentiality terms herein.

ARTICLE VI – PUBLICATION

The Parties shall publish the Results of the Phase 2 Clinical Trial at the earliest opportunity that is consistent with the protection of the confidentiality of Development Plan Technology. Corbus reserves the first right to publish or publicly present the data generated during the performance of, or as a result of, the Development Plan (the "Results"), subject to the following terms and conditions. To the extent Corbus decides not to publish or publicly present the Results, Corbus shall in its sole discretion allow CFF to publish or publicly present such Results in accordance with this Article VI, and such consent will be binding if, and only if, provided in writing in accordance with the notice provisions contained herein. The Party proposing to publish or publicly present the Results (the "Publishing Party") will submit a draft of any proposed manuscript, speech, poster or other disclosure to the other Party (the "Non-Publishing Party") for comments at least sixty (60) days prior to submission for publication or oral presentation. The Non-Publishing Party shall notify the Publishing Party in writing within thirty (30) days of receipt of such draft with its comments, which shall be reasonably incorporated by the Publishing Party. The comments of the Non-Publishing Party shall include but not be limited to whether such draft contains (a) information of the Non-Publishing Party which it considers to be Confidential Information under the provisions of Article V hereof, (b) information that if published would have an adverse effect on a Patent which the Non-Publishing Party intends to file or has filed, or (c) information, including but not limited to chemical structures of a Product, which the Non-Publishing Party reasonably believes would be likely to have a material adverse impact on the development or commercialization of a Product. In any such notification, the Non-Publishing Party shall indicate with specificity its suggestions regarding the manner and degree to which the Publishing Party may disclose such information. In the case of item (a) above, no Party shall publish the Confidential Information of the other Party without the prior written consent of such other Party in violation of Article V of this Agreement. In the case of item (b) above, the Non-Publishing Party may request a delay and the Publishing Party shall delay such publication, for a period not exceeding an additional ninety (90) days, to permit the timely preparation and filing of a patent application or an application for a certificate of invention on the information involved. In the case of item (c) above, if the Publishing Party shall disagree with the Non-Publishing Party's assessment of the impact of the publication, then the issue shall be referred to the Program Coordinator of each Party who shall attempt in good faith to reach a fair and equitable resolution of this disagreement. If the disagreement is not resolved in this manner within fourteen (14) days of referral to the respective Program Coordinators, then the decision of publication shall be subject to the Dispute Resolution provisions at Section 11.2, subject always to the confidentiality provisions of Article V hereof. The Parties agree that authorship of any publication will be determined based on the customary standards then being applied in the relevant scientific journal.

Corbus shall acknowledge the financial support of CFF in all Development Plan publications.

-24-

ARTICLE VII – INDEMNIFICATION AND INSURANCE

7.1 Indemnification by Corbus. Corbus shall indemnify, defend and hold harmless CFF, its Affiliates, and their respective directors, officers, employees and agents (including, without limitation, the CFF Designees) (each, a "<u>CFF Indemnitee</u>"), from and against any and all claims, suits and demands of Third Parties and losses, liabilities, damages for personal injury, property damage or otherwise, costs, penalties, fines and expenses (including reasonable fees of attorneys) (collectively, "<u>Losses</u>") arising out of or resulting from: (a) the conduct of the Development Plan by Corbus and any breach of, or inaccuracy in, any of representations or warranties made by Corbus in this Agreement, or any breach or violation of any covenant or agreement of Corbus in or pursuant to this Agreement; and (b) any claim of infringement or misappropriation of intellectual property with respect to the Development Plan or any Product. Corbus will have no obligation to indemnify CFF to the extent that the Losses arise out of or result from, directly or indirectly, any breach of, or inaccuracy in, any representation or warranty made by CFF in this Agreement, or any breach or violation of any covenant or agreement, or the negligence or willful misconduct by or of any of the CFF Indemnitees.

7.2 Claims Procedures. Each CFF Indemnitee shall give notice Corbus promptly after receipt by a CFF Indemnitee of notice of the commencement of any action, suit or proceeding. Subject to Section 7.3, Corbus shall have the right to assume and manage the defense thereof (with counsel reasonably satisfactory to the CFF Indemnitee), including the right to settle, compromise and/or litigate with respect to any such claim (but only after obtaining Corbus's prior written consent with respect to any proposed settlement, compromise or litigation; provided, however, that Corbus shall not be required to obtain the CFF Indemnitee's prior written consent in connection with any proposed settlement, compromise or litigation if, in connection with and following any such settlement, compromise or litigation, the CFF Indemnitee (a) has no liability (monetary or otherwise), (b) has not waived any of its rights and has not admitted to any wrongdoing or guilt, (c) is not subject to any injunction or other equitable or non-monetary relief, and (d) receives a full and unconditional release of all applicable claims and liability).

-25-

7.3 Participation; Assuming Control of the Defense. Notwithstanding Section 7.2 above, CFF may participate in the defense of any claim at its sole expense, with counsel reasonably acceptable to Corbus; provided, however, if (a) there is a conflict of interest that would prevent Corbus, on the one hand, and CFF, on the other hand, from being represented by a single law firm in the defense of such action; in each such instance, or (b) there shall be one or more additional or other defenses available to CFF that are not available to Corbus, then in each such instance Corbus shall pay the reasonable fees and expenses of one law firm serving as counsel for CFF, which law firm shall be subject to the prior consent of Corbus, which consent shall not be unreasonably withheld, conditioned or delayed.

7.4 Insurance. Corbus shall maintain at its own expense, with a reputable insurance carrier, coverage for Corbus, its Affiliates, and their respective employees written on a per occurrence basis commensurate with a reasonable assessment of the risks associated with the conduct of the Development Plans. Maintenance of such insurance coverage will not relieve Corbus of any responsibility under this agreement for damages in excess of insurance limits or otherwise. Corbus shall provide CFF with an insurance certificate from the insurers, brokers or agents evidencing the applicable insurance coverage. At its request, CFF may review Corbus' insurance coverages no more than one time per year.

-26-

7.5 Limitation of Liability. Neither Party shall be liable to the other Party for any special, indirect, incidental, consequential, punitive or exemplary damages, including, but not limited to, lost profits, in connection with such Party's breach of this Agreement.

ARTICLE VIII – PATENTABLE INVENTIONS

8.1 Ownership. All inventions relating to the Development Plan invented, conceived or made and all data and know-how generated with respect thereto exclusively by Corbus or its Affiliates (directly or through others acting on its behalf) during the term of this Agreement (a "<u>Corbus Sole Invention</u>") and all inventions relating to the Development Plan invented, conceived or made and all data and know-how generated with respect thereto exclusively by CFF or its Affiliates (directly or through others acting on its behalf) during the term of this Agreement (a "<u>CFF Sole Invention</u>") shall be solely owned by the Party conceiving or making the invention or generating the data or know-how claimed. All inventions relating to the Development Plan invented, conceived or made and all data and know-how generated with respect thereto by both Parties or their respective Affiliates (directly or through others acting on its behalf) during the term of this Agreement (a "<u>Joint Invention</u>") shall be jointly owned by the CFF and Corbus. Inventorship shall be determined in accordance with United States laws of inventorship.

8.2 Exclusive License Grant. CFF hereby grants, and agrees to grant to Corbus, the consideration of which is acknowledged, an exclusive (even as to CFF) fully paid up worldwide license with the right to grant sublicenses to all its rights under the CFF Patents and Joint Patents for all purposes and to CFF Sole Inventions, Joint Inventions, and all information, methods, data and know-how that CFF controls and is useful to the Development Plan. CFF acknowledges and agrees that it does not retain any rights to any Sole Invention or any Joint Invention or any Patents claiming such Inventions for any purpose whatsoever.

-27-

8.3 Preparation. Corbus will control in its sole discretion the preparation, filing, prosecution, maintenance and enforcement of all Corbus Patents, CFF Sole Inventions, CFF Patents and Joint Patents. CFF will have the right to review, and Corbus will deliver to CFF, all patent applications related to CFF Sole Inventions and Joint Inventions prior to their filing. Notwithstanding the foregoing, nothing herein shall obligate Corbus to prepare or file a patent application directed to any Sole Invention or Joint Invention. CFF agrees to execute any documents of assignment, declaration, or otherwise reasonably necessary for Corbus to file, prosecute, maintain and enforce the Corbus Patents, CFF Patents and Joint Patents.

8.4 Costs. Corbus shall be responsible for all costs incurred in the preparation, prosecution, maintenance and enforcement of Corbus Patents, CFF Patents, and Joint Patents.

8.5 Abandonment. Notwithstanding any contrary provision contained herein, prior to Corbus (or any Affiliate, licensee, sublicensee, transferee or successor of Corbus) abandoning any Patent or patent application related to any Product (including abandonment for failure to pay any required fees) for any reason, Corbus shall promptly notify CFF, or cause CFF to be notified, of such pending abandonment, whereupon CFF shall have the right and opportunity to prosecute or maintain the applicable Patent at CFF's own expense. Corbus hereby agrees to exercise its good faith efforts to obtain such consents, on CFF's behalf, as may be necessary, advisable and/or appropriate for CFF to exercise its rights under this Section 8.5.

8.6 No License. Nothing herein shall be construed as a grant or obligation of grant of any license of any kind or a change of title from Corbus to CFF or any Third Party under any Patent owned or controlled by Corbus unless explicitly stated herein.

-28-

ARTICLE IX - TERM AND TERMINATION

9.1 Term. This Agreement shall become effective as of the Effective Date and, unless earlier terminated pursuant to the other provisions of this Article IX, shall terminate at such time as when there are no longer any payment obligations owing from Corbus to CFF under Article IV hereto.

9.2 Termination by CFF For Cause. Notwithstanding any provision contained herein or in any other document to the contrary, CFF may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement upon the occurrence of any of the following events (each, a "<u>Default</u>") (provided, however, that, in each instance (other than pursuant to Section 9.2(c)), Corbus shall have thirty (30) days following the earlier of Corbus's receipt of written notice from CFF to Corbus of the occurrence of a Default or Corbus becoming aware of such Default to cure such Default):

hereunder;

made; and/or

9.2.2 Any representation or warranty made by Corbus in this Agreement is not true in any material respects as of the date

9.2.1 Any material breach or default by Corbus in the performance of any of its material covenants or obligations

9.2.3 A case or proceeding (i) under the bankruptcy laws of the United States now or hereafter in effect is filed against Corbus or all or substantially all of its assets and such petition or application is not dismissed within sixty (60) days after the date of its filing or Corbus shall file any answer admitting and not contesting such petition, or (ii) under the bankruptcy laws of the United States now or hereafter in effect or under any insolvency, reorganization, receivership, dissolution or liquidation law or statute of any jurisdiction now or hereafter in effect (whether at law or equity) is filed by Corbus for all or substantially all of its assets.

-29-

9.3 Termination for CFF Breach. Corbus may, without prejudice to any other remedies available to it at law or in equity, terminate this Agreement in the event CFF shall have (a) materially breached or defaulted in the performance of any of its material covenants or obligations hereunder or (b) any representation or warranty made by CFF in this Agreement is not true in any material respects as of the date made, and such breach or default shall have continued for thirty (30) days after written notice thereof was provided to CFF by Corbus.

9.4 General Effect of Termination; Survival.

9.4.1 Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of any Party prior to such termination or expiration. Such termination or expiration shall not relieve any Party from obligations which are expressly indicated to survive termination of this Agreement.

9.4.2 If this Agreement is terminated for any reason, all of the Parties' rights and obligations under, and/or the provisions contained in Sections 3.2 and 9.4 and Articles IV, V, VI, VII, VIII, X and XI shall survive termination or expiration of this Agreement.

9.4.3 Subject to Section 8.4, upon termination or expiration of this Agreement, Corbus will retain ownership or exclusive rights to the Corbus Development Plan Technology and the inventions licensed to it by CFF pursuant to Article VIII of this Agreement (including intellectual property rights).

9.5 Prior Agreement. The Parties previously entered into the Prior Agreement. The terms of the Prior Agreement are not intended to be affected by this Agreement, and whether or not this Agreement is terminated, the Prior Agreement shall remain in full force and effect.

-30-

ARTICLE X – REPRESENTATIONS AND WARRANTIES

10.1 Representations and Warranties of Corbus. Corbus represents and warrants to CFF that: (i) this Agreement has been duly executed and delivered by Corbus and constitutes the valid and binding obligation of Corbus, enforceable against Corbus in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles; (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of Corbus and its directors and stockholders; (iii) the individual executing this Agreement on behalf of Corbus is duly authorized to do so; and (iv) no provision contained in this Agreement violates any other agreement to which Corbus is bound or otherwise subject; and (v) without the Award provided for in this Agreement, the development of the Product for use in the Field either would not be conducted by Corbus or would be substantially delayed.

10.2 Representations and Warranties of CFF. CFF represents and warrants to Corbus that: (a) this Agreement has been duly executed and delivered by CFF and constitutes the valid and binding obligation of CFF, enforceable against CFF in accordance with its terms, except as enforceability may be limited by bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles; (b) the execution, delivery and performance of this Agreement have been duly authorized by all necessary action on the part of CFF and its directors; (c) the individual executing this Agreement on behalf of CFF is duly authorized to do so; and (d) no provision contained in this Agreement violates any other agreement to which CFF is bound or otherwise subject.

ARTICLE XI – MISCELLANEOUS PROVISIONS

11.1 Governing Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Maryland.

-31-

11.2 Dispute Resolution.

11.2.1 In the event of any dispute, claim or controversy arising out of, relating to or in any way connected to the interpretation of any provision of this Agreement, the performance of either Party under this Agreement or any other matter under this Agreement, including any action in tort, contract or otherwise, at equity or law (a "Dispute"), either Party may at any time provide the other Party with written notice specifying the nature and terms of such Dispute in reasonable detail. As soon as practicable after receipt of such notice, the chief executive officers of each of the Parties or their designees shall meet at a mutually agreed upon time and location for the purpose of resolving such Dispute. Each Party shall engage in good faith discussions and/or negotiations for a period of up to thirty (30) days to attempt to resolve the Dispute or negotiate an interpretation or revision of the applicable portion of this Agreement which is mutually agreeable to both Parties without the necessity of formal dispute resolution procedures relating thereto.

11.2.2 In the event that such Dispute is not resolved by the Parties in accordance with subparagraph (a), either Party may pursue the resolution of such Dispute in a court of competent jurisdiction.

11.3 Waiver. No provision of this Agreement may be waived except in writing by both Parties hereto. No failure or delay by either Party hereto in exercising any right or remedy hereunder or under applicable law will operate as a waiver thereof, or a waiver of any right or remedy on any subsequent occasion.

11.4 Force Majeure. Neither Party will be in breach hereof by reason of its delay in the performance of or failure to perform any of its obligations hereunder, if that delay or failure is caused by strikes, acts of God or the public enemy, riots, incendiaries, interference by civil or military authorities, compliance with governmental priorities for materials, or any fault beyond its reasonable control. In such event Corbus or CFF, as the case may be, shall immediately notify the other Party of such inability and of the period for which such inability is expected to continue. The Party giving such notice shall thereupon be excused from such of its obligations under this Agreement as it is thereby disabled from performing for so long as it is so disabled. To the extent possible, each Party shall use reasonable efforts to minimize the duration of any force majeure.

-32-

11.5 Severability. Should one or more provisions of this Agreement be or become invalid, then the Parties hereto shall attempt to agree upon valid provisions in substitution for the invalid provisions, which in their economic effect come so close to the invalid provisions that it can be reasonably assumed that the Parties would have accepted this Agreement with those new provisions. If the Parties are unable to agree on such valid provisions, the invalidity of such one or more provisions of this Agreement shall nevertheless not affect the validity of the Agreement as a whole, unless the invalid provisions are of such essential importance for this Agreement that it may be reasonably presumed that the Parties would not have entered into this Agreement without the invalid provisions.

11.6 Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement, without the consent of the other Party, (i) to any of its Affiliates, if the assigning Party unconditionally guarantees the full performance of its Affiliate's obligations hereunder, or (ii) in connection with such Party's merger, consolidation or transfer, license or sale of all or substantially all of the assets of such Party to which this Agreement relates, provided, that the successor, surviving entity, purchaser of assets, transferee, or other similar party, as applicable, expressly assumes in full in writing such Party's obligations under this Agreement. Any purported assignment in contravention of this Section 11.6 shall, at the option of the non-assigning Party, be null and void and of no effect. No assignment shall release either Party from responsibility for the performance of any accrued obligation of such Party hereunder. This Agreement shall be binding upon and enforceable against the successor to, or any permitted assignees from, either of the Parties hereto.

-33-

11.7 Counterparts. This Agreement may be executed in duplicate, each of which shall be deemed to be original and both of which shall constitute one and the same Agreement.

11.8 No Agency. Nothing herein contained shall be deemed to create an agency, joint venture, partnership or similar relationship between CFF and Corbus. Notwithstanding any of the provisions of this Agreement, neither Party to this Agreement shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever, and all contracts, expenses and liabilities in connection with or relating to the obligations of each Party under this Agreement shall be made, paid, and undertaken exclusively by such Party on its own behalf and not as an agent or representative of the other.

11.9 Notice. All communications between the Parties with respect to any of the provisions of this Agreement will be sent to the addresses set out below, or to such other addresses as may be designated by one party to the other by notice pursuant hereto, by prepaid, certified air mail (which shall be deemed received by the other Party on the seventh (7th) business day following deposit in the mails), or by facsimile transmission, or other electronic means of communication (which shall be deemed received when transmitted), with confirmation by first class letter, postage pre-paid, given by the close of business on or before the next following business day, or by a nationally recognized overnight courier (which shall be deemed received on the date of delivery):

-34-

if to CFF:

Dr. Preston Campbell, III President and CEO 4550 Montgomery Ave. Suite 1100N Bethesda, Maryland 20814 Phone: Fax: E-mail: <u>Pcampbell@cff.org</u>

with a copy to:

Kenneth I. Schaner, Esq. Schaner & Lubitz, PLLC 4550 Montgomery Ave. Suite 1100N Bethesda, Maryland 20814 Phone: 240-482-2848 Fax: 202-470-2241 E-mail: <u>ken@schanerlaw.com</u>

if to Corbus:

Yuval Cohen, CEO Corbus Pharmaceuticals, Inc 100 River Ridge Drive Norwood, MA 02062 Phone: 617-963-0100 Fax: 617-663-6085 E-mail: <u>ycohen@CorbusPharma.com</u>

with a copy to:

Lowenstein Sandler LLP 65 Livingston Avenue Roseland, New Jersey 07068 Attn: Michael J. Lerner, Esq. Phone: 973-597-6395 E-mail: <u>mlerner@lowenstein.com</u>

-35-

11.10 Headings. The paragraph headings are for convenience only and will not be deemed to affect in any way the language of the provisions to which they refer.

11.11 Entire Agreement. This Agreement contains the entire understanding of the Parties relating to the matters referred to herein, and may only be amended by a written document, duly executed on behalf of the respective Parties.

11.12 No Impairment. Corbus will not, by amendment of its organizational or governing documents, or through reorganization, recapitalization, consolidation, merger, dissolution, sale, transfer or assignment of assets, issuance of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms, provisions, covenants or agreements of this Agreement, but rather will at all times in good faith assist in the carrying out of all such terms, provisions, covenants and agreements and in the taking of all such actions as may be necessary, advisable or appropriate in order to protect the rights of CFF against impairment.

[Remainder of page intentionally left blank]



IN WITNESS WHEREOF, the undersigned have executed this Research, Development and Commercialization Agreement as of the date first written above.

| CYSTIC FIBROSIS FOUNDATION | | CORBUS PHARMACEUTICALS, INC. | |
|----------------------------|----------------------|------------------------------|--|
| By: | /s/ Preston Campbell | By: /s/ Yuval Cohen | |
| Name | : Preston Campbell | Name: Yuval Cohen | |
| Title: | President and CEO | Title: CEO | |
| [Signature Page] | | | |

EXHIBIT A

Development Plan

A Multicenter, Randomized, Double-blind, Placebo-controlled Phase 2 Trial to Evaluate Efficacy and Safety of Lenabasum in Cystic Fibrosis

INVESTIGATIONAL PRODUCT: Lenabasum

INDICATION: Cystic fibrosis

INVESTIGATIONAL SITES/LOCATIONS: Up to 100 sites in North America, Europe, Israel and Australia are planned

OBJECTIVES AND ENDPOINTS:

| Primary efficacy objective | Primary endpoint | |
|---|---|--|
| To evaluate the efficacy of lenabasum 20 mg twice per day (BID) compared to placebo in the treatment of cystic fibrosis (CF) by assessing the rate of pulmonary exacerbations (PEx) using primary definition of PEx | Rate of PEx using primary definition of PEx with lenabasum 20 mg BID, compared to placebo, during the treatment period | |
| Secondary efficacy objective | Secondary endpoints | |
| 1. To evaluate the efficacy of lenabasum 20 mg BID compared to placebo in the treatment of CF by assessing other efficacy endpoints | a. Event rate of PEx using secondary definition of PEx with lenabasum 20 mg BID compared to placebo b. Time to first new PEx using primary definition of PEx with lenabasum 20 mg BID compared to placebo c. Time to first PEx using secondary definition of PEx with lenabasum 20 mg BID compared to placebo d. Change from baseline in CFQ-R respiratory symptom domain with lenabasum 20 mg BID compared to placebo e. Change from baseline in FEV1 % predicted with lenabasum 20 mg BID | |

compared to placebo

| 2. To evaluate the efficacy of lenabasum 5 mg BID compared to placebo in the treatment of CF | a. Rate of pulmonary exacerbations (PEx) using primary definition of PEx with lenabasum 5 mg BID compared to placebo, during the treatment period b. Event rate of PEx using secondary definition of PEx with lenabasum 5 mg BID compared to placebo c. Time to first new PEx using primary definition of PEx with lenabasum 5 mg BID compared to placebo d. Time to first PEx using secondary definition of PEx with lenabasum 5 mg BID compared to placebo e. Change from baseline in CFQ-R respiratory symptom domain with lenabasum 5 mg BID compared to placebo f. Change from baseline in FEV1 % predicted with lenabasum 5 mg BID compared to placebo |
|--|---|
| Tertiary efficacy objective | Tertiary endpoints |
| [*] | a. [*] b. [*] c. [*] d. [*] e. [*] f. [*] g. [*] |

| Pharmacokinetic (PK) objec | ctives PK endpoints | |
|----------------------------|---------------------|--|
| [*] | [*] | |
| [*] | [*] | |
| [*] | [*] | |
| [*] | [*] | |
| | | |

Safety objectives

To evaluate safety of lenabasum 20 mg BID and lenabasum 5 mg BID treatment and placebo treatment

To evaluate tolerability of lenabasum 20 mg BID and lenabasum 5 mg BID treatment

• TEAEs

• Changes in vital signs, physical examination, blood and urine laboratory safety tests and electrocardiograms

Treatment discontinuations with lenabasum treatments compared to placebo

Safety endpoints

STUDY DESIGN:

This is a multicenter, double-blind, randomized, placebo-controlled, parallel group trial of efficacy and safety of treatment of CF subjects with lenabasum 20 mg BID and lenabasum 5 mg BID.

This trial includes analyses of event rate of and time to PEx. In this study, primary definition of PEx is based on the physician decision to treat with oral, intravenous or inhaled antibiotic(s) in the presence of at least 4/12 Fuch's criteria. [*].

The target population is males and females with $CF \ge 12$ years of age with $FEV1 \ge 40\%$ predicted and < 100% predicted in 12 months before screening. The target population will be enriched for subjects with increased risk of a new PEx [*]. Subjects must have 2 or 3 new PEx treated with intravenous (IV) antibiotics in the 12 months before screening. Alternatively, if the subject had only 1 new PEx treated with IV antibiotics in the last 12 months, then that subject must have ≥ 1 other new PEx treated with oral antibiotics in the last 12 months before screening; [*].

See Table 1 below for the eligibility criterion by number of new PEx in the 12 months before screening.

Table 1 Eligibility by Number of New PEx in 12 Months before Screening

| New PEx treated with New PEx treated with oral | | |
|--|----------------|--------------------------|
| intravenous antibiotics, N | antibiotics, N | Eligible by PEx criteria |
| 2 or 3 | No requirement | Yes |
| 1 | ≥ 1 | Yes |
| 0, > 3 | Not applicable | No |

[*] subjects will be screened to identify a target of 415 eligible subjects. [*].

Subjects will be randomized centrally to treatment assignment before dosing in a 2:1:2 ratio to 1 of 3 treatment cohorts:

1. Cohort 1: Lenabasum 20 mg BID, n = 166

- 2. Cohort 2: Lenabasum 5 mg BID, n = 83
- 3. Cohort 3: Placebo BID, n = 166.

[*].

Duration and Visits

[*]. Active dosing with study drug is 28 weeks. [*].

[*] they will return 4 weeks after the last dose of study drug [*].

[*].

[*].

Efficacy Assessments

- [*]
- [*]
- [*]
- [*]
- CFQ-R questionnaire at screening, [*]
- [*]
- [*]

Safety Assessments

- [*]
- [*]
- [*]
- [*]
- [*]
STUDY SCHEMATIC

[*]

SUBJECTS (PLANNED): 415 subjects

PATIENT POPULATION:

Target population for this study is subjects \geq 12 years of age with known diagnosis of CF, with history of prior PEx in the last 12 months, [*].

STUDY PRODUCTS, DOSE AND MODE OF ADMINISTRATION

Study drugs are [*] of lenabasum 20 mg, lenabasum 5 mg and placebo.

- Lenabasum: The preparation of lenabasum that will be used in this study is [*]
- Placebo: [*]

Lenabasum and placebo capsules are identical in terms of appearance. Both are packaged in the same type container closures with the same number of capsules.

[*].

DURATION OF TREATMENT: 28 weeks

DISCONTINUATION FROM TREATMENT:

Removal of Subjects from Therapy or Assessments:

An individual subject will have study drug permanently discontinued if any of the following occur in the subject in question:

- Withdrawal of consent
- Pregnancy

- Any serious TEAE probably or definitely-related to lenabasum
- Any life-threatening AE.

[*].

Premature Termination or Suspension of the Study:

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. If any of the following events occur in a subject during enrollment, study entry and randomization of new subjects into the study will be suspended until review of the event in question occurs by the Data Monitoring Committee (DMC):

- [*]
- [*]
- [*]
- [*]

Administration of study drug may continue during the time of review in subjects who are already receiving study drug, based on the judgment of the Chief Medical Officer of Corbus.

An expedited and cumulative review of safety data and the circumstances of the event(s) in question will be conducted by the DMC, with additional external expertise as needed, to make recommendations to Corbus whether screening, randomization, and/or dosing can resume or should be discontinued, whether the protocol should be modified, or whether the study should be discontinued permanently. Upon consideration of a cumulative review of safety and other data, the study can be discontinued permanently by Corbus.

Written notification, documenting the reason for study suspension or termination, will be provided by Corbus to the investigators and the respective country regulatory authorities. If the study is suspended or prematurely terminated, the investigators will promptly inform the reviewing Independent Ethics Committee/Institutional Review Board (hereafter referred to as the Ethics Committee or EC) at each site and will provide the reason(s) for the suspension or termination. Review and approval by the reviewing EC at each site is required for resumption of the study in the event the study is interrupted.

STATISTICAL ANALYSES:

The Statistical Analysis Plan will be completed before database locking and unblinding.

The study is expected to enroll approximately 415 subjects, with \sim 166 subjects each in the lenabasum 20 mg BID and placebo BID cohorts and \sim 83 subjects in the lenabasum 5 mg BID cohort [*].

[*]

[*]

- [*]
- [*]

Efficacy comparisons will be made between each dose of lenabasum and placebo. The event rate of new PEx will be compared between the lenabasum and placebo groups [*].

For time to first PEx, [*] will be used for comparing the [*] between the active and placebo groups. [*].

[*] endpoints such as [*], change in CFQ-R domain scores, change in FEV1 % predicted, [*],[*],[*], and [*] will be analyzed using [*].

[*]

- [*]
- [*]
- . .
- [*]

EXHIBIT B

Milestone Payments and Budget

Milestone Payments

| Milestone | Milestone Payment | Expected Milestone Completion Date |
|-------------------------|-------------------|------------------------------------|
| Upon Contract Execution | 10% (\$2,500,000) | [*] |
| [*] | 15% (\$3,750,000) | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| [*] | [*] | [*] |
| | | |

BUDGET

[*][NOTE: Approximately seven pages of this Exhibit B for which confidential treatment has been requested have been omitted and filed separately with the Securities and Exchange Commission.]

EXHIBIT C

CFF Patents

None.

<u>Exhibit D</u>

Warrants Awarded to CFF

Warrant Certificate No. F-1

NEITHER THE SECURITIES REPRESENTED BY THIS CERTIFICATE NOR THE SECURITIES ISSUABLE UPON THE EXERCISE OF THIS WARRANT HAVE BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS, AND NEITHER SUCH SECURITIES NOR ANY INTEREST THEREIN MAY BE OFFERED, SOLD, ASSIGNED OR OTHERWISE TRANSFERRED UNLESS (1) A REGISTRATION STATEMENT WITH RESPECT THERETO IS EFFECTIVE UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS, OR (2) AN EXEMPTION FROM SUCH REGISTRATION EXISTS AND THE COMPANY RECEIVES AN OPINION OF COUNSEL TO THE HOLDER OF SUCH SECURITIES, WHICH COUNSEL AND OPINION ARE SATISFACTORY TO THE COMPANY, THAT SUCH SECURITIES MAY BE OFFERED, SOLD, PLEDGED, ASSIGNED OR TRANSFERRED IN THE MANNER CONTEMPLATED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR APPLICABLE STATE SECURITIES LAWS.

Effective Date: January 26, 2018

Void After: January 26, 2025

CORBUS PHARMACEUTICALS HOLDINGS, INC.

WARRANT TO PURCHASE COMMON STOCK

Corbus Pharmaceuticals Holdings, Inc., a Delaware corporation (the "**Company**"), for value received on January 26, 2018 (the "**Effective Date**"), hereby issues to The Cystic Fibrosis Foundation (the "**Holder**") this warrant (the "**Warrant**") to purchase, 1,000,000 shares (each such share as from time to time adjusted as hereinafter provided being a "**Warrant Share**" and all such shares being the "**Warrant Shares**") of the Company's Common Stock (as defined below), at the Exercise Price (as defined below), as adjusted from time to time as provided herein, on or before January 26, 2025 (the "**Expiration Date**"), all subject to the following terms and conditions.

As used in this Warrant, (i) "**Business Day**" means any day other than Saturday, Sunday or any other day on which commercial banks in the City of New York, New York, are authorized or required by law or executive order to close; (ii) "**Common Stock**" means the common stock of the Company, par value \$0.0001 per share, including any securities issued or issuable with respect thereto or into which or for which such shares may be exchanged for, or converted into, pursuant to any stock dividend, stock split, stock combination, recapitalization, reclassification, reorganization or other similar event; (iii) "**Exercise Price**" means \$13.20 per share of Common Stock, subject to adjustment as provided herein; (iv) "**Trading Day**" means any day on which the Common Stock is traded (or available for trading) on its principal Trading Market (as defined below); and (v) "**Affiliate**" means any person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, a person, as such terms are used and construed in Rule 144 promulgated under the Securities Act of 1933, as amended (the "**Securities Act**"). For purposes hereof, "**Trading Market**" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Select Market, the NASDAQ Global Market, the NASDAQ Capital Market, or any other national securities exchange, as well as the OTC Bulletin Board or any tier of the OTC Markets.

1. DURATION AND EXERCISE OF WARRANTS

(a) <u>Exercise Period</u>. Commencing on the Effective Date of this Warrant, the Holder may exercise this Warrant for up to 500,000 shares of Common Stock (the "**Initial Exercise Amount**"). Upon the Completion of the CF Trial (as defined below), the Holder may exercise this Warrant for the remaining 500,000 shares of Common Stock (the "**Additional Exercise Amount**") issuable pursuant to the terms of this Warrant. At no point in time, may the Holder exercise this Warrant for more than 1,000,000 shares of Common Stock in the aggregate. The Holder may exercise this Warrant, in whole or in part (in accordance with the limitations set forth in this Section 1(a)), on any Business Day on or before 5:00 P.M., Eastern Time, on the Expiration Date, at which time this Warrant shall become void and of no value. For purposes of this Warrant, the term "**Completion of the CF Trial**" shall mean completion of the final Milestone by the Company and receipt of the final Milestone Payment by the Company from Cystic Fibrosis Foundation as set forth in Exhibit B to the Cystic Fibrosis Program Related Investment Agreement by and between Corbus Pharmaceuticals, Inc. and Cystic Fibrosis Foundation dated January 26, 2018.

(b) Exercise Procedures.

(i) While this Warrant remains outstanding and exercisable in accordance with Section 1(a), the Holder may exercise this Warrant in whole or in part at any time and from time to time by:

(A) delivery to the Company of a duly executed copy of the Notice of Exercise attached as Exhibit A;

(B) surrender of this Warrant to the Secretary of the Company at its principal offices or at such other office or agency as the Company may specify in writing to the Holder; and

(C) payment of the then-applicable Exercise Price per share multiplied by the number of Warrant Shares being purchased upon exercise of the Warrant (such amount, the "Aggregate Exercise Price") made in the form of cash, or by certified check, bank draft or money order payable in lawful money of the United States of America.

(ii) Upon the exercise of this Warrant in compliance with the provisions of Section 1(a) and this Section 1(b), the Company shall promptly issue and cause to be delivered to the Holder a certificate for the Warrant Shares purchased by the Holder. Each exercise of this Warrant shall be effective immediately prior to the close of business on the date (the "Date of Exercise") that the conditions set forth in this Section 1(b) have been satisfied, as the case may be. On the first Business Day following the date on which the Company has received each of the Notice of Exercise and the Aggregate Exercise Price (the "Exercise Delivery Documents"), the Company shall transmit an acknowledgment of receipt of the Exercise Delivery Documents to the Company's transfer agent (the "Transfer Agent"). On or before the second Business Day following the date on which the Company has received all of the Exercise Delivery Documents (the "Share Delivery Date"), the Company shall (X) provided that the Transfer Agent is participating in The Depository Trust Company ("DTC") Fast Automated Securities Transfer Program, upon the request of the Holder, credit such aggregate number of shares of Common Stock to which the Holder is entitled pursuant to such exercise to the Holder's or its designee's balance account with DTC through its Deposit Withdrawal Agent Commission system, or (Y) if the Transfer Agent is not participating in the DTC Fast Automated Securities Transfer Program, issue and dispatch by overnight courier to the address as specified in the Notice of Exercise, a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of shares of Common Stock to which the Holder is entitled pursuant to such exercise. Upon delivery of the Exercise Delivery Documents, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the certificates evidencing such Warrant Shares.

(c) <u>Partial Exercise</u>. This Warrant shall be exercisable, either in its entirety or, from time to time, for part only of the number of Warrant Shares referenced by this Warrant for which the Warrant is then currently exercisable. If this Warrant is submitted in connection with any exercise pursuant to Section 1 and the number of Warrant Shares represented by this Warrant submitted for exercise is greater than the actual number of Warrant Shares being acquired upon such an exercise, then the Company shall as soon as practicable after any exercise and at its own expense, issue a new Warrant of like tenor representing the right to purchase the number of Warrant Shares purchasable immediately prior to such exercise under this Warrant, less the number of Warrant Shares with respect to which this Warrant is exercised.

(d) <u>Disputes</u>. In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall promptly issue to the Holder the number of Warrant Shares that are not disputed and resolve such dispute in accordance with Section 16.

2. ISSUANCE OF WARRANT SHARES

(a) The Company covenants that all Warrant Shares will, upon issuance in accordance with the terms of this Warrant, be (i) duly authorized, fully paid and non-assessable, and (ii) free from all liens, charges and security interests, with the exception of claims arising through the acts or omissions of any Holder and except as arising from applicable Federal and state securities laws.

(b) The Company shall register this Warrant upon records to be maintained by the Company for that purpose in the name of the record holder of such Warrant from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner thereof for the purpose of any exercise thereof, any distribution to the Holder thereof and for all other purposes.

(c) The Company will not, by amendment of its certificate of incorporation, by-laws or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed hereunder by the Company, but will at all times in good faith assist in the carrying out of all the provisions of this Warrant and in the taking of all action necessary or appropriate in order to protect the rights of the Holder to exercise this Warrant, or against impairment of such rights.

3. ADJUSTMENTS OF EXERCISE PRICE, NUMBER AND TYPE OF WARRANT SHARES

(a) The Exercise Price and the number of shares purchasable upon the exercise of this Warrant shall be subject to adjustment from time to time upon the occurrence of certain events described in this Section 3; <u>provided</u>, that notwithstanding the provisions of this Section 3, the Company shall not be required to make any adjustment if and to the extent that such adjustment would require the Company to issue a number of shares of Common Stock in excess of its authorized but unissued shares of Common Stock, less all amounts of Common Stock that have been reserved for issue upon the conversion of all outstanding securities convertible into shares of Common Stock and the exercise of all outstanding options, warrants and other rights exercisable for shares of Common Stock. If the Company does not have the requisite number of authorized but unissued shares of Common Stock to make any adjustment, the Company shall use its commercially reasonable efforts to obtain the necessary stockholder consent to increase the authorized number of shares of Common Stock to make such an adjustment pursuant to this Section 3.

(i) <u>Subdivision or Combination of Stock</u>. In case the Company shall at any time subdivide (whether by way of stock dividend, stock split or otherwise) its outstanding shares of Common Stock into a greater number of shares, the Exercise Price in effect immediately prior to such subdivision shall be proportionately reduced and the number of Warrant Shares, the Initial Exercise Amount and the Additional Exercise Amount shall be proportionately increased, and conversely, in case the outstanding shares of Common Stock of the Company shall be combined (whether by way of stock combination, reverse stock split or otherwise) into a smaller number of shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased and the number of Warrant Shares, the Exercise Price in effect immediately prior to such combination shall be proportionately increased and the number of Warrant Shares, the Initial Exercise Amount and the Additional Exercise Amount shall be proportionately decreased. The Exercise Price, the Warrant Shares, the Initial Exercise Amount and the Additional Exercise Amount, as so adjusted, shall be readjusted in the same manner upon the happening of any successive event or events described in this Section 3(a)(i).

(ii) <u>Dividends in Stock, Property, Reclassification</u>. If at any time, or from time to time, all of the holders of Common Stock (or any shares of stock or other securities at the time receivable upon the exercise of this Warrant) shall have received or become entitled to receive, without payment therefore:

(A) any shares of stock or other securities that are at any time directly or indirectly convertible into or exchangeable for Common Stock, or any rights or options to subscribe for, purchase or otherwise acquire any of the foregoing by way of dividend or other distribution, or

(B) additional stock or other securities or property (including cash) by way of spin-off, split-up, reclassification, combination of shares or similar corporate rearrangement (other than shares of Common Stock issued as a stock split or adjustments in respect of which shall be covered by the terms of Section 3(a)(i) above), then and in each such case, the Exercise Price and the number of Warrant Shares to be obtained upon exercise of this Warrant shall be adjusted proportionately, and the Holder hereof shall, upon the exercise of this Warrant, be entitled to receive, in addition to the number of shares of Common Stock receivable thereupon, and without payment of any additional consideration therefor, the amount of stock and other securities and property (including cash in the cases referred to above) that such Holder would hold on the date of such exercise had such Holder been the holder of record of such Common Stock as of the date on which holders of Common Stock received or became entitled to receive such shares or all other additional stock and other securities and property. The Exercise Price and the Warrant Shares, as so adjusted, shall be readjusted in the same manner upon the happening of any successive event or events described in this Section 3(a)(ii).

(iii) Reorganization, Reclassification, Consolidation, Merger or Sale. If any recapitalization, reclassification or reorganization of the capital stock of the Company, or any consolidation or merger of the Company with another corporation, or the sale of all or substantially all of its assets or other transaction shall be effected in such a way that holders of Common Stock shall be entitled to receive stock, securities, or other assets or property (an "Organic Change"), then, as a condition of such Organic Change, lawful and adequate provisions shall be made by the Company whereby the Holder hereof shall thereafter have the right to purchase and receive (in lieu of the shares of the Common Stock of the Company immediately theretofore purchasable and receivable upon the exercise of the rights represented by this Warrant) such shares of stock, securities or other assets or property as may be issued or payable with respect to or in exchange for a number of outstanding shares of such Common Stock equal to the number of shares of such stock immediately theretofore purchasable and receivable assuming the full exercise of the rights represented by this Warrant. In the event of any Organic Change, appropriate provision shall be made by the Company with respect to the rights and interests of the Holder to the end that the provisions hereof (including, without limitation, provisions for adjustments of the Exercise Price and of the number of shares purchasable and receivable upon the exercise of this Warrant) shall thereafter be applicable, in relation to any shares of stock, securities or assets thereafter deliverable upon the exercise hereof. The Company will not affect any such consolidation, merger or sale unless, prior to the consummation thereof, the successor corporation (if other than the Company) resulting from such consolidation or merger or the corporation purchasing such assets shall assume by written instrument reasonably satisfactory in form and substance to the Holder executed and mailed or delivered to the registered Holder hereof at the last address of such Holder appearing on the books of the Company, the obligation to deliver to such Holder such shares of stock, securities or assets as, in accordance with the foregoing provisions, such Holder may be entitled to purchase. If there is an Organic Change, then the Company shall cause to be mailed to the Holder at its last address as it shall appear on the books and records of the Company, at least 10 calendar days before the effective date of the Organic Change, a notice stating the date on which such Organic Change is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares for securities, cash, or other property delivered upon such Organic Change; provided, that the failure to mail such notice or any defect therein or in the mailing thereof shall not affect the validity of the corporate action required to be specified in such notice. The Holder is entitled to exercise this Warrant during the 10-day period for the amount of shares of Common Stock for which this Warrant is then currently exercisable commencing on the date of such notice to the effective date of the event triggering such notice. In any event, the successor corporation (if other than the Company) resulting from such consolidation or merger or the corporation purchasing such assets shall be deemed to assume such obligation to deliver to such Holder such shares of stock, securities or assets even in the absence of a written instrument assuming such obligation to the extent such assumption occurs by operation of law.

(b) <u>Certificate as to Adjustments</u>. Upon the occurrence of each adjustment or readjustment pursuant to this Section 3, the Company at its expense shall promptly compute such adjustment or readjustment in accordance with the terms hereof and furnish to each Holder a certificate setting forth such adjustment or readjustment and showing in detail the facts upon which such adjustment or readjustment is based. The Company shall promptly furnish or cause to be furnished to such Holder a like certificate setting forth: (i) such adjustments and readjustments; and (ii) the number of shares and the amount, if any, of other property which at the time would be received upon the exercise of the Warrant.

(c) <u>Certain Events</u>. If any event occurs as to which the other provisions of this Section 3 are not strictly applicable but the lack of any adjustment would not fairly protect the purchase rights of the Holder under this Warrant in accordance with the basic intent and principles of such provisions, or if strictly applicable would not fairly protect the purchase rights of the Holder under this Warrant in accordance with the basic intent and principles of such provisions, then the Company's Board of Directors will, in good faith, make an appropriate adjustment to protect the rights of the Holder; <u>provided</u>, that no such adjustment pursuant to this Section 3(c) will increase the Exercise Price or decrease the number of Warrant Shares as otherwise determined pursuant to this Section 3.

4. RESERVED

5. TRANSFERS AND EXCHANGES OF WARRANT AND WARRANT SHARES

(a) <u>Registration of Transfers and Exchanges</u>. Subject to Section 5(c), upon the Holder's surrender of this Warrant, with a duly executed copy of the Form of Assignment attached as **Exhibit B**, to the Secretary of the Company at its principal offices or at such other office or agency as the Company may specify in writing to the Holder, the Company shall register the transfer of all or any portion of this Warrant. Upon such registration of transfer, the Company shall issue a new Warrant, in substantially the form of this Warrant, evidencing the acquisition rights transferred to the transfere and a new Warrant, in similar form, evidencing the remaining acquisition rights not transferred, to the Holder requesting the transfer.

(b) <u>Warrant Exchangeable for Different Denominations</u>. The Holder may exchange this Warrant for a new Warrant or Warrants, in substantially the form of this Warrant, evidencing in the aggregate the right to purchase the number of Warrant Shares which may then be purchased hereunder, each of such new Warrants to be dated the date of such exchange and to represent the right to purchase such number of Warrant Shares as shall be designated by the Holder. The Holder shall surrender this Warrant with duly executed instructions regarding such re-certification of this Warrant to the Secretary of the Company at its principal offices or at such other office or agency as the Company may specify in writing to the Holder.

(c) <u>Restrictions on Transfers</u>. This Warrant may not be transferred at any time without: (i) registration under the Securities Act; or (ii) an exemption from such registration and a written opinion of legal counsel addressed to the Company that the proposed transfer of the Warrant may be effected without registration under the Securities Act, which opinion will be in form and from counsel reasonably satisfactory to the Company.

(d) <u>Permitted Transfers and Assignments</u>. Notwithstanding any provision to the contrary in this Section 5, the Holder may transfer, with or without consideration, this Warrant or any of the Warrant Shares (or a portion thereof) to the Holder's Affiliates without obtaining the opinion from counsel that may be required by Section 5(c)(ii), <u>provided</u>, that the Holder delivers to the Company and its counsel certification, documentation, and other assurances reasonably required by the Company's counsel to enable the Company's counsel to render an opinion to the Company's Transfer Agent that such transfer does not violate applicable securities laws.

6. MUTILATED OR MISSING WARRANT CERTIFICATE

If this Warrant is mutilated, lost, stolen or destroyed, upon request by the Holder, the Company will, at its expense, issue, in exchange for and upon cancellation of the mutilated Warrant, or in substitution for the lost, stolen or destroyed Warrant, a new Warrant, in substantially the form of this Warrant, representing the right to acquire the equivalent number of Warrant Shares; <u>provided</u>, that, as a prerequisite to the issuance of a substitute Warrant, the Company may require satisfactory evidence of loss, theft or destruction as well as an indemnity from the Holder of a lost, stolen or destroyed Warrant.

7. PAYMENT OF TAXES

The Company will pay all transfer and stock issuance taxes attributable to the preparation, issuance and delivery of this Warrant and the Warrant Shares (and replacement Warrants) including, without limitation, all documentary and stamp taxes; <u>provided</u>, <u>however</u>, that the Company shall not be required to pay any tax in respect of the transfer of this Warrant, or the issuance or delivery of certificates for Warrant Shares or other securities in respect of the Warrant Shares to any person or entity other than to the Holder.

8. FRACTIONAL WARRANT SHARES

No fractional Warrant Shares shall be issued upon exercise of this Warrant. The Company, in lieu of issuing any fractional Warrant Share, shall round up the number of Warrant Shares issuable to nearest whole share.

9. NO STOCK RIGHTS AND LEGEND

No holder of this Warrant, as such, shall be entitled to vote or be deemed the holder of any other securities of the Company that may at any time be issuable on the exercise hereof, nor shall anything contained herein be construed to confer upon the holder of this Warrant, as such, the rights of a stockholder of the Company or the right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or give or withhold consent to any corporate action or to receive notice of meetings or other actions affecting stockholders (except as provided herein), or to receive dividends or subscription rights or otherwise (except as provide herein).

Each certificate for Warrant Shares initially issued upon the exercise of this Warrant, and each certificate for Warrant Shares issued to any subsequent transferee of any such certificate, shall be stamped or otherwise imprinted with a legend in substantially the following form:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS, AND NEITHER SUCH SECURITIES NOR ANY INTEREST THEREIN MAY BE OFFERED, SOLD, PLEDGED, ASSIGNED OR OTHERWISE TRANSFERRED UNLESS (1) A REGISTRATION STATEMENT WITH RESPECT THERETO IS EFFECTIVE UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS, OR (2) AN EXEMPTION FROM SUCH REGISTRATION EXISTS AND THE COMPANY RECEIVES AN OPINION OF COUNSEL TO THE HOLDER OF SUCH SECURITIES, WHICH COUNSEL AND OPINION ARE REASONABLY SATISFACTORY TO THE COMPANY, THAT SUCH SECURITIES MAY BE OFFERED, SOLD, PLEDGED, ASSIGNED OR TRANSFERRED IN THE MANNER CONTEMPLATED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT OR APPLICABLE STATE SECURITIES LAWS."

10. LOCK-UP

Any Warrant Shares acquired pursuant to an exercise of this Warrant must not be transferred, sold, hypothecated or otherwise disposed for a period of one year from the date on which the Share Delivery Date .

11. NOTICES

All notices, consents, waivers, and other communications under this Warrant must be in writing and will be deemed given to a party when (a) delivered to the appropriate address by hand or by nationally recognized overnight courier service (costs prepaid); (b) sent by facsimile or e-mail with confirmation of transmission by the transmitting equipment; (c) received or rejected by the addressee, if sent by certified mail, return receipt requested, if to the registered Holder hereof; or (d) seven (7) days after the placement of the notice into the mails (first class postage prepaid), to the Holder at the address, facsimile number, or e-mail address furnished by the registered Holder to the Company in accordance with the Subscription Agreement by and between the Company and the Holder, or if to the Company, to it at One Kendall Square, Bldg 200, Cambridge, MA 02139, Attn: Yuval Cohen, CEO (or to such other address, facsimile number, or e-mail address as the Holder or the Company as a party may designate by notice the other party).

12. SEVERABILITY

If a court of competent jurisdiction holds any provision of this Warrant invalid or unenforceable, the other provisions of this Warrant will remain in full force and effect. Any provision of this Warrant held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

13. BINDING EFFECT

This Warrant shall be binding upon and inure to the sole and exclusive benefit of the Company, its successors and assigns, the registered Holder or Holders from time to time of this Warrant and the Warrant Shares.

14. SURVIVAL OF RIGHTS AND DUTIES

This Warrant shall terminate and be of no further force and effect on the earlier of 5:00 P.M., Eastern Time, on the Expiration Date or the date on which this Warrant has been exercised in full.

15. GOVERNING LAW

This Warrant will be governed by and construed under the laws of the State of New York without regard to conflicts of laws principles that would require the application of any other law.

16. DISPUTE RESOLUTION

In the case of a dispute as to the determination of the Exercise Price or the arithmetic calculation of the Warrant Shares, the Company shall submit the disputed determinations or arithmetic calculations via facsimile within two (2) Business Days of receipt of the Notice of Exercise giving rise to such dispute, as the case may be, to the Holder. If the Holder and the Company are unable to agree upon such determination or calculation of the Exercise Price or the Warrant Shares within three Business Days of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall, within two Business Days, submit via facsimile (a) the disputed determination of the Exercise Price to an independent, reputable investment bank selected by the Company and approved by the Holder or (b) the disputed arithmetic calculation of the Warrant Shares to the Company's independent, outside accountant. The Company shall cause at its expense the investment bank or the accountant, as the case may be, to perform the determinations or calculations and notify the Company and the Holder of the results no later than ten (10) Business Days from the time it receives the disputed determinations or calculations. Such investment bank's or accountant's determination or calculation, as the case may be, shall be binding upon all parties absent demonstrable error.

17. NOTICES OF RECORD DATE

Upon (a) any establishment by the Company of a record date of the holders of any class of securities for the purpose of determining the holders thereof who are entitled to receive any dividend or other distribution, or right or option to acquire securities of the Company, or any other right; or (b) any capital reorganization, reclassification, recapitalization, merger or consolidation of the Company with or into any other corporation, any transfer of all or substantially all the assets of the Company, or any voluntary or involuntary dissolution, liquidation or winding up of the Company, or the sale, in a single transaction, of a majority of the Company shall mail to the Holder at least ten (10) Business Days, or such longer period as may be required by law, prior to the record date specified therein, a notice specifying; (i) the date established as the record date for the purpose of such dividend, distribution, option or right and a description of such dividend, option or right; (ii) the date on which any such reorganization, reclassification, transfer, consolidation, merger, dissolution, liquidation or winding up, or sale is expected to become effective;and (iii) the date, if any, fixed as to when the holders of record of Common Stock shall be entitled to exchange their shares of Common Stock for securities or other property deliverable upon such reorganization, reclassification, transfer, consolation, merger, dissolution, reclassification, transfer, consolation, merger, dissolution, reclassification, transfer, consolation frecord of Common Stock shall be entitled to exchange their shares of Common Stock for securities or other property deliverable upon such reorganization, reclassification, transfer, consolation, merger, dissolution, liquidation or winding up.

18. RESERVATION OF SHARES

The Company shall reserve and keep available out of its authorized but unissued shares of Common Stock for issuance upon the exercise of this Warrant, free from pre-emptive rights, such number of shares of Common Stock for which this Warrant shall from time to time be exercisable. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation. Without limiting the generality of the foregoing, the Company covenants that it will use commercially reasonable efforts to take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and use commercially reasonable efforts to obtain all such authorizations, exemptions or consents, including but not limited to consents from the Company's stockholders or Board of Directors or any public regulatory body, as may be necessary to enable the Company to perform its obligations under this Warrant.

19. NO THIRD PARTY RIGHTS

This Warrant is not intended, and will not be construed, to create any rights in any parties other than the Company and the Holder, and no person or entity may assert any rights as third-party beneficiary hereunder.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Company has caused this Warrant to be duly executed as of the date first set forth above.

CORBUS PHARMACEUTICALS HOLDINGS, INC.

By: Name: Yuval Cohen Title: Chief Executive Officer

EXHIBIT A

NOTICE OF EXERCISE

(To be executed by the Holder of Warrant if such Holder desires to exercise Warrant)

To Corbus Pharmaceuticals Holdings, Inc.:

The undersigned hereby irrevocably elects to exercise this Warrant and to purchase thereunder, [] full shares of Corbus Pharmaceuticals Holdings, Inc. Common Stock issuable upon exercise of the Warrant and delivery of:

\$[] (in cash as provided for in the foregoing Warrant) and any applicable taxes payable by the undersigned pursuant to such Warrant.

The undersigned requests that certificates for such shares be issued in the name of:

(Please print name, address and social security or federal employer identification number (if applicable))

If the shares issuable upon this exercise of the Warrant are not all of the Warrant Shares which the Holder is entitled to acquire upon the exercise of the Warrant, the undersigned requests that a new Warrant evidencing the rights not so exercised be issued in the name of and delivered to:

(Please print name, address and social security or federal employer identification number (if applicable))

Name of Holder (print): (Signature): (By:) (Title:) Dated:

EXHIBIT B

FORM OF ASSIGNMENT

FOR VALUE RECEIVED, [] hereby sells, assigns and transfers to each assignee set forth below all of the rights of the undersigned under the Warrant (as defined in and evidenced by the attached Warrant) to acquire the number of Warrant Shares set opposite the name of such assignee below and in and to the foregoing Warrant with respect to said acquisition rights and the shares issuable upon exercise of the Warrant:

| Name of Assignee | Address | Number of Shares |
|------------------|---------|------------------|
| | | |

If the total of the Warrant Shares are not all of the Warrant Shares evidenced by the foregoing Warrant, the undersigned requests that a new Warrant evidencing the right to acquire the Warrant Shares not so assigned be issued in the name of and delivered to the undersigned.

Name of Holder (print): (Signature): (By:) (Title:) Dated:

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Corbus Pharmaceuticals Holdings, Inc. on Form S-3 (No. 333-222447) and Form S-8 (Nos. 333-200350, 333-201898, 333-210428 and 333-216547) of our report dated March 12, 2018, on our audits of the consolidated financial statements as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017, which report is included in this Annual Report on Form 10-K to be filed on or about March 12, 2018.

/s/ EisnerAmper LLP

EISNERAMPER LLP Iselin, New Jersey March 12, 2018

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, 2017 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 12, 2018

/s/ Yuval Cohen

Yuval Cohen Chief Executive Officer (Principal Executive Officer)

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, 2017 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;
 - 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 12, 2018

/s/ Sean Moran

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

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, 2017, 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.

Dated: March 12, 2018

By: /s/ Yuval Cohen

Yuval Cohen Chief Executive Officer (Principal Executive Officer)

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, 2017, 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.

Dated: March 12, 2018

By: /s/ Sean Moran

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