Filed Pursuant to Rule 424(b)(5)
Registration No. 333-222447

The information contained in this preliminary prospectus supplement and the accompanying prospectus is not complete and may be changed. A registration statement relating to the securities has been declared effective by the Securities and Exchange Commission. This preliminary prospectus supplement and the accompanying prospectus are not an offer to sell these securities, and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated January 24, 2019

PRELIMINARY PROSPECTUS SUPPLEMENT
(To Prospectus dated January 17, 2018)

Shares

Corbus Pharmaceuticals Holdings, Inc.

Common Stock

We are offering shares of our common stock to be sold in this offering. The public offering price is $ per share.

Our common stock is listed on the Nasdaq Global Market under the symbol "CRBP." On January 23, 2019, the last reported sales price of our common stock on the Nasdaq Global Market was $7.38 per share.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and may elect to comply with certain reduced public company reporting requirements for future filings.

Investing in our common stock involves risks. Before buying any shares, you should read the discussion of material risks of investing in our common stock in "Risk Factors" beginning on page S-5 of this prospectus supplement, on page 3 of the accompanying prospectus and in the documents incorporated by reference in this prospectus supplement.

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

	PER SHARE	TOTAL
Public offering price	$	$
Underwriting discounts and commissions (1)	$	$
Proceeds to us, before expenses	$	$

(1) We have agreed to reimburse the underwriters for certain of their reasonable out-of-pocket expenses. See "Underwriting" beginning on page S-33 for more information on this offering and the underwriting agreements.

Delivery of the shares of common stock is expected to be made on or about January , 2019. We have granted the underwriters an option for a period of 30 days to purchase up to additional shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be $ and the total proceeds to us, before expenses, will be $.

Joint Book-Running Managers

Jefferies **RBC Capital Markets**

The date of this prospectus supplement is January , 2019.

TABLE OF CONTENTS

PROSPECTUS SUPPLEMENT

PROSPECTUS

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference into this prospectus supplement and the accompanying prospectus. The second part, the accompanying prospectus dated January 17, 2018, including the documents incorporated by reference therein, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement, on the one hand, and the information contained in the accompanying prospectus or in any document incorporated by reference that was filed with the Securities and Exchange Commission, or the SEC, before the date of this prospectus supplement, on the other hand, you should rely on the information in this prospectus supplement. If any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in the accompanying prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

We have not, and the underwriters have not, authorized anyone to provide you with information different from or inconsistent with the information contained in or incorporated by reference in this prospectus supplement, the accompanying prospectus and in any free writing prospectus that we have authorized for use in connection with this offering. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus is accurate only as of the date of those respective documents, regardless of the time of delivery of those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus in their entirety before making an investment decision. You should also read and consider the information in the documents to which we have referred you in the sections of this prospectus supplement entitled “Additional Information” and “Incorporation of Certain Information by Reference.”

We and the underwriters are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of our common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of our common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

All references in this prospectus supplement or the accompanying prospectus to “Corbus,” the “Company,” “we,” “us,” or “our” mean Corbus Pharmaceuticals Holdings, Inc. and its subsidiaries unless we state otherwise or the context otherwise indicates. This prospectus supplement 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 prospectus supplement 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’ trademarks, service marks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Other trademarks, service marks and trade names appearing in this prospectus supplement are the property of their respective owners.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit or incorporated by reference to the registration statement of which this prospectus forms a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

SUMMARY

This summary highlights selected information about us and this common stock offering. This summary is not complete and may not contain all of the information that is important to you. We encourage you to read this prospectus supplement and the accompanying prospectus, including the information under the caption "Risk Factors" and the information we incorporate by reference, in its entirety.

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 lead product candidate, lenabasum, is a novel synthetic, oral, endocannabinoid drug designed to resolve chronic inflammation and fibrotic processes. We are currently developing lenabasum to treat four life-threatening diseases: systemic sclerosis (SSc), cystic fibrosis (CF), dermatomyositis (DM) and systemic lupus erythematosus (SLE).

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

Lenabasum has generated positive clinical data in three consecutive Phase 2 studies in diffuse cutaneous SSc, CF and skin-predominant DM. Lenabasum is currently being evaluated in a Phase 3 SSc study that 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, we received guidance from the FDA on the protocol design for the next clinical study and announced the commencement of an international Phase 3 study on December 17, 2018. This trial is a 1-year, double-blind, randomized, placebo-controlled study testing efficacy and safety of lenabasum and is expected to enroll 150 adults with DM. Subjects are randomized to receive lenabasum 20 mg twice per day, lenabasum 5 mg twice per day, or placebo twice per day in a 2:1:2 ratio. The primary efficacy outcome is American College of Rheumatology/European League Against Rheumatism 2016 Total Improvement Score (TIS) in adult dermatomyositis and polymyositis, a composite measure of improvement from baseline in six endpoints: Physician Global Activity, Patient Global Activity, Health Assessment Questionnaire, Manual Muscle Testing, muscle enzymes, and extra-muscular activity. Change in the Cutaneous Dermatomyositis Activity and Severity Index (CDASI) activity score is a secondary efficacy outcome. Open-label extension studies are ongoing in SSc, CF and DM following the completion of the Phase 2 studies in these indications.

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

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

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

Recent Developments

License Agreement

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

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

In consideration of the license and other rights granted by us, Kaken will pay us a $27,000,000 upfront cash payment within 30 days of the date of the Collaboration Agreement and is obligated to pay potential milestone payments to us totaling up to approximately $173,000,000 for achievement of certain development, sales and regulatory milestones, with part of the milestone payments being calculated in Japanese yen, and therefore subject to change based on the conversion rate to U.S. dollars in effect at the time of payment. In addition, during the Royalty Term (as defined below), Kaken is obligated to pay us royalties, under certain conditions, in the double digits, which royalties shall be reduced in certain circumstances. In particular, for so long as we supply Licensed Products to Kaken pursuant to a supply agreement to be entered into by the parties, royalty payments shall be payable for each unit of Licensed Product that we supply as a percentage of the Japanese National Health Insurance price of the Licensed Product. During any time in which a supply agreement is not in effect, royalty payments shall be changed to a rate to be agreed upon by the parties in good faith.

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

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

Royalty Payment

Pursuant to the terms of the Cystic Fibrosis Program Related Investment Agreement between us and the Cystic Fibrosis Foundation, or CFF (the "Investment Agreement"), under which we received the 2018 CFF Award described above, we will owe to CFF a royalty payment equal to 10% of any amounts we receive as payment under the Collaboration Agreement, provided that the total royalties that we will be required to pay under the Investment Agreement resulting from income from licenses or sales subject to the Investment Agreement are capped at five times the total amount of the 2018 CFF Award, and we may credit such royalties against any royalties on net sales otherwise owed to CFF under the Investment Agreement. Accordingly, we will be required to pay CFF $2,700,000 within 60 days of our receipt of the $27,000,000 upfront cash payment from Kaken described above.

Patent Issuance

On December 18, 2018, the U.S. Patent and Trademark Office (USPTO) issued U.S. Patent No. 10,154,986 to us with claims directed to the pharmaceutical compositions comprising lenabasum. The patent expires in February 2034.

Corporate Information

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. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our securities.

THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding immediately after this offering	shares
Option to purchase additional shares from us	We have granted the underwriters the option, exercisable for 30 days from the date of this prospectus supplement, to purchase up to additional shares of our common stock.
Use of proceeds	We intend to use the net proceeds to us from this offering to fund our continued development of lenabasum and the Jenrin Compounds and for general corporate purposes, which may include funding preclinical studies and clinical trials, manufacturing lenabasum and the Jenrin Compounds for clinical trials and commercial launch, and acquisitions or investments in businesses, products or technologies that are complementary, and to increase our working capital and fund capital expenditures. See "Use of Proceeds" on page S-31.
Risk Factors	In analyzing an investment in the shares of common stock being offered pursuant to this prospectus supplement, you should carefully consider, along with other matters included or incorporated by reference in this prospectus supplement or the accompanying prospectus, the information set forth under "Risk Factors" in this prospectus supplement, the accompanying prospectus and the risks discussed in the documents incorporated by reference in this prospectus supplement.
Nasdaq Global Market symbol	"CRBP"

The number of shares of common stock to be outstanding after this offering is based on 57,247,496 shares of common stock outstanding on December 31, 2018 and excludes:

- 9,593,990 shares of common stock issuable upon the exercise of outstanding options at a weighted average exercise price of $4.51 per share, of which 5,967,701 options were vested as of December 31, 2018;
- 2,283,500 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $6.34 per share, of which 1,783,500 warrants are exercisable as of December 31, 2018; and
- 5,072,241 shares of common stock available for future issuance under our 2014 Equity Incentive Plan as of December 31, 2018.

Except as otherwise noted, all information in this prospectus assumes no exercise by the underwriters of their option to purchase additional shares of common stock from us.

RISK FACTORS

An investment in our shares of common stock involves a high degree of risk. Prior to making a decision about investing in our shares of common stock, you should carefully consider the risks, uncertainties and assumptions discussed under Item 1A, "Risk Factors," in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and any subsequent updates described in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, all of which are incorporated herein by reference and may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future, together with information in this prospectus and any other information incorporated by reference into this prospectus, including the risk factors set forth below. See the sections of this prospectus supplement entitled "Additional Information" and "Incorporation of Certain Information by Reference." Additional risks and uncertainties not presently known to us, or that we currently view as immaterial, may also harm our business. If any of these risks occur, our business, financial condition and operating results could be harmed, the trading price of our common stock could decline and you could lose part or all of your investment.

This prospectus supplement also 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 certain factors, including the risks faced by us described below and elsewhere in this prospectus. See "Special Note Regarding Forward-Looking Statements" for information relating to these forward-looking statements.

Risk Related to our Company and our Business

Risks Related to Our Financial Position and Need for Capital

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

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

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

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

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

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

We expect to incur substantial expenses without corresponding revenues unless and until we are able to obtain regulatory approval and successfully commercialize any of our drug candidates. We have been engaged in developing lenabasum since 2009, and we licensed the exclusive worldwide rights to develop, manufacture and market drug candidates from Jenrin Discovery LLC ("Jenrin") in the third quarter of 2018. To date, we have not generated any revenue from our drug candidates and we expect to incur significant expense to complete our clinical program for our drug candidates in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of our drug candidates in any indication in the United States or internationally. Even if we are able to commercialize our drug candidates, there can be no assurance that we will generate significant revenues or ever achieve profitability.

Our net losses for the years ended December 31, 2017, 2016 and 2015 were approximately $32,422,000, $19,999,000 and $8,851,000, respectively, and our net losses for the nine months ended September 30, 2018 and 2017 were approximately $38,366,000 and $21,728,000, respectively. As of September 30, 2018, we had an accumulated deficit of approximately $104,064,000.

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

Our 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 our drug candidates. As of September 30, 2018, our consolidated cash and cash equivalents balance was approximately $55.7 million. On January 5, 2018, we entered into a Controlled Equity OfferingSM Sales Agreement (the "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 $11.2 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 $12.5 million in the first nine months of 2018 upon our achievement of milestones related to the progress of the Phase 2b Clinical Trial, as set forth in the Investment Agreement. We expect that the remainder of the 2018 CFF Award will be paid 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 $55.7 million at September 30, 2018, together with (i) the $27 million upfront cash payment due from Kaken within 30 days from the date of the Collaboration Agreement and (ii) the up to $25 million of proceeds that we expect to receive under the 2018 CFF Award, of which we have received $12.5 million to date, to be sufficient to meet our operating and capital requirements into the first quarter of 2020, 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, or pursuant to the Investment Agreement due to the dependency of our receiving future payments thereunder on our achieving certain milestones described therein. If we are not successful in raising additional capital, we may not be able to continue as a going concern. We may seek additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt.

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

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

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

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

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

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

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

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

- the FDA or comparable foreign regulatory authorities or institutional review boards, or IRBs, may disagree with the design or implementation of our clinical trials;
- we may not be able to provide acceptable evidence of the safety and efficacy of our drug candidates;

- the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA, the European Medicines Agency, or EMA, or other comparable foreign regulatory authorities for marketing approval;

- the dosing of our drug candidates in a particular clinical trial may not be at an optimal level;

- patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our drug candidates;

- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; 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 any of our drug candidates for the foregoing or any other reasons will prevent us from commercializing such product candidate as a prescription product, and our ability to generate revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of our clinical trials or that such trials will be considered by regulators to have shown safety or efficacy of our product candidates. The FDA, EMA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We have only limited experience in filing the applications necessary to gain regulatory approvals and we 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 such indications. Our drug candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

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

In addition, if the current U.S. federal government shutdown were to continue for a prolonged period of time, the FDA review and approval process could be delayed. Resolving such delays could force us or our collaborators to incur significant costs, could limit our allowed activities or the allowed activities of our collaborators, could diminish any competitive advantages that we or our collaborators may attain or could adversely affect our business, financial condition, results of operations and prospects, the value of our common stock and our ability to bring new products to market as forecasted.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

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

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

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

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

- demonstration of clinical safety and efficacy;
- relative convenience, pill burden and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe our drug candidates and of the target patient population to try new therapies;
- safety, tolerability and efficacy of our drug candidates compared to competing products;
- the introduction of any new products that may in the future become available to treat indications for which our drug candidates may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which our drug candidates may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of our drug candidates in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA-approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

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

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

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

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

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

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

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

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension of any ongoing clinical trials;

- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;

- suspension of, or imposition of restrictions on, operations, including costly new manufacturing requirements; or

- product seizure or detention or refusal to permit the import or export of product.

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

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

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

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

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

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

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

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

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

If we enter into collaboration agreements for one or more of our drug candidates, the success of such drug candidates will depend in great part upon our and our collaborators' success in promoting them as superior to other treatment

alternatives. We believe that our drug candidates can be proven to offer disease treatment with notable advantages over drugs in terms of patient compliance and effectiveness. However, there can be no assurance that we will be able to prove these advantages or that the advantages will be sufficient to support the successful commercialization of our drug candidates.

We currently have 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 our drug candidates.

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 our drug candidates, which would adversely affect our business, operating results and financial condition.

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our drug candidates;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and

- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Although we intend to design the clinical trials for our drug candidates in consultation with CROs, we expect that the CROs will manage 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 our drug candidates for the subject indications may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or our drug candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures.

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

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

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

- the FDA failing to grant permission to proceed and placing the clinical study on hold;

- subjects failing to enroll or remain in our trials at the rate we expect;
- a facility manufacturing any of our drug candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of cGMP requirements or other applicable requirements, or cross-contaminations of product in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- subjects choosing an alternative treatment for the indications for which we are developing our drug candidates, or participating in competing clinical studies;
- subjects experiencing severe or unexpected drug-related adverse effects;
- reports of similar technologies and products raising safety and/or efficacy concerns;
- third-party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or employing methods consistent with the clinical trial protocol, cGCP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner;
- inspections of clinical study sites by the FDA or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications;
- one or more IRBs refusing to approve, suspending or terminating the study at an investigational site precluding enrollment of additional subjects, or withdrawing its approval of the trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- deviations of the clinical sites from trial protocols or dropping out of a trial;
- adding new clinical trial sites;
- the inability of the CRO to execute any clinical trials for any reason; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of a trial.

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

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

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

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

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

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

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

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

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

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

Risks Relating to Our Intellectual Property Rights

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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, 2018, we had 77 full-time employees. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may

have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our drug candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth.

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

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

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Yuval Cohen, our Chief Executive Officer, 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 our drug candidates. Competition for skilled personnel in our market is intense and competition for experienced scientists may limit our ability to hire and retain highly qualified personnel on acceptable terms. Despite our efforts to retain valuable employees, members of our management, scientific and medical teams may terminate their employment with us on short notice. 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 our drug candidates.

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

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

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

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

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

Risks Related to our Common Stock

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

Our officers, directors, and five percent stockholders collectively owned approximately 19.1% of our outstanding shares of common stock as of September 30, 2018. 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 Nasdaq 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 September 30, 2018, we had outstanding options to purchase an aggregate of 9,434,241 shares of our common stock at a weighted average exercise price of $4.46 per share and warrants to purchase an aggregate of 2,283,500 shares of our common stock at a weighted average exercise price of $6.34 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.

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 applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We currently do not have an internal audit function, and we will need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

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

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

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. As of December 31, 2018, we had 77 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 2017 comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new tax legislation, or the Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses); limitation of the deduction of net operating losses generated in tax years beginning after December 31, 2017 to 80% of taxable income, indefinite carryforward of net operating losses generated in tax years after 2018 and elimination of net operating loss carrybacks; changes in the treatment of offshore earnings regardless of whether they are repatriated; current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations, mandatory capitalization of research and development expenses beginning in 2022; immediate deductions for certain new investments instead of deductions for depreciation expense over time; further deduction limits on executive compensation; and modifying, repealing and creating many other business deductions and credits, including the reduction in the orphan drug credit from 50% to 25% of qualifying expenditures. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. This periodic report does not discuss any such tax legislation or the manner in which it might affect us or our stockholders in the future. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation.

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

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

Additional Risks Relating To The Offering

If you purchase shares of common stock sold in this offering, you will experience immediate and substantial dilution in your investment.

Purchasers of common stock in this offering will experience immediate dilution to the extent of the difference between the public offering price per share of common stock and the net tangible book value per share of common stock immediately after this offering. After giving effect to the sale of shares of our common stock at the public offering price of $ per share, and after deducting underwriting discounts and commissions and estimated offering expenses, you will experience immediate dilution of $ per share, representing the difference between our net tangible book value per share as of September 30, 2018 after giving effect to this offering and the public offering price. See "Dilution" for a more detailed discussion of the dilution you will incur if you purchase shares of common stock in this offering.

Our management team may invest or spend the proceeds of this offering in ways with which you may not agree or in ways which may not yield a significant return.

Our management will have broad discretion over the use of proceeds from this offering. The net proceeds from this offering will be used to fund our continued development of lenabasum and the Jenrin Compounds and for general corporate purposes, which may include funding preclinical studies and clinical trials, manufacturing lenabasum and the Jenrin Compounds for clinical trials and commercial launch, and acquisitions or investments in businesses, products or technologies that are complementary, and to increase our working capital and fund capital expenditures. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products; however, we have no current commitments or obligations to do so.

Our management will have considerable discretion in the application of the net proceeds from this offering, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not increase our operating results or enhance the value of our common stock. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

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

As of December 31, 2018, we had outstanding options to purchase an aggregate of 9,593,990 shares of our common stock at a weighted average exercise price of $4.51 per share and warrants to purchase an aggregate of 2,283,500 shares of our common stock at a weighted average exercise price of $6.34 per share. The exercise of such outstanding options and warrants will result in further dilution of your investment. If our existing stockholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus and the information incorporated herein by reference contain forward-looking statements within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties. All statements, other than statements of historical facts, included or incorporated by reference in this prospectus supplement and the accompanying prospectus regarding our strategy, future events, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our limited operating history;
- our anticipated timing for clinical development, regulatory submissions, commencement and completion of clinical trials and product approvals;
- the results of our clinical trials, including the possibility of unfavorable clinical trial results or that results from our clinical trials will reach similar results in future trials;
- actual or anticipated variations in our operating results;
- our cash position;
- market conditions in our industry;
- 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 other proprietary rights;
- our ability to retain key personnel;
- 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;
- our ability to adequately support growth;
- our expectations related to the use of proceeds from this offering and prior offerings and other financing efforts; and
- our estimates regarding expenses, future revenue, capital requirements and ability to satisfy our capital needs.

Forward-looking statements may also concern our expectations relating to our subsidiaries and other affiliates. We caution you that the foregoing list may not contain all of the forward-looking statements made in this prospectus supplement, the accompanying prospectus and the information incorporated herein and therein.

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

You should read this prospectus supplement, the accompanying prospectus, the documents that we incorporate by reference into this prospectus supplement, including the documents to which we have referred you in the sections of this prospectus supplement entitled “Additional Information” and “Incorporation of Certain Information by Reference” completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

USE OF PROCEEDS

We estimate that the net proceeds we will receive from this offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise in full their option to purchase additional shares, we estimate that the net proceeds from this offering will be approximately $ million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the proceeds of the proposed offering to fund our continued development of lenabasum and the Jenrin Compounds and for general corporate purposes, which may include funding preclinical studies and clinical trials, manufacturing lenabasum and the Jenrin Compounds for clinical trials and commercial launch, and acquisitions or investments in businesses, products or technologies that are complementary, and to increase our working capital and fund capital expenditures. We have not determined the amount of net proceeds to be used specifically for such purposes and, as a result, management will retain broad discretion over the allocation of net proceeds. The occurrence of unforeseen events or changed business conditions could result in the application of the net proceeds from this offering in a manner other than as described in this prospectus supplement. Pending their uses, we intend to invest the net proceeds of this offering in interest-bearing bank accounts or in short-term, interest-bearing, investment-grade securities.

DILUTION

Purchasers of common stock in this offering will experience immediate dilution to the extent of the difference between the public offering price per share of common stock and the net tangible book value per share of common stock immediately after this offering.

Our net tangible book value as of September 30, 2018 was approximately $42.9 million, or $0.75 per share of common stock. Net tangible book value per share is determined by dividing total tangible assets, which excludes intangible assets, less total liabilities, by the aggregate number of shares of common stock outstanding as of September 30, 2018. After giving effect to the sale by us of shares of common stock at the public offering price of $ per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of September 30, 2018 would have been approximately $ million, or $ per share. This represents an immediate increase in net tangible book value of $ per share to our existing stockholders and an immediate dilution of $ per share issued to the new investors purchasing securities in this offering.

The following table illustrates this dilution on a per-share basis:

Public offering price per share of common stock		$
Net tangible book value per share as of September 30, 2018	$ 0.75	
Increase per share attributable to new investors	$	
Net tangible book value per share after this offering		$
Dilution per share to new investors		$

If the underwriters exercise in full their option to purchase additional shares of common stock in this offering at the public offering price of $ per share, our net tangible book value after the offering would be $ per share, the increase in the net tangible book value to existing stockholders would be $ per share, and the dilution to new investors purchasing securities in this offering would be $ per share.

The above table excludes:

- 9,434,241 shares of common stock issuable upon the exercise of outstanding options at a weighted average exercise price of $4.46 per share, of which 5,671,042 options were vested as of September 30, 2018;
- 2,283,500 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $6.34 per share, of which 1,783,500 warrants are exercisable as of September 30, 2018; and
- 5,241,990 shares of common stock available for future issuance under our 2014 Equity Incentive Plan as of September 30, 2018.

To the extent that options or warrants are exercised, new options are issued under our 2014 Equity Incentive Plan, or we issue additional shares of common stock in the future, there may be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated January , 2019, among us, Jefferies LLC and RBC Capital Markets, LLC, as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	
RBC Capital Markets, LLC	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus supplement and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per share of common stock. After the offering, the initial public offering price and concession to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus supplement.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	$	$	$	$
Underwriting discounts and commissions paid by us	$	$	$	$
Proceeds to us, before expenses	$	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $. We have also agreed to reimburse the underwriters up to $15,000 for their legal counsel and FINRA fees. In accordance with Financial Industry Regulatory Authority, Inc. Rule 5110, such reimbursed fees are deemed underwriting compensation for this offering.

Listing

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

Stamp Taxes

If you purchase shares of common stock offered in this prospectus supplement, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus supplement.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus supplement, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above.

No Sales of Similar Securities

We and our officers and directors have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer to sell, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended, or enter into any swap, hedge or similar arrangement, or

- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or

- make any demand for, or exercise any right with respect to, the registration under the Securities Act of 1933, as amended, of the offer and sale of any such securities, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or

- publicly announce an intention to do any of the foregoing for a period of 90 days after the date of this prospectus without the prior written consent of Jefferies LLC and RBC Capital Markets, LLC.

This restriction terminates after the close of trading of the common stock on and including the 90th day after the date of this prospectus supplement.

Jefferies LLC and RBC Capital Markets, LLC may, in their sole discretion and at any time or from time to time before the termination of the 90-day period, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, they and certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member is purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on the Nasdaq Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus supplement and the accompanying prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus supplement and accompanying prospectus in electronic format, the information on the underwriters’ websites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus supplement and the accompanying prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Disclaimers About Non-U.S. Jurisdictions

Canada

(A) Resale Restrictions

The distribution of the securities in Canada is being made only in the provinces of Ontario, Quebec, Alberta and British Columbia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the securities in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the securities.

(B) Representations of Canadian Purchasers

By purchasing the securities in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the securities without the benefit of a prospectus qualified under those securities laws as it is an "accredited investor" as defined under National Instrument 45-106 – *Prospectus Exemptions*,
- the purchaser is a "permitted client" as defined in National Instrument 31-103 - *Registration Requirements, Exemptions and Ongoing Registrant Obligations*,
- where required by law, the purchaser is purchasing as principal and not as agent, and
- the purchaser has reviewed the text above under Resale Restrictions.

(C) Conflicts of Interest

Canadian purchasers are hereby notified that Jefferies LLC and RBC Capital Markets, LLC are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 – *Underwriting Conflicts* from having to provide certain conflict of interest disclosure in this document.

(D) Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

(E) Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

(F) Taxation and Eligibility for Investment

Canadian purchasers of the securities should consult their own legal and tax advisors with respect to the tax consequences of an investment in the securities in their particular circumstances and about the eligibility of the securities for investment by the purchaser under relevant Canadian legislation.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), an offer to the public of any common shares which are the subject of the offering contemplated by this prospectus supplement and the accompanying prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer common shares to the public" in relation to the common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common shares to be offered so as to enable an investor to decide to purchase or subscribe to the common shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

MiFID II Product Governance

Any distributor subject to MiFID II that is offering, selling or recommending the shares of common stock is responsible for undertaking its own target market assessment in respect of the shares of common stock and determining its own distribution channels for the purposes of the MiFID product governance rules under Commission Delegated Directive (EU) 2017/593 ("Delegated Directive"). Neither the issuer nor the underwriters make any representations or warranties as to a distributor's compliance with the Delegated Directive.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong ("SFO") and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong ("CO") or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of the shares of common stock is directed only at (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

(a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

(b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

(i) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

(ii) where no consideration is or will be given for the transfer;

(iii) where the transfer is by operation of law;

(iv) as specified in Section 276(7) of the SFA; or

(v) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "relevant person").

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the common stock being offered will be passed upon for us by Lowenstein Sandler LLP, New York, New York. Covington & Burling LLP, New York, New York is counsel for the underwriters in connection with this offering.

EXPERTS

The consolidated balance sheets of Corbus Pharmaceuticals Holdings, Inc. and Subsidiary 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, have been audited by EisnerAmper LLP, independent registered public accounting firm, as stated in their report which is incorporated herein by reference. Such financial statements have been incorporated herein by reference in reliance on the report of such firm given upon their authority as experts in accounting and auditing.

ADDITIONAL INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read and copy any materials we file with the SEC at its Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 and at its regional offices, a list of which is available on the Internet at http://www.sec.gov/contact/addresses.htm. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers, such as us, that file electronically with the SEC. Additionally, you may access our filings with the SEC through our website at http://www.corbuspharma.com. The information on our website is not part of this prospectus.

We will provide you without charge, upon your oral or written request, with a copy of any or all reports, proxy statements and other documents we file with the SEC, as well as any or all of the documents incorporated by reference in this prospectus (other than exhibits to such documents unless such exhibits are specifically incorporated by reference into such documents). Requests for such copies should be directed to:

Corbus Pharmaceuticals Holdings, Inc.
500 River Ridge Drive
Norwood, MA 02062
Telephone number: (617) 963-0100

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the common stock offered with this prospectus. This prospectus does not contain all of the information in the registration statement, parts of which we have omitted, as allowed under the rules and regulations of the SEC. You should refer to the registration statement for further information with respect to us and the common stock. Copies of the registration statement, including exhibits, may be inspected without charge at the SEC's Public Reference Room and on the SEC's website at the addresses set forth above.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with it into this prospectus, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the SEC will automatically update and supersede information contained in this prospectus and any accompanying prospectus supplement.

We incorporate by reference the documents listed below that we have previously filed with the SEC:

- Our Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 12, 2018;
- our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2018, filed with the SEC on May 10, 2018, June 30, 2018, filed with the SEC on August 8, 2018 and September 30, 2018, filed with the SEC on November 8, 2018;
- our Current Reports on Form 8-K filed with the SEC on January 5, 2018, January 8, 2018, January 30, 2018, April 13, 2018, May 24, 2018, June 6, 2018, June 13, 2018, July 25, 2018, September 20, 2018 and January 3, 2019 (other than any portions thereof deemed furnished and not filed);
- the information specifically incorporated by reference into our Annual Report on Form 10-K from our Definitive Proxy Statement on Schedule 14A filed with the SEC on April 13, 2018; and
- the description of our common stock, par value $0.0001 per share, contained in our Form 8-A filed on April 14, 2015, including any amendment or report filed for the purpose of updating such description.

All reports and other documents that we file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus but before the termination of the offering of the securities hereunder will also be considered to be incorporated by reference into this prospectus from the date of the filing of these reports and documents, and will supersede the information herein; provided, however, that all reports, exhibits and other information that we "furnish" to the SEC will not be considered incorporated by reference into this prospectus. We undertake to provide without charge to each person (including any beneficial owner) who receives a copy of this prospectus, upon written or oral request, a copy of all of the preceding documents that are incorporated by reference (other than exhibits, unless the exhibits are specifically incorporated by reference into these documents). You may request a copy of these materials in the manner set forth under the heading "Additional Information," above.

Any statements contained in a document incorporated by reference in this prospectus supplement shall be deemed to be modified, superseded or replaced for purposes of this prospectus supplement and the accompanying prospectus to the extent that a statement contained in this prospectus supplement (or in any other subsequently filed document which also is incorporated by reference in this prospectus supplement) modifies, supersedes or replaces such statement. Any statement so modified, superseded or replaced shall not be deemed, except as so modified, superseded or replaced, to constitute a part of this prospectus supplement and the accompanying prospectus. Statements contained in this prospectus supplement, the accompanying prospectus and any document incorporated by reference as to the contents of any contract, agreement or other document referred to are not necessarily complete, and in each instance reference is made to the copy of the contract, agreement or other document filed as an exhibit to the registration statement or any incorporated document, each statement being so qualified by this reference.

PROSPECTUS

Corbus Pharmaceuticals Holdings, Inc.

$200,000,000

Common Stock
Preferred Stock
Warrants
Debt Securities
Subscription Rights
Units

We may offer, issue and sell from time to time together or separately, in one or more offerings, any combination of (i) our common stock, (ii) our preferred stock, which we may issue in one or more series, (iii) warrants, (iv) senior or subordinated debt securities, (v) subscription rights and (vi) units. The debt securities may consist of debentures, notes, or other types of debt. The debt securities, preferred stock, warrants and subscription rights may be convertible into, or exercisable or exchangeable for, common or preferred stock or other securities of ours. The units may consist of any combination of the securities listed above.

The aggregate public offering price of the securities that we are offering will not exceed $200,000,000. We will offer the securities in an amount and on terms that market conditions will determine at the time of the offering. Our common stock is listed on the Nasdaq Global Market under the symbol "CRBP." The last reported sale price for our common stock on January 4, 2018 as quoted on the Nasdaq Global Market was $8.35 per share. You are urged to obtain current market quotations of our common stock. We have no preferred stock, warrants, debt securities, subscription rights or units listed on any market. Each prospectus supplement will indicate if the securities offered thereby will be listed on any securities exchange.

Investing in our securities involves risk. You should carefully consider the risks that we refer you to under the section captioned "Risk Factors" in this prospectus on page 3 before buying our securities.

Should we offer any of the securities described in this prospectus, we will provide you with the specific terms of the particular securities being offered in supplements to this prospectus. You should read this prospectus and any supplement, together with additional information described under the headings "Additional Information" and "Incorporation of Certain Information by Reference" carefully before you invest. This prospectus may not be used to sell securities unless accompanied by a prospectus supplement.

We may sell these securities directly to our stockholders or to other purchasers or through agents on our behalf or through underwriters or dealers as designated from time to time. If any agents or underwriters are involved in the sale of any of these securities, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions or discounts.

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

The date of this prospectus is January 17, 2018

TABLE OF CONTENTS

Corbus Pharmaceuticals Holdings, Inc. is referred to herein as “Corbus,” “the Company,” “we,” “us,” and “our,” unless the context indicates otherwise.

You may only rely on the information contained in this prospectus and the accompanying prospectus supplement or that we have referred you to. We have not authorized anyone to provide you with different information. This prospectus and any prospectus supplement do not constitute an offer to sell or a solicitation of an offer to buy any securities other than the securities offered by this prospectus and the prospectus supplement. This prospectus and any prospectus supplement do not constitute an offer to sell or a solicitation of an offer to buy any securities in any circumstances in which such offer or solicitation is unlawful. Neither the delivery of this prospectus or any prospectus supplement nor any sale made hereunder shall, under any circumstances, create any implication that there has been no change in our affairs since the date of this prospectus or such prospectus supplement or that the information contained by reference to this prospectus or any prospectus supplement is correct as of any time after its date.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission ("SEC") using a "shelf" registration process. Under this shelf registration process, we may from time to time offer and sell, in one or more offerings, any or all of the securities described in this prospectus, separately or together, up to an aggregate offering price of $200,000,000. This prospectus provides you with a general description of our securities being offered. When we issue the securities being offered by this prospectus, we will provide a prospectus supplement (which term includes, as applicable, the at-the-market sales agreement prospectus filed with the registration statement of which this prospectus forms a part) that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described under the heading "Additional Information" and "Incorporation of Certain Information by Reference."

PROSPECTUS SUMMARY

The following summary highlights some information from this prospectus. It is not complete and does not contain all of the information that you should consider before making an investment decision. You should read this entire prospectus, including the "Risk Factors" section on page 3 and the disclosures to which that section refers you, the financial statements and related notes and the other more detailed information appearing elsewhere or incorporated by reference into this prospectus before investing in any of the securities described in this prospectus.

About Us

We are a 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 anabasum is a novel synthetic oral endocannabinoid-mimetic drug that is intended to resolve chronic inflammation and halt fibrotic processes without causing immunosuppression. Anabasum has generated positive clinical data in three consecutive Phase 2 studies in diffuse cutaneous systemic sclerosis, cystic fibrosis and dermatomyositis. Anabasum is also being evaluated in open-label extension studies in systemic sclerosis and skin-predominant dermatomyositis and in a Phase 3 study in systemic sclerosis, and we are currently planning for and finalizing the design of a Phase 2b study in cystic fibrosis and expect to commence the study in the first quarter of 2018.

Anabasum 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 muscle cells. Anabasum stimulates the production of Specialized Pro-Resolving Lipid Mediators (SPMs) that act to resolve inflammation and halt fibrosis by activating endogenous pathways. These endogenous resolution pathways are normally activated in healthy individuals during the course of normal immune responses but are dysfunctional in patients with chronic inflammatory and fibrotic diseases. Through its activation of the CB2 receptor, anabasum is designed to drive innate immune responses from the activation phase through completion of the resolution phase. The CB2 receptor plays an endogenous role in modulating and resolving inflammation by, in effect, turning heightened inflammation "off" and restoring homeostasis.

We are currently developing anabasum to treat four life-threatening diseases: systemic sclerosis; cystic fibrosis; diffuse cutaneous, skin-predominant dermatomyositis; and systemic lupus erythematosus, or SLE. The United States Food and Drug Administration, or the FDA, has granted anabasum Orphan Designation as well as Fast Track Status for both cystic fibrosis and systemic sclerosis. The European Medicines Authority, or the EMA, has granted anabasum Orphan Designation for both cystic fibrosis and systemic sclerosis.

Recent Developments

Initiation of Phase 3 Clinical Study in Systemic Sclerosis

On December 14, 2017, we announced the initiation of a Phase 3 "RESOLVE-1" clinical study of anabasum for the treatment of diffuse cutaneous systemic sclerosis. The international multicenter Phase 3 RESOLVE-1 study is a double-blind, randomized, placebo-controlled study assessing the efficacy and safety of anabasum for the treatment of systemic sclerosis. The study will 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 anabasum 5 mg twice per day, anabasum 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 systemic sclerosis. Secondary outcomes of the RESOLVE-1 study include patient- and physician-reported outcomes, forced vital capacity, 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.

Initiation of Phase 2 Clinical Study in Systemic Lupus Erythematosus

On December 22, 2017, we announced the initiation of a Phase 2 clinical study of anabasum for the treatment of systemic lupus erythematosus, or SLE. This 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 will be conducted at 15 sites in the United States and will enroll 100 adult SLE patients with active musculoskeletal disease. Subjects will be randomized in a 1:1:1:1 ratio to one of four cohorts to receive placebo or three different doses of anabasum 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 and British Isles Lupus Activity Group scoring systems, and patient-reported outcomes.

Intellectual Property Updates

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 anabasum, Corbus' lead product in development for the treatment of inflammatory diseases. The patent provides intellectual property protection for Corbus' use of anabasum to treat inflammatory diseases in the United States through 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 anabasum for the treatment of multiple fibrotic diseases, including the Company's lead indications: systemic sclerosis, dermatomyositis, cystic fibrosis as well as others. The patent provides intellectual property protection in the United States for the use of anabasum through 2034.

Corporate Information

Our principal executive offices are located at 100 River Ridge Drive, Norwood, Massachusetts 02062, and our telephone number is (617) 963-0100. Our website address is www.corbuspharma.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our securities.

RISK FACTORS

Before purchasing any of the securities you should carefully consider the risk factors set forth below and incorporated by reference in this prospectus from our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and any subsequent updates described in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as the risks, uncertainties and additional information set forth in our SEC reports on Forms 10-K, 10-Q and 8-K and in the other documents incorporated by reference in this prospectus. For a description of these reports and documents, and information about where you can find them, see "Additional Information" and "Incorporation of Certain Information By Reference." Additional risks not presently known or that we presently consider to be immaterial could subsequently materially and adversely affect our financial condition, results of operations, business and prospects.

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 anabasum and for evaluating anabasum in our clinical trials;
- successfully complete the clinical trials necessary to obtain regulatory approval for the marketing of anabasum;
- secure market exclusivity and/or adequate intellectual property protection for anabasum;
- attract and retain an experienced management and advisory team;
- secure acceptance of anabasum in the medical community and with third party payors and consumers;
- launch commercial sales of anabasum, 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 anabasum. We have been engaged in developing anabasum since 2009. To date, we have not generated any revenue from anabasum and we expect to incur significant expense to complete our clinical program for anabasum in the United States and elsewhere. We may never be able to obtain regulatory approval for the marketing of anabasum in any indication in the United States or internationally. Even if we are able to commercialize anabasum 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 nine months ended September 30, 2017 and 2016 and for the years ended December 31, 2016 and December 31, 2015 were approximately $21,728,000, $12,428,000, $19,999,000 and $8,851,000, respectively. As of September 30, 2017, we had an accumulated deficit of approximately $55,004,000.

If we were to obtain FDA approval for anabasum, 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, dermatomyositis and systemic lupus erythematosus, or SLE. We may elect to pursue FDA approval for anabasum 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 anabasum. As of September 30, 2017, we held cash and cash equivalents of approximately $36.6 million. In October 2017, we completed 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 and received net proceeds of approximately $35.0 million. We expect our cash and cash equivalents at September 30, 2017 together with the proceeds from the October 2017 offering and the remaining milestone payment of $500,000 from Cystic Fibrosis Foundation Therapeutics, Inc., which we received in November 2017, to be sufficient to meet our operating and capital requirements into the fourth quarter of 2019 based on current planned expenditures.

Other than the Controlled Equity Offering[SM] Sales Agreement, or the Sales Agreement, between us and Cantor Fitzgerald & Co., dated January 5, 2018, pursuant to which we may offer and sell up to $50.0 million of shares of our common stock from time to time through Cantor Fitzgerald & Co. acting as sales agent, 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 Sales Agreement due to limiting terms contained therein and sales thereunder being subject to market conditions. 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 anabasum 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 anabasum 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 anabasum. If we are unable to generate revenues from anabasum, our ability to create stockholder value will be limited.

Our only product candidate currently is anabasum, for which we have completed Phase 1 safety studies which we are evaluating in subsequent clinical studies. We do not generate revenues from any FDA approved drug products and have no other product candidates in development. 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 anabasum, which may never occur.

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

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 anabasum. 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 anabasum 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 anabasum, including regulatory approval, are not successful for its planned indications, or if adequate demand for anabasum 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 anabasum'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 anabasum 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 anabasum;

- the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; 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 anabasum 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 pre-clinical or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate.

We have only limited experience in filing the applications necessary to gain regulatory approvals and expect to rely on consultants and third party contract research organizations, or CROs, with expertise in this area to assist us in this process. Securing FDA approval requires the submission of pre-clinical, clinical and/or pharmacokinetic data, information about product manufacturing processes and inspection of facilities and supporting information to the FDA for each therapeutic indication to establish a product candidate's safety and efficacy for each indication. Anabasum 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 anabasum 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 anabasum 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 anabasum may not be successful.

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

Anabasum is our only product candidate in development. If we fail to successfully commercialize anabasum, 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 anabasum. We cannot be certain that anabasum will prove to be sufficiently effective and safe to meet applicable regulatory standards for any indication. If we fail to successfully commercialize anabasum as a treatment for cystic fibrosis, systemic sclerosis, dermatomyositis, 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 anabasum, 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 anabasum will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of anabasum 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 anabasum and of the target patient population to try new therapies;
- safety, tolerability and efficacy of anabasum compared to competing products;
- the introduction of any new products that may in the future become available to treat indications for which anabasum may be approved;
- new procedures or methods of treatment that may reduce the incidences of any of the indications in which anabasum may show utility;
- pricing and cost-effectiveness;
- the inclusion or omission of anabasum 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 anabasum 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 anabasum 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 anabasum 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 anabasum not commercially viable. For example, regulatory authorities may approve anabasum for fewer or more limited indications than we request, may not approve the price we intend to charge for anabasum, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve anabasum 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 anabasum. 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 anabasum.

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

Even if we obtain United States regulatory approval of anabasum 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. Anabasum 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 anabasum 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 anabasum, 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 anabasum 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 anabasum.

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 anabasum, 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 anabasum 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 anabasum;

- 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 anabasum obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to anabasum. 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 anabasum 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 anabasum, restrict or regulate post-approval activities and affect our ability to profitably sell anabasum. 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 anabasum, 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, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized 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. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for anabasum and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners, and incur substantial costs to ensure compliance. Subsequent to the 2016 presidential election, some members of the U.S. Congress are working to repeal the Health Care Reform Law. More recently, President Trump and the Republican majorities in both houses of the U.S. Congress have been seeking to repeal or replace all or portions of the Health Care Reform Law, but to date they have been unable to agree on any such legislation. 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.

Despite initiatives to invalidate the Health Care Reform Law, at this time it appears the implementation of the Health Care Reform Law will continue. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal 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 anabasum in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize anabasum in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for anabasum 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 anabasum 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 anabasum 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 anabasum, and our commercialization of anabasum 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 anabasum 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 anabasum 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 manufacturers if and when anabasum is approved for commercialization.

The facilities used by our contract manufacturers to manufacture anabasum 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 anabasum. 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 anabasum 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 anabasum, 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 anabasum, 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 anabasum.

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 anabasum product or should cease doing business with us, we could experience significant interruptions in the supply of anabasum or may not be able to create a supply of anabasum at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of anabasum 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 anabasum 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 anabasum if we decided to transfer the manufacture of anabasum 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 anabasum, 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 anabasum at commercial scale on a cost-effective basis. If the commercial-scale manufacturing costs of anabasum 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, anabasum, 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 anabasum 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, anabasum, is currently classified as a Schedule I controlled substance as defined in the Controlled Substance Act ("CSA"). This designation is based on anabasum's chemical structure and pharmacology (namely, it being a synthetic endocannabinoid mimetic that binds to the CB2 receptor). Even though anabasum'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 anabasum 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 anabasum. 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 anabasum. The parties responsible for the manufacturing, distribution and export of anabasum 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 anabasum 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 anabasum 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 anabasum.

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 anabasum 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 anabasum 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 anabasum 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 anabasum could have a material adverse effect on our business, results of operations and financial condition.

The import and export of anabasum requires import and export licenses. However, because anabasum 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 anabasum 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 anabasum.

We expect that we will rely on third parties to assist us in conducting clinical trials for anabasum. 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 anabasum 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 anabasum 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 anabasum 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 anabasum 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 anabasum. 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 anabasum. As a result, our financial results and the commercial prospects for anabasum 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 anabasum 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 anabasum 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 anabasum, 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 anabasum 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 anabasum, 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 anabasum. 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 anabasum 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 anabasum for the treatment of cystic fibrosis and systemic sclerosis. We also intend to seek orphan drug status for anabasum for the treatment of dermatomyositis. 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 anabasum for dermatomyositis 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 anabasum for the treatment of dermatomyositis, 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 anabasum 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 for our product candidate. 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 anabasum 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 anabasum 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 anabasum 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 anabasum and its uses may never be approved by United States or foreign patent offices and the existing patents and patent applications relating to anabasum 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 anabasum, 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 anabasum 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.

Anabasum 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 anabasum 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 anabasum, 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 anabasum from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to anabasum or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market anabasum 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 anabasum 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 anabasum 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 January 4, 2018, we had 48 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 anabasum 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.

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 anabasum. 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 anabasum.

We face a potential risk of product liability as a result of the clinical testing of anabasum and will face an even greater risk if we commercialize anabasum or any other future product. For example, we may be sued if any product we develop, including anabasum, 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 anabasum. 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 anabasum 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 anabasum; 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 12.6% of our outstanding shares of common stock as of January 4, 2018. 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.

Even if an active market for our common stock develops, of which no assurances can be given, 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 September 30, 2017, we had outstanding options to purchase an aggregate of 7,724,779 shares of our common stock at a weighted average exercise price of $3.66 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. 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.

We will incur significantly increased costs and devote substantial management time as a result of operating as a public company, 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 applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. We currently do not have an internal audit function, and we will need to hire or contract for additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

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

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

Proper systems of internal controls over financial accounting and disclosure are critical to the operation of a public company. As of January 4, 2018, we had 48 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 will need to include 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.

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.

FORWARD-LOOKING STATEMENTS

This prospectus, including the documents that we incorporate by reference, contains forward-looking statements as that term is defined in the federal securities laws. The events described in forward-looking statements contained in this prospectus, including the documents that we incorporate by reference, may not occur. Generally, these statements relate to our business plans or strategies, projected or anticipated benefits or other consequences of our plans or strategies, financing plans, projected or anticipated benefits from acquisitions that we may make, or projections involving anticipated revenues, earnings or other aspects of our operating results or financial position, and the outcome of any contingencies. Any such forward-looking statements are based on current expectations, estimates and projections of management. We intend for these forward-looking statements to be covered by the safe-harbor provisions for forward-looking statements. Words such as "may," "expect," "believe," "anticipate," "project," "plan," "intend," "estimate," and "continue," and their opposites and similar expressions are intended to identify forward-looking statements. We caution you that these statements are not guarantees of future performance or events and are subject to a number of uncertainties, risks and other influences, many of which are beyond our control that may influence the accuracy of the statements and the projections upon which the statements are based. Factors that may affect our results include, but are not limited to, the risks and uncertainties discussed in the "Risk Factors" section on page 3 of this prospectus, in our Annual Report on Form 10-K or in other reports we file with the Securities and Exchange Commission.

Any one or more of these uncertainties, risks and other influences could materially affect our results of operations and whether forward-looking statements made by us ultimately prove to be accurate. Our actual results, performance and achievements could differ materially from those expressed or implied in these forward-looking statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether from new information, future events or otherwise.

You should rely only on the information in this prospectus. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely upon it.

USE OF PROCEEDS

Unless we inform you otherwise in the prospectus supplement, we will use the net proceeds from the sale of the securities offered by this prospectus and the exercise price from the exercise of any convertible securities, if any, for general corporate purposes, which may include funding research, development and product manufacturing, clinical trials, acquisitions or investments in businesses, products or technologies that are complementary to our own, increasing our working capital, reducing indebtedness, and capital expenditures.

When particular securities are offered, the prospectus supplement relating to that offering will set forth our intended use of the net proceeds received from the sale of those securities we sell. Pending the application of the net proceeds for these purposes, we expect to invest the proceeds in short-term, interest-bearing instruments or other investment-grade securities.

RATIOS OF COMBINED FIXED CHARGES AND PREFERRED STOCK DIVIDENDS TO EARNINGS

The following table sets forth our consolidated ratios of earnings to combined fixed charges and preferred stock dividends for the nine months ended September 30, 2017 and for the years ended December 31, 2016, 2015, 2014, 2013 and 2012. We do not have any outstanding shares of preferred stock and therefore have not paid any preferred stock dividends.

Ratios of Combined Fixed Charges and Preferred Stock Dividends to Earnings

Nine months ended September 30,	Year ended December 31,				
2017	**2016**	**2015**	**2014**	**2013**	**2012**
(1)	(1)	(1)	(1)	(1)	(1)

(1) Due to our losses from continuing operations for the nine months ended September 30, 2017 and for the years ended December 31, 2016, 2015, 2014, 2013 and 2012, earnings were insufficient to cover fixed charges by $21.7 million, $20.0 million, $8.9 million, $2.5 million, $0.6 million, and $0.0 million, respectively. For this reason, no ratios are provided.

THE SECURITIES WE MAY OFFER

General

The descriptions of the securities contained in this prospectus, together with the applicable prospectus supplements, summarize all of the material terms and provisions of the various types of securities that we may offer. We will describe in the applicable prospectus supplement relating to any securities the particular terms of the securities offered by that prospectus supplement. If we indicate in the applicable prospectus supplement, the terms of the securities may differ from the terms we have summarized below. We may also include in the prospectus supplement information about material United States federal income tax considerations relating to the securities, and the securities exchange, if any, on which the securities will be listed.

We may sell from time to time, in one or more offerings:

- common stock;
- preferred stock;
- debt securities;
- subscription rights to purchase shares of common stock, preferred stock or debt securities;
- warrants to purchase shares of common stock or preferred stock; and
- units consisting of any combination of the securities listed above.

In this prospectus, we refer to the common stock, preferred stock, debt securities, subscription rights, warrants and units collectively as "securities." The total dollar amount of all securities that we may sell will not exceed $200,000,000.

If we issue debt securities at a discount from their original stated principal amount, then, for purposes of calculating the total dollar amount of all securities issued under this prospectus, we will treat the initial offering price of the debt securities as the total original principal amount of the debt securities.

This prospectus may not be used to consummate a sale of securities unless it is accompanied by a prospectus supplement.

DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of:

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

As of close of business on January 4, 2018, 55,603,427 shares of common stock were issued and outstanding and no shares of preferred stock were issued and outstanding.

The additional shares of our authorized capital stock available for issuance may be issued at times and under circumstances so as to have a dilutive effect on earnings per share and on the equity ownership of the holders of our common stock. The ability of our board of directors to issue additional shares of stock could enhance the board's ability to negotiate on behalf of the stockholders in a takeover situation but could also be used by the board to make a change-in-control more difficult, thereby denying stockholders the potential to sell their shares at a premium and entrenching current management. The following description is a summary of the material provisions of our capital stock. You should refer to our certificate of incorporation, as amended and bylaws, both of which are on file with the SEC as exhibits to previous SEC filings, for additional information. The summary below is qualified by provisions of applicable law.

Common Stock

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

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

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

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

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

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

Transfer Agent and Registrar

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

Preferred Stock

We are authorized to issue up to 10,000,000 shares of preferred stock, all of which are undesignated. Our board of directors has the authority, within the limitations and restrictions prescribed by law and without stockholder approval, to provide by resolution for the issuance of shares of preferred stock, and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference and the number of shares constituting any series of the designation of such series, by delivering an appropriate certificate of amendment to our amended and restated certificate of incorporation to the Delaware Secretary of State pursuant to the Delaware General Corporation Law (the "DGCL"). The issuance of preferred stock could have the effect of decreasing the market price of the common stock, impeding or delaying a possible takeover and adversely affecting the voting and other rights of the holders of our common stock.

If we offer a specific series of preferred stock under this prospectus, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the certificate establishing the terms of the preferred stock with the SEC. To the extent required, this description will include:

- the title and stated value;
- the number of shares offered, the liquidation preference per share and the purchase price;
- the dividend rate(s), period(s) and/or payment date(s), or method(s) of calculation for such dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption, if applicable;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;
- voting rights, if any, of the preferred stock;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the affairs of Corbus; and
- any material limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of Corbus.

Transfer Agent and Registrar for Preferred Stock

The transfer agent and registrar for any series or class of preferred stock will be set forth in each applicable prospectus supplement.

Anti-takeover Effects of Delaware Law and our Certificate of Incorporation, as amended

Our certificate of incorporation, as amended, and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control. These provisions are as follows:

- they provide that special meetings of stockholders may be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the board of directors;

- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes to the our board of directors; and

- they allow us to issue, without stockholder approval, up to 10,000,000 shares of preferred stock, with such designations, rights, and preferences as may be determined from time to time by our board of directors that could adversely affect the rights and powers of the holders of the common stock, including dividend, liquidation, conversion, voting, or other rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying or preventing a change in control of our company, all without further action by our stockholders.

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

- prior to the time of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

- on or subsequent to the time of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

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

Stockholder Action by Written Consent

Our certificate of incorporation, as amended, specifically denies the ability of stockholders to take action by written consent of the stockholders in lieu of a meeting.

Potential Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the DGCL and subject to any limitations set forth in our certificate of incorporation, as amended. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

DESCRIPTION OF STOCK WARRANTS

We summarize below some of the provisions that will apply to the warrants unless the applicable prospectus supplement provides otherwise. This summary may not contain all information that is important to you. The complete terms of the warrants will be contained in the applicable warrant certificate and warrant agreement. These documents have been or will be included or incorporated by reference as exhibits to the registration statement of which this prospectus is a part. You should read the warrant certificate and the warrant agreement. You should also read the prospectus supplement, which will contain additional information and which may update or change some of the information below.

General

We may issue, together with common or preferred stock as units or separately, warrants for the purchase of shares of our common or preferred stock. The terms of each warrant will be discussed in the applicable prospectus supplement relating to the particular series of warrants. The form(s) of certificate representing the warrants and/or the warrant agreement will be, in each case, filed with the SEC as an exhibit to a document incorporated by reference in the registration statement of which this prospectus is a part on or prior to the date of any prospectus supplement relating to an offering of the particular warrant. The following summary of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to a particular series of warrants.

The prospectus supplement relating to any series of warrants that are offered by this prospectus will describe, among other things, the following terms to the extent they are applicable to that series of warrants:

- the procedures and conditions relating to the exercise of the warrants;
- the number of shares of our common or preferred stock, if any, issued with the warrants;
- the date, if any, on and after which the warrants and any related shares of our common or preferred stock will be separately transferable;
- the offering price of the warrants, if any;
- the number of shares of our common or preferred stock which may be purchased upon exercise of the warrants and the price or prices at which the shares may be purchased upon exercise;
- the date on which the right to exercise the warrants will begin and the date on which the right will expire;
- a discussion of the material United States federal income tax considerations applicable to the exercise of the warrants;
- anti-dilution provisions of the warrants, if any;
- call provisions of the warrants, if any; and
- any other material terms of the warrants.

Each warrant may entitle the holder to purchase for cash, or, in limited circumstances, by effecting a cashless exercise for, the number of shares of our common or preferred stock at the exercise price that is described in the applicable prospectus supplement. Warrants will be exercisable during the period of time described in the applicable prospectus supplement. After that period, unexercised warrants will be void. Warrants may be exercised in the manner described in the applicable prospectus supplement.

A holder of a warrant will not have any of the rights of a holder of our common or preferred stock before the stock is purchased upon exercise of the warrant. Therefore, before a warrant is exercised, the holder of the warrant will not be entitled to receive any dividend payments or exercise any voting or other rights associated with shares of our common or preferred stock which may be purchased when the warrant is exercised.

Transfer Agent and Registrar

The transfer agent and registrar, if any, for any warrants will be set forth in the applicable prospectus supplement.

DESCRIPTION OF DEBT SECURITIES

This prospectus describes certain general terms and provisions of debt securities that we may offer. The debt securities may be issued pursuant to, in the case of senior debt securities, a senior indenture, and in the case of subordinated debt securities, a subordinated indenture, in each case in the forms filed as exhibits to this registration statement, which we refer to as the “indentures.” The indentures will be entered into between us and a trustee to be named prior to the issuance of any debt securities, which we refer to as the “trustee.” The indentures will not limit the amount of debt securities that can be issued thereunder and will provide that the debt securities may be issued from time to time in one or more series pursuant to the terms of one or more securities resolutions or supplemental indentures creating such series.

We have summarized below the material provisions of the indentures and the debt securities or indicated which material provisions will be described in the related prospectus supplement for any offering of debt securities. These descriptions are only summaries, and you should refer to the relevant indenture for the particular offering of debt securities itself which will describe completely the terms and definitions of the offered debt securities and contain additional information about the debt securities.

Terms

When we offer to sell a particular series of debt securities, we will describe the specific terms of the securities in a prospectus supplement. The prospectus supplement will set forth the following terms, as applicable, of the debt securities offered thereby:

- the designation, aggregate principal amount, currency or composite currency and denominations;
- the price at which such debt securities will be issued and, if an index formula or other method is used, the method for determining amounts of principal or interest;
- the maturity date and other dates, if any, on which principal will be payable;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- whether the debt securities rank as senior debt, senior subordinated debt, subordinated debt or any combination thereof, and the terms of any subordination;
- the interest rate (which may be fixed or variable), if any;
- the date or dates from which interest will accrue and on which interest will be payable, and the record dates for the payment of interest;
- the manner of paying principal and interest;
- the place or places where principal and interest will be payable;
- the terms of any mandatory or optional redemption by us or any third party including any sinking fund;
- the terms of any conversion or exchange;
- the terms of any redemption at the option of holders or put by the holders;
- any tax indemnity provisions;
- if the debt securities provide that payments of principal or interest may be made in a currency other than that in which the debt securities are denominated, the manner for determining such payments;
- the portion of principal payable upon acceleration of a Discounted Debt Security (as defined below);
- whether and upon what terms debt securities may be defeased;
- any events of default or covenants in addition to or in lieu of those set forth in the indentures;
- provisions for electronic issuance of debt securities or for the issuance of debt securities in uncertificated form; and
- any additional provisions or other special terms not inconsistent with the provisions of the indentures, including any terms that may be required or advisable under United States or other applicable laws or regulations, or advisable in connection with the marketing of the debt securities.

Debt securities of any series may be issued as registered debt securities or uncertificated debt securities, in such denominations as specified in the terms of the series.

Securities may be issued under the indentures as Discounted Debt Securities to be offered and sold at a substantial discount from the principal amount thereof. Special United States federal income tax and other considerations applicable thereto will be described in the prospectus supplement relating to such Discounted Debt Securities. “Discounted Debt Security” means a security where the amount of principal due upon acceleration is less than the stated principal amount.

We are not obligated to issue all debt securities of one series at the same time and, unless otherwise provided in the prospectus supplement, we may reopen a series, without the consent of the holders of the debt securities of that series, for the issuance of additional debt securities of that series. Additional debt securities of a particular series will have the same terms and conditions as outstanding debt securities of such series, except for the date of original issuance and the offering price, and will be consolidated with, and form a single series with, such outstanding debt securities.

Ranking

The senior debt securities will rank equally with all of our other senior and unsubordinated debt. Our secured debt, if any, will be effectively senior to the senior debt securities to the extent of the value of the assets securing such debt. The subordinated debt securities will be subordinate and junior in right of payment to all of our present and future senior indebtedness to the extent and in the manner described in the prospectus supplement and as set forth in the board resolution, officer's certificate or supplemental indenture relating to such offering.

We have only a stockholder's claim on the assets of our subsidiaries. This stockholder's claim is junior to the claims that creditors of our subsidiaries have against our subsidiaries. Holders of our debt securities will be our creditors and not creditors of any of our subsidiaries. As a result, all the existing and future liabilities of our subsidiaries, including any claims of their creditors, will effectively be senior to the debt securities with respect to the assets of our subsidiaries. In addition, to the extent that we issue any secured debt, the debt securities will be effectively subordinated to such secured debt to the extent of the value of the assets securing such secured debt.

The debt securities will be obligations exclusively of Corbus Pharmaceuticals Holdings, Inc. To the extent that our ability to service our debt, including the debt securities, may be dependent upon the earnings of our subsidiaries, our ability to do so will be dependent on the ability of our subsidiaries to distribute those earnings to us as dividends, loans or other payments.

Certain Covenants

Any covenants that may apply to a particular series of debt securities will be described in the prospectus supplement relating thereto.

Successor Obligor

The indentures provide that, unless otherwise specified in the securities resolution or supplemental indenture establishing a series of debt securities, we shall not consolidate with or merge into, or transfer all or substantially all of our assets to, any person in any transaction in which we are not the survivor, unless:

- the person is organized under the laws of the United States or a jurisdiction within the United States;
- the person assumes by supplemental indenture all of our obligations under the relevant indenture, the debt securities and any coupons;
- immediately after the transaction no Default (as defined below) exists; and
- we deliver to the trustee an officers' certificate and opinion of counsel stating that the transaction complies with the foregoing requirements and that all conditions precedent provided for in the indenture relating to the transaction have been complied with.

In such event, the successor will be substituted for us, and thereafter all of our obligations under the relevant indenture, the debt securities and any coupons will terminate.

The indentures provide that these limitations shall not apply if our board of directors makes a good faith determination that the principal purpose of the transaction is to change our state of incorporation.

Exchange of Debt Securities

Registered debt securities may be exchanged for an equal aggregate principal amount of registered debt securities of the same series and date of maturity in such authorized denominations as may be requested upon surrender of the registered debt securities at an agency of the Company maintained for such purpose and upon fulfillment of all other requirements of such agent.

Default and Remedies

Unless the securities resolution or supplemental indenture establishing the series otherwise provides (in which event the prospectus supplement will so state), an "Event of Default" with respect to a series of debt securities will occur if:

(1) we default in any payment of interest on any debt securities of such series when the same becomes due and payable and the default continues for a period of 30 days;

(2) we default in the payment of all or any part of the principal and premium, if any, of any debt securities of such series when the same becomes due and payable at maturity or upon redemption, acceleration or otherwise and such default shall continue for five or more days;

(3) we default in the performance of any of our other agreements applicable to the series and the default continues for 30 days after the notice specified below;

(4) a court of competent jurisdiction enters an order or decree under any Bankruptcy Law (as defined below) that:

(A) is for relief against us in an involuntary case,

(B) appoints a Custodian (as defined below) for us or for any substantial part of our property, or

(C) orders the winding up or liquidation of us, and the order or decree remains unstayed and in effect for 90 days;

(5) we, pursuant to or within the meaning of any Bankruptcy Law:

(A) commence a voluntary case,

(B) consent to the entry of an order for relief against us in an involuntary case,

(C) consent to the appointment of a Custodian for us or for any substantial part of our property, or

(D) make a general assignment for the benefit of our creditors; or

(6) there occurs any other Event of Default provided for in such series.

The term "Bankruptcy Law" means Title 11 of the United States Code or any similar Federal or State law for the relief of debtors. The term "Custodian" means any receiver, trustee, assignee, liquidator or a similar official under any Bankruptcy Law.

"Default" means any event which is, or after notice or passage of time would be, an Event of Default. A Default under subparagraph (3) above is not an Event of Default until the trustee or the holders of at least 25% in principal amount of the series notify us of the Default and we do not cure the Default within the time specified after receipt of the notice.

The trustee may require indemnity satisfactory to it before it enforces the indentures or the debt securities of the series. Subject to certain limitations, holders of a majority in principal amount of the debt securities of the series may direct the trustee in its exercise of any trust or power with respect to such series. Except in the case of Default in payment on a series, the trustee may withhold from securityholders of such series notice of any continuing Default if the trustee determines that withholding notice is in the interest of such securityholders. We are required to furnish the trustee annually a brief certificate as to our compliance with all conditions and covenants under the indentures.

The indentures do not have cross-default provisions. Thus, a default by us on any other debt, including any other series of debt securities, would not constitute an Event of Default.

Amendments and Waivers

The indentures and the debt securities or any coupons of the series may be amended, and any Default may be waived as follows:

Unless the securities resolution or supplemental indenture otherwise provides (in which event the applicable prospectus supplement will so state), the debt securities and the indentures may be amended with the consent of the holders of a majority in principal amount of the debt securities of all series affected voting as one class. Unless the securities resolution or supplemental indenture otherwise provides (in which event the applicable prospectus supplement will so state), a Default other than a Default in payment on a particular series may be waived with the consent of the holders of a majority in principal amount of the debt securities of the series. However, without the consent of each securityholder affected, no amendment or waiver may:

- change the fixed maturity of or the time for payment of interest on any debt security;
- reduce the principal, premium or interest payable with respect to any debt security;
- change the place of payment of a debt security or the currency in which the principal or interest on a debt security is payable;
- change the provisions for calculating any redemption or repurchase price with respect to any debt security;
- adversely affect any holder's right to receive payment of principal and interest or to institute suit for the enforcement of any such payment;

- reduce the amount of debt securities whose holders must consent to an amendment or waiver;
- make any change that materially adversely affects the right to convert any debt security;
- waive any Default in payment of principal of or interest on a debt security; or
- adversely affect any holder's rights with respect to redemption or repurchase of a debt security.

Without the consent of any securityholder, the indentures or the debt securities may be amended to:

- provide for assumption of our obligations to securityholders in the event of a merger or consolidation requiring such assumption;
- cure any ambiguity, omission, defect or inconsistency;
- conform the terms of the debt securities to the description thereof in the prospectus and prospectus supplement offering such debt securities;
- create a series and establish its terms;
- provide for the acceptance of appointment by a successor trustee or to facilitate the administration of the trusts by more than one trustee;
- provide for uncertificated or unregistered securities;
- make any change that does not adversely affect the rights of any securityholder;
- add to our covenants; or
- make any other change to the indentures so long as no debt securities are outstanding.

Conversion Rights

Any securities resolution or supplemental indenture establishing a series of debt securities may provide that the debt securities of such series will be convertible at the option of the holders thereof into or for our common stock or other equity or debt instruments. The securities resolution or supplemental indenture may establish, among other things, (1) the number or amount of shares of common stock or other equity or debt instruments for which $1,000 aggregate principal amount of the debt securities of the series is convertible, as may be adjusted pursuant to the terms of the relevant indenture and the securities resolution; and (2) provisions for adjustments to the conversion rate and limitations upon exercise of the conversion right. The indentures provide that we will not be required to make an adjustment in the conversion rate unless the adjustment would require a cumulative change of at least 1% in the conversion rate. However, we will carry forward any adjustments that are less than 1% of the conversion rate and take them into account in any subsequent adjustment of the conversion rate.

Legal Defeasance and Covenant Defeasance

Debt securities of a series may be defeased in accordance with their terms and, unless the securities resolution or supplemental indenture establishing the terms of the series otherwise provides, as set forth below. We at any time may terminate as to a series all of our obligations (except for certain obligations, including obligations with respect to the defeasance trust and obligations to register the transfer or exchange of a debt security, to replace destroyed, lost or stolen debt securities and coupons and to maintain paying agencies in respect of the debt securities) with respect to the debt securities of the series and any related coupons and the relevant indenture, which we refer to as legal defeasance. We at any time may terminate as to a series our obligations with respect to any restrictive covenants which may be applicable to a particular series, which we refer to as covenant defeasance.

We may exercise our legal defeasance option notwithstanding our prior exercise of our covenant defeasance option. If we exercise our legal defeasance option, a series may not be accelerated because of an Event of Default. If we exercise our covenant defeasance option, a series may not be accelerated by reference to any covenant which may be applicable to a series.

To exercise either defeasance option as to a series, we must (1) irrevocably deposit in trust with the trustee (or another trustee) money or U.S. Government Obligations (as defined below), deliver a certificate from a nationally recognized firm of independent accountants expressing their opinion that the payments of principal and interest when due on the deposited U.S. Government Obligations, without reinvestment, plus any deposited money without investment will provide cash at such times and in such amounts as will be sufficient to pay the principal and interest when due on all debt securities of such series to maturity or redemption, as the case may be; and (2) comply with certain other conditions. In particular, we must obtain an opinion of tax counsel that the defeasance will not result in recognition of any gain or loss to holders for federal income tax purposes.

"U.S. Government Obligations" means direct obligations of the United States or any agency or instrumentality of the United States, the payment of which is unconditionally guaranteed by the United States, which, in either case, have the full faith and credit of the United States pledged for payment and which are not callable at the issuer's option, or certificates representing an ownership interest in such obligations.

Regarding the Trustee

Unless otherwise indicated in a prospectus supplement, the trustee will also act as depository of funds, transfer agent, paying agent and conversion agent, as applicable, with respect to the debt securities. In certain circumstances, we or the securityholders may remove the trustee as the trustee under a given indenture. The indenture trustee may also provide additional unrelated services to us as a depository of funds, registrar, trustee and similar services.

Governing Law

The indentures and the debt securities will be governed by New York law, except to the extent that the Trust Indenture Act of 1939 is applicable.

DESCRIPTION OF SUBSCRIPTION RIGHTS

We may issue subscription rights to purchase our common stock or debt securities. These subscription rights may be offered independently or together with any other security offered hereby and may or may not be transferable by the stockholder receiving the subscription rights in such offering. In connection with any offering of subscription rights, we may enter into a standby arrangement with one or more underwriters or other purchasers pursuant to which the underwriters or other purchasers may be required to purchase any securities remaining unsubscribed for after such offering.

The prospectus supplement relating to any subscription rights we offer, if any, will, to the extent applicable, include specific terms relating to the offering, including some or all of the following:

- the price, if any, for the subscription rights;
- the exercise price payable for our common stock or debt securities upon the exercise of the subscription rights;
- the number of subscription rights to be issued to each stockholder;
- the number and terms of our common stock or debt securities which may be purchased per each subscription right;
- the extent to which the subscription rights are transferable;
- any other terms of the subscription rights, including the terms, procedures and limitations relating to the exchange and exercise of the subscription rights;
- the date on which the right to exercise the subscription rights shall commence, and the date on which the subscription rights shall expire;
- the extent to which the subscription rights may include an over-subscription privilege with respect to unsubscribed securities or an over-allotment privilege to the extent the securities are fully subscribed; and
- i f applicable, the material terms of any standby underwriting or purchase arrangement which may be entered into by us in connection with the offering of subscription rights.

DESCRIPTION OF UNITS

We may issue units comprised of one or more of the other securities described in this prospectus in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each included security (but, to the extent convertible securities are included in the units, the holder of the units will be deemed the holder of the convertible securities and not the holder of the underlying securities). The unit agreement under which a unit is issued, if any, may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date. The applicable prospectus supplement may describe:

- the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;
- any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units;
- the terms of the unit agreement governing the units;
- United States federal income tax considerations relevant to the units; and
- whether the units will be issued in fully registered global form.

This summary of certain general terms of units and any summary description of units in the applicable prospectus supplement do not purport to be complete and are qualified in their entirety by reference to all provisions of the applicable unit agreement and, if applicable, collateral arrangements and depositary arrangements relating to such units. The forms of the unit agreements and other documents relating to a particular issue of units will be filed with the SEC each time we issue units, and you should read those documents for provisions that may be important to you.

FORMS OF SECURITIES

Each debt security and, to the extent applicable, warrant, subscription right and unit, will be represented either by a certificate issued in definitive form to a particular investor or by one or more global securities representing the entire issuance of securities. Certificated securities in definitive form and global securities will be issued in registered form. Definitive securities name you or your nominee as the owner of the security, and in order to transfer or exchange these securities or to receive payments other than interest or other interim payments, you or your nominee must physically deliver the securities to the trustee, registrar, paying agent or other agent, as applicable. Global securities name a depositary or its nominee as the owner of the debt securities or warrants represented by these global securities. The depositary maintains a computerized system that will reflect each investor's beneficial ownership of the securities through an account maintained by the investor with its broker/dealer, bank, trust company or other representative, as we explain more fully below.

Global Securities

Registered Global Securities. We may issue the registered debt securities and, to the extent applicable, warrants, subscription rights and units, in the form of one or more fully registered global securities that will be deposited with a depositary or its nominee identified in the applicable prospectus supplement and registered in the name of that depositary or nominee. In those cases, one or more registered global securities will be issued in a denomination or aggregate denominations equal to the portion of the aggregate principal or face amount of the securities to be represented by registered global securities. Unless and until it is exchanged in whole for securities in definitive registered form, a registered global security may not be transferred except as a whole by and among the depositary for the registered global security, the nominees of the depositary or any successors of the depositary or those nominees.

If not described below, any specific terms of the depositary arrangement with respect to any securities to be represented by a registered global security will be described in the prospectus supplement relating to those securities. We anticipate that the following provisions will apply to all depositary arrangements.

Ownership of beneficial interests in a registered global security will be limited to persons, called participants, that have accounts with the depositary or persons that may hold interests through participants. Upon the issuance of a registered global security, the depositary will credit, on its book-entry registration and transfer system, the participants' accounts with the respective principal or face amounts of the securities beneficially owned by the participants. Any dealers, underwriters or agents participating in the distribution of the securities will designate the accounts to be credited. Ownership of beneficial interests in a registered global security will be shown on, and the transfer of ownership interests will be effected only through, records maintained by the depositary, with respect to interests of participants, and on the records of participants, with respect to interests of persons holding through participants. The laws of some states may require that some purchasers of securities take physical delivery of these securities in definitive form. These laws may impair your ability to own, transfer or pledge beneficial interests in registered global securities.

So long as the depositary, or its nominee, is the registered owner of a registered global security, that depositary or its nominee, as the case may be, will be considered the sole owner or holder of the securities represented by the registered global security for all purposes under the applicable indenture or warrant agreement. Except as described below, owners of beneficial interests in a registered global security will not be entitled to have the securities represented by the registered global security registered in their names, will not receive or be entitled to receive physical delivery of the securities in definitive form and will not be considered the owners or holders of the securities under the applicable indenture or warrant agreement. Accordingly, each person owning a beneficial interest in a registered global security must rely on the procedures of the depositary for that registered global security and, if that person is not a participant, on the procedures of the participant through which the person owns its interest, to exercise any rights of a holder under the applicable indenture or warrant agreement. We understand that under existing industry practices, if we request any action of holders or if an owner of a beneficial interest in a registered global security desires to give or take any action that a holder is entitled to give or take under the applicable indenture or warrant agreement, the depositary for the registered global security would authorize the participants holding the relevant beneficial interests to give or take that action, and the participants would authorize beneficial owners owning through them to give or take that action or would otherwise act upon the instructions of beneficial owners holding through them.

Principal, premium, if any, interest payments on debt securities and any payments to holders with respect to warrants represented by a registered global security registered in the name of a depositary or its nominee will be made to the depositary or its nominee, as the case may be, as the registered owner of the registered global security. None of the Company, the trustees, the warrant agents or any other agent of the Company, the trustees or the warrant agents will have any responsibility or liability for any aspect of the records relating to payments made on account of beneficial ownership interests in the registered global security or for maintaining, supervising or reviewing any records relating to those beneficial ownership interests.

We expect that the depositary for any of the securities represented by a registered global security, upon receipt of any payment of principal, premium, interest or other distribution of underlying securities or other property to holders on that registered global security, will immediately credit participants' accounts in amounts proportionate to their respective beneficial interests in that registered global security as shown on the records of the depositary. We also expect that payments by participants to owners of beneficial interests in a registered global security held through participants will be governed by standing customer instructions and customary practices, as is now the case with the securities held for the accounts of customers in bearer form or registered in "street name," and will be the responsibility of those participants.

If the depositary for any of these securities represented by a registered global security is at any time unwilling or unable to continue as depositary or ceases to be a clearing agency registered under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and a successor depositary registered as a clearing agency under the Exchange Act is not appointed by us within 90 days, we will issue securities in definitive form in exchange for the registered global security that had been held by the depositary. Any securities issued in definitive form in exchange for a registered global security will be registered in the name or names that the depositary gives to the relevant trustee or warrant agent or other relevant agent of ours or theirs. It is expected that the depositary's instructions will be based upon directions received by the depositary from participants with respect to ownership of beneficial interests in the registered global security that had been held by the depositary.

PLAN OF DISTRIBUTION

Initial Offering and Sale of Securities

Unless otherwise set forth in a prospectus supplement accompanying this prospectus, we may sell the securities being offered hereby, from time to time, by one or more of the following methods:

- to or through underwriting syndicates represented by managing underwriters;
- through one or more underwriters without a syndicate for them to offer and sell to the public;
- through dealers or agents; and
- to investors directly in negotiated sales or in competitively bid transactions.

Offerings of securities covered by this prospectus also may be made into an existing trading market for those securities in transactions at other than a fixed price, either:

- on or through the facilities of the Nasdaq Global Market or any other securities exchange or quotation or trading service on which those securities may be listed, quoted, or traded at the time of sale; and/or
- to or through a market maker other than on the securities exchanges or quotation or trading services set forth above.

Those at-the-market offerings, if any, will be conducted by underwriters acting as principal or agent of the Company, who may also be third-party sellers of securities as described above. The prospectus supplement with respect to the offered securities will set forth the terms of the offering of the offered securities, including:

- the name or names of any underwriters, dealers or agents;
- the purchase price of the offered securities and the proceeds to us from such sale;
- any underwriting discounts and commissions or agency fees and other items constituting underwriters' or agents' compensation;
- any initial public offering price and any discounts or concessions allowed or reallowed or paid to dealers;
- any securities exchange on which such offered securities may be listed; and
- any underwriter, agent or dealer involved in the offer and sale of any series of the securities.

The distribution of the securities may be effected from time to time in one or more transactions:

- at fixed prices, which may be changed;
- at market prices prevailing at the time of the sale;
- at varying prices determined at the time of sale; or
- at negotiated prices.

Each prospectus supplement will set forth the manner and terms of an offering of securities including:

- whether that offering is being made to underwriters, through agents or directly to the public;
- the rules and procedures for any auction or bidding process, if used;
- the securities' purchase price or initial public offering price; and
- the proceeds we anticipate from the sale of the securities, if any.

In addition, we may enter into derivative or hedging transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. The applicable prospectus supplement may indicate, in connection with such a transaction, that the third parties may sell securities covered by and pursuant to this prospectus and an applicable prospectus supplement. If so, the third party may use securities pledged by us or borrowed from us or others to settle such sales and may use securities received from us to close out any related short positions. We may also loan or pledge securities covered by this prospectus and an applicable prospectus supplement to third parties, who may sell the loaned securities or, in an event of default in the case of a pledge, sell the pledged securities pursuant to this prospectus and the applicable prospectus supplement.

Sales Through Underwriters

If underwriters are used in the sale of some or all of the securities covered by this prospectus, the underwriters will acquire the securities for their own account. The underwriters may resell the securities, either directly to the public or to securities dealers, at various times in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The obligations of the underwriters to purchase the securities will be subject to certain conditions. Unless indicated otherwise in a prospectus supplement, the underwriters will be obligated to purchase all the securities of the series offered if any of the securities are purchased.

Any initial public offering price and any concessions allowed or reallowed to dealers may be changed intermittently.

Sales Through Agents

Unless otherwise indicated in the applicable prospectus supplement, when securities are sold through an agent, the designated agent will agree, for the period of its appointment as agent, to use specified efforts to sell the securities for our account and will receive commissions from us as will be set forth in the applicable prospectus supplement.

Securities bought in accordance with a redemption or repayment under their terms also may be offered and sold, if so indicated in the applicable prospectus supplement, in connection with a remarketing by one or more firms acting as principals for their own accounts or as agents for us. Any remarketing firm will be identified and the terms of its agreement, if any, with us and its compensation will be described in the prospectus supplement. Remarketing firms may be deemed to be underwriters in connection with the securities remarketed by them.

If so indicated in the applicable prospectus supplement, we may authorize agents, underwriters or dealers to solicit offers by certain specified institutions to purchase securities at a price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a future date specified in the prospectus supplement. These contracts will be subject only to those conditions set forth in the applicable prospectus supplement, and the prospectus supplement will set forth the commissions payable for solicitation of these contracts.

Direct Sales

We may also sell offered securities directly to institutional investors or others. In this case, no underwriters or agents would be involved. The terms of such sales will be described in the applicable prospectus supplement.

General Information

Broker-dealers, agents or underwriters may receive compensation in the form of discounts, concessions or commissions from us and/or the purchasers of securities for whom such broker-dealers, agents or underwriters may act as agents or to whom they sell as principal, or both. This compensation to a particular broker-dealer might be in excess of customary commissions.

Underwriters, dealers and agents that participate in any distribution of the offered securities may be deemed “underwriters” within the meaning of the Securities Act of 1933, as amended (the “Securities Act”), so any discounts or commissions they receive in connection with the distribution may be deemed to be underwriting compensation. Those underwriters and agents may be entitled, under their agreements with us, to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution by us to payments that they may be required to make in respect of those civil liabilities. Certain of those underwriters or agents may be customers of, engage in transactions with, or perform services for, us or our affiliates in the ordinary course of business. We will identify any underwriters or agents, and describe their compensation, in a prospectus supplement. Any institutional investors or others that purchase offered securities directly, and then resell the securities, may be deemed to be underwriters, and any discounts or commissions received by them from us and any profit on the resale of the securities by them may be deemed to be underwriting discounts and commissions under the Securities Act.

We will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act, if we enter into any material arrangement with a broker, dealer, agent or underwriter for the sale of securities through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer. Such prospectus supplement will disclose:

- the name of any participating broker, dealer, agent or underwriter;
- the number and type of securities involved;
- the price at which such securities were sold;
- any securities exchanges on which such securities may be listed;
- the commissions paid or discounts or concessions allowed to any such broker, dealer, agent or underwriter, where applicable; and
- other facts material to the transaction.

In order to facilitate the offering of certain securities under this prospectus or an applicable prospectus supplement, certain persons participating in the offering of those securities may engage in transactions that stabilize, maintain or otherwise affect the price of those securities during and after the offering of those securities. Specifically, if the applicable prospectus supplement permits, the underwriters of those securities may over-allot or otherwise create a short position in those securities for their own account by selling more of those securities than have been sold to them by us and may elect to cover any such short position by purchasing those securities in the open market.

In addition, the underwriters may stabilize or maintain the price of those securities by bidding for or purchasing those securities in the open market and may impose penalty bids, under which selling concessions allowed to syndicate members or other broker-dealers participating in the offering are reclaimed if securities previously distributed in the offering are repurchased in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also affect the price of securities to the extent that it discourages resales of the securities. No representation is made as to the magnitude or effect of any such stabilization or other transactions. Such transactions, if commenced, may be discontinued at any time.

In order to comply with the securities laws of certain states, if applicable, the securities must be sold in such jurisdictions only through registered or licensed brokers or dealers. In addition, in certain states the securities may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Rule 15c6-1 under the Exchange Act generally requires that trades in the secondary market settle in two business days, unless the parties to any such trade expressly agree otherwise. Your prospectus supplement may provide that the original issue date for your securities may be more than two scheduled business days after the trade date for your securities. Accordingly, in such a case, if you wish to trade securities on any date prior to the second business day before the original issue date for your securities, you will be required, by virtue of the fact that your securities initially are expected to settle in more than two scheduled business days after the trade date for your securities, to make alternative settlement arrangements to prevent a failed settlement.

This prospectus, any applicable prospectus supplement and any applicable pricing supplement in electronic format may be made available on the Internet sites of, or through other online services maintained by, us and/or one or more of the agents and/or dealers participating in an offering of securities, or by their affiliates. In those cases, prospective investors may be able to view offering terms online and, depending upon the particular agent or dealer, prospective investors may be allowed to place orders online.

Other than this prospectus, any applicable prospectus supplement and any applicable pricing supplement in electronic format, the information on our website or the website of any agent or dealer, and any information contained in any other website maintained by any agent or dealer:

- is not part of this prospectus, any applicable prospectus supplement or any applicable pricing supplement or the registration statement of which they form a part;
- has not been approved or endorsed by us or by any agent or dealer in its capacity as an agent or dealer, except, in each case, with respect to the respective website maintained by such entity; and
- should not be relied upon by investors.

There can be no assurance that we will sell all or any of the securities offered by this prospectus.

This prospectus may also be used in connection with any issuance of common stock or preferred stock upon exercise of a warrant if such issuance is not exempt from the registration requirements of the Securities Act.

In addition, we may issue the securities as a dividend or distribution or in a subscription rights offering to our existing securityholders. In some cases, we or dealers acting with us or on our behalf may also purchase securities and reoffer them to the public by one or more of the methods described above. This prospectus may be used in connection with any offering of our securities through any of these methods or other methods described in the applicable prospectus supplement.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, the validity of the securities offered hereby will be passed upon for us by Lowenstein Sandler LLP, New York, New York. If the validity of the securities offered hereby in connection with offerings made pursuant to this prospectus are passed upon by counsel for the underwriters, dealers or agents, if any, such counsel will be named in the prospectus supplement relating to such offering.

EXPERTS

The consolidated balance sheets of Corbus Pharmaceuticals Holdings, Inc. and subsidiary as of December 31, 2016 and 2015 and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years then ended, have been audited by EisnerAmper LLP, an independent registered public accounting firm as stated in their report dated March 8, 2017, which is incorporated herein by reference. Such consolidated financial statements have been incorporated herein by reference in reliance on the report of such firm, given upon their authority as experts in auditing and accounting.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Section 145 of the DGCL provides that we may indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal or investigative (other than an action by us or in our right) by reason of the fact that he is or was our director, officer, employee or agent, or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action, suit or proceeding if he acted in good faith and in a manner he or she reasonably believed to be in or not opposed to our best interests, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Section 145 further provides that we similarly may indemnify any such person serving in any such capacity who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by is or in our right to procure judgment in our favor, against expenses actually and reasonably incurred in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he reasonably believed to be in or not opposed to our best interests and except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to us unless and only to the extent that the Delaware Court of Chancery or such other court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our certificate of incorporation, as amended, limits the liability of our directors to the fullest extent permitted by Delaware law. In addition, we have entered into indemnification agreements with certain of our directors and officers whereby we have agreed to indemnify those directors and officers to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director or officer was, or is threatened to be made, a party by reason of the fact that such director or officer is or was a director, officer, employee or agent of the Company, provided that such director or officer acted in good faith and in a manner that the director or officer reasonably believed to be in, or not opposed to, the best interests of the Company.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and officers who, by reason of the fact that he or she is one of our officers or directors of our company, is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, related to their board role with the company.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

ADDITIONAL INFORMATION

This prospectus is part of a Registration Statement on Form S-3 that we have filed with the SEC relating to the shares of our securities being offered hereby. This prospectus does not contain all of the information in the Registration Statement and its exhibits. The Registration Statement, its exhibits and the documents incorporated by reference in this prospectus and their exhibits, all contain information that is material to the offering of the Securities hereby. Whenever a reference is made in this prospectus to any of our contracts or other documents, the reference may not be complete. You should refer to the exhibits that are a part of the Registration Statement in order to review a copy of the contract or documents. The Registration Statement and the exhibits are available at the SEC's Public Reference Room or through its Website.

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read and copy any materials we file with the SEC at its Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 and at its regional offices, a list of which is available on the Internet at http://www.sec.gov/contact/addresses.htm. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site at http://www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers, such as us, that file electronically with the SEC. Additionally, you may access our filings with the SEC through our website at http://www.corbuspharma.com. The information on our website is not part of this prospectus.

We will provide you without charge, upon your oral or written request, with a copy of any or all reports, proxy statements and other documents we file with the SEC, as well as any or all of the documents incorporated by reference in this prospectus or the Registration Statement (other than exhibits to such documents unless such exhibits are specifically incorporated by reference into such documents). Requests for such copies should be directed to:

Corbus Pharmaceuticals Holdings, Inc.
100 River Ridge Drive
Norwood, MA 02062
Telephone number: (617) 963-0100

You should rely only on the information in this prospectus and the additional information described above and under the heading "Incorporation of Certain Information by Reference" below. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely upon it. We are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information in this prospectus was accurate on the date of the front cover of this prospectus only. Our business, financial condition, results of operations and prospects may have changed since that date.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information that we file with it into this prospectus, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus. The information incorporated by reference is considered to be a part of this prospectus, and information that we file later with the SEC will automatically update and supersede information contained in this prospectus and any accompanying prospectus supplement.

We incorporate by reference the documents listed below that we have previously filed with the SEC:

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 8, 2017;
- our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2017, filed with the SEC on May 9, 2017, June 30, 2017, filed with the SEC on August 9, 2017 and September 30, 2017, filed with the SEC on November 8, 2017;
- our Proxy Statement on Schedule 14A filed with the SEC on April 10, 2017;
- our Current Reports on Form 8-K filed with the SEC on February 28, 2017, March 30, 2017, May 26, 2017, August 22, 2017, October 17, 2017, October 19, 2017, October 24, 2017 and November 27, 2017 (other than any portions thereof deemed furnished and not filed); and
- the description of our common stock contained in our Registration Statement on Form 8-A, filed on April 14, 2015, including any amendments thereto or reports filed for the purposes of updating this description.

All reports and other documents that we file with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus but before the termination of the offering of the securities hereunder will also be considered to be incorporated by reference into this prospectus from the date of the filing of these reports and documents, and will supersede the information herein; provided, however, that all reports, exhibits and other information that we "furnish" to the SEC will not be considered incorporated by reference into this prospectus. We undertake to provide without charge to each person (including any beneficial owner) who receives a copy of this prospectus, upon written or oral request, a copy of all of the preceding documents that are incorporated by reference (other than exhibits, unless the exhibits are specifically incorporated by reference into these documents). You may request a copy of these materials in the manner set forth under the heading "Additional Information," above.

Shares

Common Stock

PROSPECTUS SUPPLEMENT

Joint Book-Running Managers

Jefferies **RBC Capital Markets**

, 2019