Filed Pursuant to Rule 424(b)(3)
Registration No. 333-222447

PROSPECTUS

Up to $50,000,000

Common Stock

We have entered into a Controlled Equity Offering[SM] Sales Agreement, or sales agreement, with Cantor Fitzgerald & Co. relating to shares of our common stock offered by this prospectus. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million from time to time through Cantor Fitzgerald & Co., acting as sales agent.

Our common stock is listed on the Nasdaq Global Market under the symbol "CRBP." On January 16, 2018, the last reported sales price of our common stock on the Nasdaq Global Market was $7.90 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 4 of this prospectus and in the documents incorporated by reference in this prospectus.

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.

Upon delivery of a placement notice, and subject to our instructions in that notice and the terms and conditions of the sales agreement generally, Cantor Fitzgerald & Co. may sell our common stock by any method permitted by law deemed to be an "at the market offering" as defined by Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or the Securities Act. Cantor Fitzgerald & Co. is not required to sell any specific number or dollar amount of securities, but will act as a sales agent using commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreed terms between Cantor Fitzgerald & Co. and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cantor Fitzgerald & Co. will be entitled to compensation at a fixed commission rate equal to 3% of the gross sales price per share sold. In connection with the sale of our common stock on our behalf, Cantor Fitzgerald & Co. will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cantor Fitzgerald & Co. will be deemed to be underwriting commissions or discounts. See "Plan of Distribution" beginning on page 37 for additional information regarding the compensation to be paid to Cantor Fitzgerald & Co.

The date of this prospectus is January 17, 2018.

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ABOUT THIS PROSPECTUS

This prospectus is part of registration statement on Form S-3 that we have filed with the Securities and Exchange Commission, or the SEC, using a "shelf" registration process. Under the shelf registration process, we may offer shares of our common stock having an aggregate offering price of up to $50,000,000 from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of the offering.

We provide information to you about this offering of shares of our common stock in this at the market sales agreement prospectus, which describes the specific terms of this offering of common stock. To the extent there is a conflict between the information contained in this at the market sales agreement prospectus, on the one hand, and the information contained in any document incorporated by reference that was filed with the SEC before the date of this prospectus, on the other hand, you should rely on the information in this at the market sales agreement prospectus. 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 this prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

We 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. We 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 and the documents incorporated by reference in this 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 and the documents incorporated by reference in this 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 entitled "Additional Information" and "Incorporation of Certain Information by Reference."

We 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 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 must inform themselves about, and observe any restrictions relating to, the offering of our common stock and the distribution of this prospectus outside the United States. This prospectus does 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 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 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 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 and the information incorporated herein, including logos, artwork, and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. We do not intend our use or display of other companies' trade names, service marks or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

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, including the information under the caption "Risk Factors" and the information we incorporate by reference, in its entirety.

Overview

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.

THE OFFERING

Common stock offered by us	Shares of our common stock having an aggregate offering price of up to $50.0 million.
Common stock to be outstanding after this offering	Up to 61,591,450 shares of common stock, assuming sales of 5,988,023 shares in this offering at a public offering price of $8.35 per share, which was the closing price of our common stock on the Nasdaq Global Market, or Nasdaq, on January 4, 2018. The actual number of shares issued will vary depending on the sales price under this offering.
Manner of offering	"At the market" offering that may be made from time to time through our sales agent, Cantor Fitzgerald & Co. See "Plan of Distribution" beginning on page 37 of this prospectus.
Use of Proceeds	We currently intend to use the net proceeds from this offering to fund our continued development of anabasum and for general corporate purposes, which may include funding preclinical studies, clinical trials, the manufacturing of anabasum 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 32 of this prospectus.
Risk Factors	Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 4 of this prospectus and under similar headings in the other documents that are filed after the date hereof and incorporated by reference in this prospectus for a discussion of factors to consider before deciding to purchase shares of our common stock.
Nasdaq Global Market symbol	"CRBP"

The number of shares of common stock to be outstanding after this offering is based on 55,603,427 shares of common stock outstanding on January 4, 2018 and excludes:

- 7,724,779 shares of common stock issuable upon the exercise of outstanding options at a weighted average exercise price of $3.66 per share, of which 4,055,877 options were vested as of September 30, 2017;
- 1,288,500 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $1.00 per share, of which 1,288,500 warrants were exercisable as of September 30, 2017; and
- 5,425,834 shares of our common stock available for future issuance under our 2014 Equity Incentive Plan as of January 4, 2018.

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, 2016 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 entitled "Additional Information" and "Incorporation of Certain Information by Reference." Additional risks and uncertainties not presently known to us, or that we currently see 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 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 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 may 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, 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 sale 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, or 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 anabasum 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 payors, our business could be adversely affected.

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

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize 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, or 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.

Additional Risks Relating to The Offering

You may experience immediate and substantial dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered may be higher than the book value per share of our common stock, you may suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. See the section entitled "Dilution" below for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering. In addition, we have a significant number of options and restricted stock outstanding. If the holders of these securities exercise them or become vested in them, as applicable, you may incur further dilution.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. We have agreed, without the prior written consent of Cantor Fitzgerald & Co. and subject to certain exceptions set forth in the sales agreement, not to sell or otherwise dispose of any common stock or securities convertible into or exchangeable for shares of common stock, warrants or any rights to purchase or acquire common stock during the period beginning on the fifth trading day immediately prior to the delivery of any placement notice delivered by us to Cantor Fitzgerald & Co. and ending on the fifth trading day immediately following the final settlement date with respect to the shares sold pursuant to such notice. We have further agreed, subject to certain exceptions set forth in the sales agreement, not to sell or otherwise dispose of any common stock or securities convertible into or exchangeable for shares of common stock, warrants or any rights to purchase or acquire common stock in any other "at-the-market" or continuous equity transaction prior to the termination of the sales agreement with Cantor Fitzgerald & Co. Therefore, it is possible that we could issue and sell additional shares of our common stock in the public markets. We cannot predict the effect that future sales of our common stock would have on the market price of our common stock.

Our share price has been and could remain volatile.

The market price of our common stock has historically experienced and may continue to experience significant volatility. From January 2015 through January 11, 2018, the market price of our common stock has fluctuated from a high of $10.78 per share in the fourth quarter of 2016, to a low of $1.01 per share in the first quarter of 2016. Our progress in developing and commercializing our products, the impact of government regulations on our products and industry, the potential sale of a large volume of our common stock by stockholders, our quarterly operating results, changes in general conditions in the economy or the financial markets and other developments affecting us or our competitors could cause the market price of our common stock to fluctuate substantially with significant market losses. If our stockholders sell a substantial number of shares of common stock, especially if those sales are made during a short period of time, those sales could adversely affect the market price of our common stock and could impair our ability to raise capital. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies for reasons unrelated to their operating performance and may adversely affect the price of our common stock. In addition, we could be subject to a securities class action litigation as a result of volatility in the price of our stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

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 anabasum and for general corporate purposes, which may include funding preclinical studies, clinical trials, the manufacturing of anabasum 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, 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 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This 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 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; and
- 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 and the information incorporated herein.

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 and the information incorporated herein, 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, the documents that we incorporate by reference into this prospectus, including our Annual Report on Form 10-K for the year ended December 31, 2016, our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and the documents that we have filed as exhibits to our filings with the SEC 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

The amount of proceeds from this offering will depend upon the number of shares of our common stock sold and the market price at which they are sold. There can be no assurance that we will be able to sell any shares under or fully utilize the sales agreement with Cantor Fitzgerald & Co. as a source of financing. We currently intend to use the net proceeds from this offering to fund our continued development of anabasum and for general corporate purposes, which may include funding preclinical studies, clinical trials, the manufacturing of anabasum 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. Until we use the net proceeds of this offering, we intend to invest the funds in short-term, investment grade, interest-bearing securities.

The amount and timing of actual expenditures for the purposes set forth above may vary based on several factors, and our management will retain broad discretion as to the ultimate allocation of the proceeds.

MARKET PRICE OF OUR COMMON STOCK

Our common stock is listed on the Nasdaq Global Market under the symbol "CRBP." Our shares of common stock began trading on the Nasdaq Global Market under the symbol "CRBP" effective April 16, 2015. Prior to April 16, 2015, our common stock was quoted on the Over-the Counter Markets (the "OTC.QB") under the symbol "CRBP." Our shares of common stock began being quoted on the OTC.QB effective October 24, 2014.

The following table contains information about the range of high and low sale prices for our common stock for periods indicated. The source of these high and low sales prices was the Nasdaq Global Market and the OTC.QB.

Fiscal Year Ended December 31, 2017	**High Sales Price**	**Low Sales Price**
First Quarter	$ 10.50	$ 6.15
Second Quarter	$ 8.45	$ 5.30
Third Quarter	$ 7.90	$ 5.60
Fourth Quarter	$ 8.75	$ 6.40

Fiscal Year Ended December 31, 2016	**High Sales Price**	**Low Sales Price**
First Quarter	$ 1.95	$ 1.01
Second Quarter	$ 3.85	$ 1.78
Third Quarter	$ 7.88	$ 2.68
Fourth Quarter	$ 10.78	$ 4.65

Fiscal Year Ended December 31, 2015	**High Sales Price**	**Low Sales Price**
First Quarter	$ 3.25	$ 2.00
Second Quarter	$ 4.31	$ 2.63
Third Quarter	$ 4.22	$ 1.45
Fourth Quarter	$ 2.55	$ 1.50

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the price per share you pay in this offering and our pro forma net tangible book value per share after this offering. We calculate net tangible book value per share by dividing our net tangible book value, which is tangible assets less total liabilities, by the number of outstanding shares of our common stock.

Our net tangible book value as of September 30, 2017 was approximately $32.0 million, or $0.64 per share. Net tangible book value per share after this offering gives effect to the sale of $50.0 million of common stock in this offering at an assumed offering price of $8.35 per share, which was the closing price of our common stock as reported on Nasdaq on January 4, 2018, after deducting offering commissions and estimated expenses payable by us. Our net tangible book value as of September 30, 2017, after giving effect to this offering as described above, would have been approximately $80.4 million, or $1.43 per share of common stock. This represents an immediate increase in pro forma net tangible book value of $0.79 per share to existing stockholders and an immediate dilution of $6.92 per share to new investors purchasing our common stock in this offering. The following table illustrates the per share dilution:

Assumed offering price per share		$ 8.35
Net tangible book value per share as of September 30, 2017	$ 0.64	
Increase in net tangible book value per share attributable to new investors	$ 0.79	
Pro forma net tangible book value per share as of September 30, 2017, after giving effect to this offering		$ 1.43
Dilution per share to new investors in this offering		$ 6.92

The above discussion and table are based on 50,223,010 shares of our common stock outstanding as of September 30, 2017 and excludes, as of that date:

- 7,724,779 shares of common stock issuable upon the exercise of outstanding options at a weighted average exercise price of $3.66 per share, of which 4,055,877 options were vested as of September 30, 2017;
- 1,288,500 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $1.00 per share, of which 1,288,500 warrants were exercisable as of September 30, 2017; and
- 4,613,438 shares of our common stock available for future issuance under our 2014 Equity Incentive Plan as of September 30, 2017.

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.

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.

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.

PLAN OF DISTRIBUTION

We have entered into a Controlled Equity Offering[SM] sales agreement with Cantor Fitzgerald & Co. pursuant to which we may offer and sell up to $50.0 million of shares of our common stock, par value $0.0001 per share, from time to time through Cantor Fitzgerald & Co. acting as sales agent. This summary of the material provisions of the sales agreement does not purport to be a complete statement of its terms and conditions. The sales agreement has been filed with the SEC and is included as an exhibit to the registration statement of which this prospectus is a part.

Upon delivery of a placement notice, and subject to the Company's instructions in that notice, and the terms and conditions of the sales agreement generally, Cantor Fitzgerald & Co. may sell our common stock by any method permitted by law deemed to be an "at the market offering" as defined by Rule 415(a)(4) promulgated under the Securities Act.

We will pay Cantor Fitzgerald & Co. in cash, upon each sale of our common stock pursuant to the sales agreement, a commission in an amount equal to 3.0% of the aggregate gross proceeds from each sale of our common stock. Because there is no minimum offering amount required as a condition to this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have agreed to reimburse a portion of Cantor Fitzgerald & Co.'s expenses, including legal fees, in connection with this offering up to a maximum of $25,000. In accordance with FINRA Rule 5110 these reimbursed fees and expenses are deemed sales compensation to Cantor Fitzgerald & Co. in connection with this offering. We estimate that the total expenses for the offering, excluding compensation and expense reimbursement payable to Cantor Fitzgerald & Co. under the terms of the sales agreement, will be approximately $105,000.

Settlement for sales of common stock will occur on the second trading day following the date on which any sales are made, or on some other date that is agreed upon by us and Cantor Fitzgerald & Co. in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement. Sales of our common stock as contemplated in this prospectus will be settled through the facilities of The Depository Trust Company or by such other means as we and Cantor Fitzgerald & Co. may agree upon.

Cantor Fitzgerald & Co. will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of Nasdaq. In connection with the sale of the common stock on our behalf, Cantor Fitzgerald & Co. will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cantor Fitzgerald & Co. will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Cantor Fitzgerald & Co. against certain civil liabilities, including liabilities under the Securities Act.

The offering of our common stock pursuant to the sales agreement will terminate as permitted therein. We or Cantor Fitzgerald & Co. may terminate the sales agreement at any time upon ten (10) days' prior notice.

Cantor Fitzgerald & Co. and its affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Cantor Fitzgerald & Co. will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

This prospectus in electronic format may be made available on a website maintained by Cantor Fitzgerald & Co. and Cantor Fitzgerald & Co. may distribute this prospectus electronically.

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 Cantor Fitzgerald & Co. in connection with this 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.

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.
100 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, 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 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. November 27, 2017, January 5, 2018 and January 8, 2018 (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 10, 2017; 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 between the date of the initial registration statement and the effectiveness of the registration statement, and following the effectiveness of the registration statement until 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 shall be deemed to be modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus (or in any other subsequently filed document which also is incorporated by reference in this prospectus) 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. Statements contained in this 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.

Up to $50,000,000

Common Stock

PROSPECTUS

January 17, 2018