UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2016

OR

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

Commission File Number 001-36912

CIDARA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**46-1537286**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
6310 Nancy Ridge Drive, Suite 101 San Diego, CA 92121	**(858) 752-6170**
(Address of Principal Executive Offices)	**(Registrant's Telephone Number, Including Area Code)**

Securities registered pursuant to Section 12(b) of the Act: Common Stock, Par Value $0.0001 Per Share; Common stock traded on the NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

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

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

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definition of "large accelerated filer", "accelerated filer", and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a small reporting company)	Small reporting company	☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The NASDAQ Global Market on June 30, 2016, was approximately $118.6 million.

The number of shares of Registrant's Common Stock outstanding as of February 28, 2017 was 16,801,184.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Schedule 14A in connection with the registrant's 2017 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such definitive proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the Registrant's fiscal year ended December 31, 2016.

CIDARA THERAPEUTICS, INC.

Table of Contents

CIDARA THERAPEUTICS, INC.
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. We may, in some cases, use words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our anticipated timing for preclinical development, regulatory submissions, commencement and completion of clinical trials and product approvals;
- our plans to research, develop and commercialize our product candidates;
- our ability to fund our working capital requirements;
- our expected clinical trial designs and regulatory pathways;
- our ability to obtain and maintain regulatory approval of our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to successfully commercialize, and our expectations regarding future therapeutic and commercial potential with respect to, our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our products that are approved;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our expectations for the attributes of our product and development candidates, including pharmaceutical properties, efficacy, safety and dosing regimens;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing;
- our expectation that our existing capital resources will be sufficient to enable us to complete our planned clinical trials;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to use our Cloudbreak immunotherapy platform to identify development candidates, or to expand our Cloudbreak immunotherapy platform to other areas of infective disease;
- our ability to identify and develop new product candidates;
- the potential for prophylactic use of any of our product candidates;
- our ability to retain and recruit key personnel;
- our financial performance; and
- developments and projections relating to our competitors or our industry.

These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail under “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this Annual Report on Form 10-K and the documents that we reference and have filed as exhibits to the Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

Item 1. Business.

We are a biotechnology company focused on the discovery, development and commercialization of novel anti-infectives for the treatment of diseases that are inadequately addressed by current standard of care therapies. We are developing a balanced pipeline of product and development candidates, with an initial focus on serious fungal and bacterial infections. Our lead product candidate is CD101 IV, an intravenous formulation of a novel echinocandin. CD101 IV is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections. In addition, we are developing CD201, our bispecific antimicrobial immunotherapy, for the treatment of multidrug-resistant bacterial infections. CD201 is the first development candidate selected from our proprietary Cloudbreak™ platform, which is designed to create compounds that direct a patient's immune system to attack and eliminate bacterial, fungal or viral pathogens.

We are focused on the anti-infectives market, which we believe has the following advantages for the development of innovative products:

- a high correlation between efficacy in preclinical animal models and outcomes of clinical trials for systemic disease;
- a regulatory environment that provides developers of anti-infectives opportunities to reduce development costs and time to market;
- an ability to commercialize anti-infective products with a focused sales and marketing organization for inpatient and outpatient settings; and
- attractive commercial opportunities in certain segments of the market, such as the estimated $3.7 billion global prescription systemic antifungal market in which there is high unmet need, high mortality rate and few new agents in development.

CD101 IV

CD101 IV is a novel molecule in the echinocandin class of antifungals. We are developing CD101 IV for the treatment and prevention of systemic *Candida* infections. These infections include candidemia and invasive candidiasis, fungal infections associated with high mortality rates. We are currently conducting a Phase 2 clinical trial of CD101 IV called the STRIVE study. We plan to enroll at least 90 patients with *Candida* bloodstream infections and invasive forms of candidiasis and expect topline results from this trial in the fourth quarter of 2017.

Cloudbreak Immunotherapy Platform and CD201

We continue to advance our Cloudbreak immunotherapy platform, which we believe has broad potential applications across a wide spectrum of infectious diseases, including bacterial, fungal and viral infections. We believe that our Cloudbreak immunotherapy platform is a fundamentally new approach for the treatment of infectious disease. To date, we have generated preclinical, *in vivo* proof of concept data in both our Cloudbreak antibacterial program and our Cloudbreak antifungal program. In September 2016, we selected a lead Cloudbreak development candidate, CD201.

CD201 is a novel, bispecific antimicrobial immunotherapy being developed for the treatment of multidrug-resistant Gram-negative bacterial infections, including those caused by pathogens harboring the *mcr-1* plasmid.

Our Strategy

Our objective is to become the leading biotechnology company in the discovery, development and commercialization of novel, best-in-class anti-infectives. Key elements of our strategy include:

- **Rapidly advance our initial antifungal and antibacterial candidates to commercialization.** We plan to leverage the favorable regulatory environment for anti-infectives to expedite the development of our product and development candidates.
- **Continue to invest in our Cloudbreak immunotherapy platform.** We believe that our Cloudbreak immunotherapy platform has broad potential applications across a wide spectrum of infectious diseases, including bacterial, fungal and viral infections. We intend to pursue the generation of new Cloudbreak development candidates to strengthen our pipeline. In addition, we will continue to establish intellectual property related to this platform, its applications and development candidates.
- **Commercialize products in the United States with a targeted sales force.** The anti-infectives market benefits from an ability to address large sales opportunities with a relatively small, specialized commercial organization. We currently intend to build and manage a targeted sales and marketing organization to commercialize our products, if approved, in the United States, addressing the relatively small base of well-defined customers in both

the hospital and outpatient settings. In geographies outside the United States, we may seek to collaborate with other parties to commercialize our products.

CD101

We acquired CD101, a novel echinocandin antifungal agent, in 2014. We believe CD101 has the potential to be differentiated from other echinocandins and other classes of antifungal agents based on its prolonged half-life, high C_{max}, or maximum concentration reached, safety and tolerability profile, lack of drug-drug interactions, tissue penetration and high AUC, or area under the curve, which measures the overall drug exposure per dose.

CD101 IV is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections. We conducted a Phase 2 clinical trial for CD101 topical for the treatment of acute vulvovaginal candidiasis, or VVC, a prevalent mucosal infection, but the efficacy results were not sufficient to warrant further development of the two formulations of CD101 topical tested.

CD101 IV

Overview of Systemic Fungal Infections and the Antifungal Market

Fungal infections pose significant medical challenges in both hospital and outpatient settings. While fungi are ubiquitous in our environment, they are usually harmless for people with a normal immune system. Most fungal infections are topical and local in nature, occurring on the skin, in the vaginal tract, or in other parts of the body. However, if fungi access and proliferate in the bloodstream, these infections become systemic and potentially life-threatening. Risk factors for systemic fungal infections include recent gastrointestinal surgery, broad-spectrum antibiotic use, central vascular catheter placement, use of total parenteral nutrition, renal failure, solid organ transplantation, bone marrow transplantation, and other forms of immune suppression.

We estimate that the annual worldwide sales of prescription systemic antifungals are approximately $3.7 billion. This includes therapies used as prophylaxis (preventive) in the inpatient and outpatient setting, therapies used for the treatment of hospitalized patients, and therapies used for the treatment of patients who are being discharged from the hospital.

The majority of hospital infections are caused by two fungi, *Candida* and *Aspergillus*. These fungi are responsible for over 90% of the approximately 97,000 annual deaths in the United States that we estimate are associated with fungal infections. Systemic *Candida* infections include candidemia and related cases of invasive candidiasis. In the United States, candidemia is the most common cause of hospital-acquired bloodstream infections. While the limited data available on hospitalized patients varies widely, rates of between one and two cases per 1,000 hospital admissions have been reported in the United States, Europe and Latin America.

Despite advances achieved in the diagnosis and treatment of candidemia, these infections continue to cause high mortality rates. According to a study published in Clinical Infectious Disease (2009), candidemia has a mortality rate of 35% within 12 weeks of diagnosis. By contrast, the CDC reports that the mortality rate due to MRSA infections is 12.8%. Further, it is estimated that each case of candidemia results in an additional 23 days of hospitalization and over $68,000 in treatment costs.

Physicians' options for the treatment of fungal infections are limited by a lack of innovative therapies.

Several factors have contributed to the low rate of antifungal and antibiotic drug development, including a previously challenging regulatory environment that necessitated large and costly clinical trials. As a result, the number of anti-infectives in development has decreased, while anti-microbial resistance has increased due to overuse of existing agents.

The current treatment alternatives for systemic fungal infections, including polyenes, azoles and currently-approved echinocandins, have limitations that we believe may be addressed by novel antifungals. While these drugs have proven to be efficacious in many patients, mortality rates remain high, and the polyenes and azoles may cause severe side effects warranting discontinuation and are known to cause drug interactions that can limit their utility.

Echinocandins, introduced in 2001, are increasingly recommended for the treatment of fungal infections in the United States. In December 2015, the Infectious Diseases Society of America, or the IDSA, released new clinical guidelines that recognize the important role of echinocandins in the initial treatment of invasive fungal infections. The guidelines recommend a shift to echinocandins as first-line treatment for invasive candidiasis and candidemia.

The approved echinocandins include caspofungin, micafungin, and anidulafungin, and are considered both well tolerated and safe relative to other antifungal drug classes. However, they must be administered daily by IV infusion, potentially extending the hospitalization of patients for the duration of therapy and limiting their use mainly to the hospital setting. Despite this limitation, the use of echinocandins in the outpatient setting is growing at ten percent per year, and the total days of therapy for this class are shifting from inpatient to outpatient therapy. This trend is reflective of increased need for

broad spectrum *Candida* coverage, increasing azole resistance and complications due to the complexity of patients, and a financial incentive to discharge patients earlier to reduce hospital costs.

In addition, the CDC reports that certain species of *Candida* are becoming increasingly resistant to available antifungals, such as the azoles and approved echinocandins. Widespread usage of antifungals in the azole class, in particular, has stimulated an increase in resistance. Non-albicans *Candida*, which have a higher rate of azole resistance, now cause approximately two-thirds of candidemia cases in the US. In a recent study of cancer patients with *Candida* infections from MD Anderson Cancer Center, patient prognosis was inversely correlated with resistance to caspofungin. Patients infected with the most drug-sensitive strains had a 28-day survival rate of 75% compared to only 25% for those with caspofungin-resistant strains.

In order to be effective, an echinocandin drug should be present early in therapy at an exposure that is as high as is safely possible. The key pharmacokinetic parameters affecting exposure include the drug's half-life, C_{max}, and AUC. The maximum dose that can be used is based on the drug's overall safety profile. With echinocandin drugs, high drug exposures early in therapy, as measured by C_{max} or AUC, maximize the antifungal therapeutic benefit of these drugs. When a fungus starts to develop resistance to a drug, the MIC rises, which means that a higher drug exposure will be required in order for the drug to have the same efficacy as it has against sensitive strains. Having a C_{max} and an AUC that are far greater than the starting MIC provides the best chance of treating infections caused by strains resistant to other antifungals, including other echinocandins. A recent analysis suggests that micafungin, the market leader in the US, achieves only 85% target attainment, meaning 15% of the time, not enough drug is available to sufficiently kill *Candida* albicans. Additionally, the EU label for caspofungin requires higher doses in obese patients, suggesting pharmacokinetics are not optimized.

Despite the widespread continued use of each class of antifungals, we believe that market opportunities exist for novel therapeutics which combine the spectrum and safety of the echinocandins with a more convenient dosing schedule enabled by improved pharmacokinetic characteristics.

Our Solution—CD101 IV for the Treatment of Candidemia and Invasive Candidiasis

Due to its novel chemical structure, CD101 IV has a prolonged half-life, a high C_{max} and a high AUC. In addition, CD101 was tested against 23 echinocandin-non-susceptible *Candida* isolates and demonstrated equivalent or greater potency against these strains compared to caspofungin, with up to eight-fold greater potency for several isolates.

These factors are in contrast to all other echinocandins, and we believe they can allow CD101 IV to be developed as a once-weekly IV therapy for the treatment and prevention of systemic fungal infections. We are developing CD101 IV to overcome the limitations of the echinocandin class and other antifungals by offering the following key benefits.

- **Potential to treat resistant pathogens.** We believe that CD101 IV can be used to treat fungal infections caused by drug-resistant fungi, including those currently resistant to echinocandins, due to its potency against resistant strains and its higher drug exposure early in the course of therapy. We expect that this higher exposure early in the course of disease will improve outcomes in infections caused by both resistant as well as non-resistant pathogens.
- **Single-agent treatment.** Rather than treating patients with an IV echinocandin followed by an oral azole solely to enable earlier hospital discharge, CD101 IV would enable extended single-agent, echinocandin treatment for the full course of therapy, thereby enabling treatment that is consistent with current guidance in the United States and European Union.
- **Shorter and less costly hospital stays, and lower outpatient costs.** Physicians with access to a once-weekly echinocandin can potentially discharge appropriate patients earlier and thereby reduce hospital costs, which account for over 70% of the overall treatment cost of candidemia. Furthermore, early discharge from the hospital setting may reduce the risk for contracting nosocomial pathogens. For patients discharged on an echinocandin, once-weekly CD101 IV could eliminate significant outpatient infusion costs for once-daily IV echinocandin therapy.
- **Improved compliance.** A once-weekly treatment of CD101 IV could facilitate compliance by eliminating the need for patients to return to a hospital or outpatient center for a daily dose of an IV echinocandin, and could eliminate the likelihood of patient non-compliance for those receiving oral step down therapy with a daily azole.
- **Enabling or improving prophylaxis regimens.** Some patients cannot receive azole prophylactic therapy due to drug interactions or poor tolerability. We expect that once weekly CD101 IV therapy could provide for better prophylactic therapy on an inpatient and outpatient basis, particularly for these patients.

The FDA has granted CD101 IV designations for Orphan Drug, Qualified Infectious Disease Product, or QIDP, and Fast Track for the treatment of candidemia and invasive candidiasis. The orphan drug designation provides eligibility for seven years of market exclusivity in the United States upon FDA approval, a waiver from payment of user fees, an exemption

from performing clinical studies in pediatric patients, and tax credits for the cost of the clinical research. The QIDP designation, provided under the Generating Antibiotic Incentives Now Act, or the GAIN Act, offers certain incentives for the development of new antibacterial or antifungal drugs, including eligibility for Fast Track designation, priority review and, if approved by the FDA, eligibility for an additional five years of marketing exclusivity. Fast Track designation enables more frequent interactions with FDA to expedite drug development and review. The seven-year period of marketing exclusivity provided through orphan designation combined with an additional five years of marketing exclusivity provided by the QIDP designation positions CD101 IV with a total of 12 years of marketing exclusivity to be granted at the time of FDA approval.

CD101 IV Clinical Results

Clinical Studies

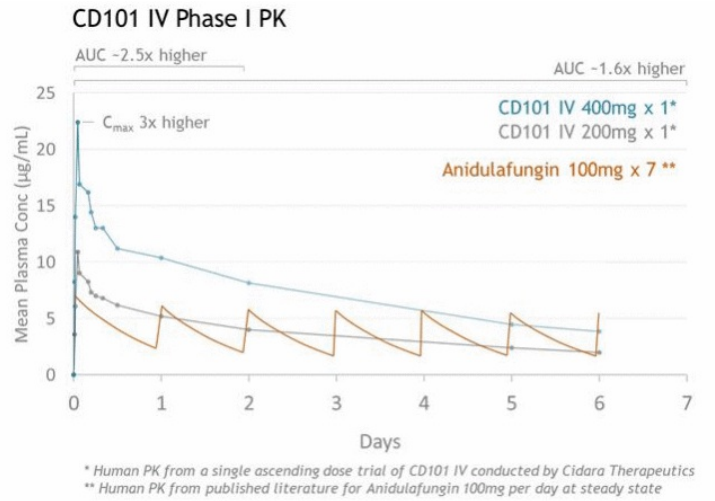
In November 2015, we obtained data from our single ascending dose (SAD) study of CD101 IV. This was a Phase 1, randomized, double-blind, placebo-controlled, dose-escalation study to determine the safety, tolerability, and pharmacokinetics of single intravenous doses of CD101 in healthy subjects. Results demonstrated that CD101 IV was well tolerated in all dose cohorts after single doses of 50 mg, 100 mg, 200 mg, and 400 mg. CD101 IV exhibited a pharmacokinetic profile consistent with preclinical data and supportive of once-weekly dosing.

In January 2016, we obtained data from our multiple ascending dose (MAD) Phase 1 study. This was a Phase 1, randomized, double-blind, placebo-controlled, dose-escalation study to determine the safety, tolerability, and pharmacokinetics of multiple intravenous doses of CD101 in healthy subjects. Results demonstrated that CD101 IV was well tolerated in all dose cohorts after multiple doses of 100 mg, 200 mg, and 400 mg. CD101 IV exhibited a pharmacokinetic profile consistent with preclinical data and supportive of once-weekly dosing.

For both Phase 1 studies, there were no serious adverse events (SAEs), severe Treatment Emergent Adverse Events (TEAEs), or relationships for overall TEAEs. The majority of TEAEs were mild, and all TEAEs completely resolved by the end of the study. There were no drug-related TEAEs resulting from clinically significant hematology or clinical chemistry laboratory abnormalities at any dose. In addition, there were no safety issues related to electrocardiograms, vital signs, or physical exam findings.

Based on clinical results to date, we expect a single dose of CD101 IV to provide sufficient drug exposure for a period of seven days. In contrast, a single dose of anidulafungin provides sufficient drug exposure for only one day. The graph below presents the pharmacokinetic results from our single ascending dose Phase 1 clinical trial.

Pharmacokinetic Properties of CD101 IV



Based on results from our single ascending dose trial, CD101 IV has a prolonged half-life of greater than 80 hours in humans. CD101 IV has the potential to be safely developed as a once-weekly IV therapy, enabling effective and convenient treatment for patients with candidemia or invasive candidiasis in the inpatient or outpatient settings.

CD101 IV demonstrated a C_{max} and an AUC significantly higher than other approved echinocandins. Based on the higher drug exposure demonstrated by CD101 IV early in the course of therapy and high, sustained tissue concentration at the site of infection, we believe that CD101 IV can be used to treat some fungal infections caused by less susceptible fungi, including some of those currently resistant to echinocandins. We expect that this higher exposure and enhanced tissue penetration early in the course of disease will improve outcomes in infections caused by both resistant as well as non-resistant pathogens.

Clinical Development Plan

Based on discussions with the FDA, we assessed the pharmacokinetics and safety of CD101 IV in single and multiple ascending dose Phase 1 clinical trials in healthy subjects. Results from these clinical trials have been used to select the dose for the STRIVE study. We plan to enroll at least 90 patients with candidemia and invasive candidiasis and expect results from this trial in the fourth quarter of 2017.

Pending results from the STRIVE study, we plan to conduct a single randomized, double-blind, controlled Phase 3 pivotal clinical trial. Based on our interactions with the FDA to date, this Phase 3 trial in candidemia and invasive candidiasis, supported by data from our Phase 1 clinical program, our STRIVE study, our planned Phase 2 clinical trial in invasive candidiasis, and additional pharmacology studies, could suffice for approval of CD101 IV for the indications of candidemia and invasive candidiasis. A total safety database of at least 300 patients will be required, and possibly more if safety concerns are noted in the course of development. We may perform additional clinical research with CD101 IV in other populations with high unmet need.

CD101 Topical

In February 2017, we reported results from our Phase 2 clinical trial of CD101 topical, called the RADIANT study, which was designed to evaluate gel and ointment topical formulations of CD101 in women with moderate-to-severe VVC.

The RADIANT study was a multicenter, randomized, open-label, active-controlled, dose-ranging trial that enrolled 125 patients into three treatment cohorts. In the first cohort, 50 patients were treated with CD101 gel; a second cohort of 50 patients was treated with CD101 ointment. The third cohort comprised 25 patients treated with oral fluconazole.

The study found that while the gel and ointment topical formulations of CD101 tested in the study were well tolerated, both formulations were similar in efficacy to each other but lower in clinical and mycological cure rates compared to oral fluconazole. As a result, we have discontinued the CD101 topical development program for VVC.

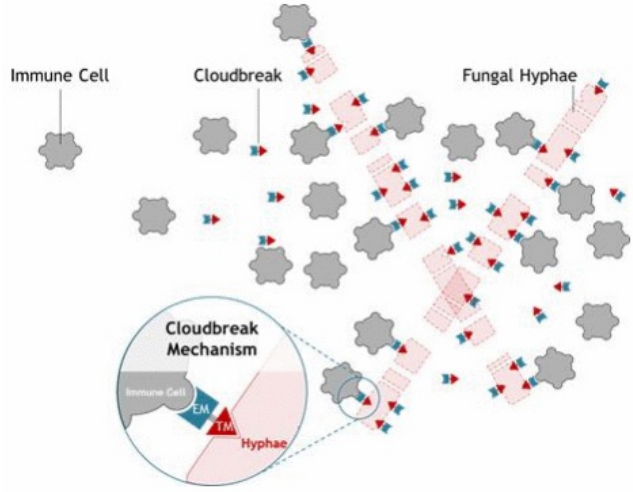
Cloudbreak Immunotherapy Platform and CD201

We continue to advance our Cloudbreak immunotherapy platform, which we believe has broad potential applications across a wide spectrum of infectious diseases, including bacterial, fungal and viral infections. We believe that our Cloudbreak immunotherapy platform is a fundamentally new approach for the treatment of infectious disease. The design of the Cloudbreak immunotherapy platform recognizes that most infectious disease is due to a temporary deficiency in the function of the immune system. Our Cloudbreak lead candidates are designed to address this deficiency by recruiting components of the patient's immune system to the site of infection, enabling more effective treatment. Similar to the way that immunotherapy has the potential to revolutionize the treatment of cancer by redirecting the immune system to destroy cancer cells, we believe that our Cloudbreak immunotherapy platform has the potential to transform the treatment of infectious disease caused by a variety of bacterial, fungal and viral pathogens.

Cloudbreak has the potential to entail both small and large molecule approaches. In either case, the candidates would consist of a targeting moiety, or TM, that recognizes a cell surface target and an effector moiety, or EM, that is recognized by the immune system. The coupling of the TM to the EM results in a bispecific molecule that can direct the immune system specifically to the targeted pathogen.

Our Cloudbreak development candidates have the potential to feature the following attributes:

- Small or large molecule components with well-defined targets and efficient testing;
- selective binding to pathogens to amplify their immunogenicity (recognition by the immune system) and thereby efficient recruitment of the innate and adaptive immune system to assist in the rapid eradication of the pathogen;
- use as adjunctive therapy along with standard of care regimens; and
- broad applicability in the treatment of infectious diseases.



To date, we have generated preclinical, *in vivo* proof of concept data in both our Cloudbreak antibacterial program and our Cloudbreak antifungal program.

CD201

Overview of Antibacterials and Resistance

Antibacterials, also called antibiotics, are drugs used to treat infections that are caused by bacteria. Prior to the introduction of the first antibiotics in the 1930s and 1940s, bacterial infections were often fatal, and invasive surgery was accompanied by a high risk of infectious complications. Today, antibacterials are used routinely to treat and prevent infection. According to IMS Health, antibiotics accounted for $38.8 billion in sales globally in 2012, with healthcare providers prescribing 272 million courses of antibacterials in the United States alone.

There are two main varieties of bacteria, based on a common laboratory staining test known as the "Gram stain." Gram-positive bacteria are surrounded by a single lipid membrane and a thick cell wall. Common Gram-positive pathogens include *Staphylococcus aureus* (including methicillin-resistant strains), *Streptococcus* species, and *Clostridium difficile*. In contrast, Gram-negative bacteria are encircled by two lipid membranes, an inner membrane and an outer membrane, with

a thinner cell wall in between. Gram-negative bacteria include *P. aeruginosa*, *A. baumannii*, and the *Enterobacteriaceae*, a family of related organisms that includes *E. coli*, *K. pneumoniae*, *Enterobacter*, *Salmonella*, and *Shigella* species. Each membrane in Gram-negative bacteria excludes different types of chemical entities, requiring Gram-negative active antibiotics to be specifically designed to permeate both membranes.

According to government agencies and physician groups, including the CDC and IDSA, one of the greatest needs for new antibiotics is to treat carbapenem-resistant *Enterobacteriaceae*, or CRE, and other drug-resistant Gram-negative pathogens. CRE leads to mortality rates of up to 50% in patients with bloodstream infections. Based on the significant increase in resistance rates in recent years, we anticipate CRE will continue to be a major health problem. For example, CDC surveillance data indicates that the rate of carbapenem resistance in *Klebsiella* species, a member of the *Enterobacteriaceae*, increased from 1.6% to 10.4% in the hospital setting in the United States between 2001 and 2011. In Italy, *K. pneumoniae* carbapenem resistance rates rose from 1 - 2% in 2006 to 32.9% in 2014.

Further, a plasmid-borne resistance gene, mcr-1, has been discovered in bacteria that are resistant to colistin. The presence of the mcr-1 gene and its ability to share its colistin resistance with other bacteria such as CRE raise the risk that pan-resistant bacteria could develop. The gene has been found primarily in *Escherichia coli*, but has also been identified in other members of the *Enterobacteriaceae* from human, animal, food and environmental samples on every continent.

According to the CDC, at least two million people each year in the United States acquire serious infections with bacteria that are resistant to one or more of the antibiotics designed to treat those infections, and each year, over 20,000 patients in the United States die from these infections. Similar problems exist throughout the world, and the World Health Organization has declared antibiotic resistance a threat to global health security. The development and spread of resistance is driven by the use of antibiotics. Once they arise, resistant bacteria can be transferred between patients and antibiotic resistance mechanisms can be transferred between bacterial species, thus increasing the problem.

Antibiotic-resistant infections not only cause significant morbidity and mortality, but also place a substantial cost burden on the healthcare system. In most cases, antibiotic-resistant infections require prolonged and/or costlier treatments, extend hospital stays, and necessitate additional doctor visits and higher healthcare expenditures compared with infections that are easily treatable with antibiotics. The CDC estimates that the excess annual cost resulting from these infections in the United States is as high as $20 billion.

Governments, in collaboration with the private sector, have begun to respond to this significant and growing unmet medical need by creating governmental and non-governmental entities tasked with addressing the problem and progressing legislation for reimbursement and regulatory reform, and economic incentives.

Our Solution - CD201

In September 2016, we selected a lead Cloudbreak development candidate, CD201. CD201 is a novel, bispecific antimicrobial immunotherapy being developed for the treatment of multidrug-resistant Gram-negative bacterial infections, including those caused by pathogens harboring the mcr-1 plasmid. CD201 is designed to work by binding to a target present on a wide range of Gram-negative bacteria, while simultaneously recruiting immune components to an infection site to coordinate localized host-mediated infection clearance.

CD201 has demonstrated antibacterial activity *in vitro* against a number of clinically significant Gram-negative bacteria, including *Klebsiella*, *Acinetobacter*, *Pseudomonas* and *Enterobacter* spp. and resistant pathogens (including bacteria resistant to carbapenems and colistin), as well as pathogens harboring the mcr-1 plasmid. CD201 also has demonstrated preliminary safety and efficacy in a number of animal models of infection.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties to manufacture supplies of CD101 IV, CD201 any other Cloudbreak development candidates, and any future product candidates.

Our third-party contract manufacturers are currently producing, and will produce in the future, our product and development candidates for use in our preclinical studies and clinical trials utilizing reliable and reproducible synthetic processes and common manufacturing techniques. We obtain our supplies from manufacturers on a purchase order basis and do not have any long-term arrangements. In addition, we do not currently have any long-term arrangements in place for bulk drug substance or drug product services. We intend to identify and qualify additional manufacturers to provide bulk drug substance and drug product services prior to submission of any NDA to the FDA if necessary to ensure sufficient commercial quantities of each product.

Intellectual Property

The proprietary nature of, and protection for, CD101 IV, CD201, our Cloudbreak immunotherapy platform, our processes and our know-how are important to our business. We seek to protect our proprietary position through patent protection in

the United States and internationally for CD101 IV, CD201, our Cloudbreak immunotherapy platform and any other technology to which we have rights where available and when appropriate. Our policy is to pursue, obtain, maintain and defend patent rights, developed internally and/or potentially licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our inventions, improvements and technology. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors-Risks Related to Our Intellectual Property."

Our success will depend significantly on our ability to:

- obtain and maintain patent and other proprietary protection for the technology, inventions and improvements we consider important to our business;
- defend and enforce our current and potential future patents;
- preserve the confidentiality of our trade secrets; and
- operate our business without infringing the patents and proprietary rights of third parties.

We have established, and will continue to build, proprietary positions for CD101, CD201 and any other product candidates and technology in the United States and abroad. As of February 28, 2017, our patent portfolio included 11 families of patent applications related to various aspects of CD101, and eight families of patent applications related to CD201 and/or our Cloudbreak immunotherapy platform.

For any issued patents related to CD101, we expect that they would expire in 2032 or 2033, excluding any additional term for patent term adjustments or applicable patent term extensions.

With respect to our Cloudbreak immunotherapy platform, including CD201, any patents that result from our currently pending applications would be expected to expire between 2034 and 2038, excluding any additional term for patent term adjustments or applicable patent term extensions.

Market exclusivity is the exclusive marketing right granted by the FDA and certain foreign equivalents upon the approval of a drug if certain statutory requirements are met. When granted, the applicable regulatory authority will not approve another application to market the same drug for the same indication during the period of market exclusivity. The length of market exclusivity depends on the type of exclusivity granted. We intend to seek market exclusivity on our candidate products where appropriate.

We have received orphan drug designation from the FDA for CD101 IV for the treatment of candidemia and invasive candidiasis. An orphan drug designation by the FDA makes CD101 IV eligible for seven years of market exclusivity for CD101 IV in candidemia and invasive candidiasis.

In addition to the orphan drug designation, CD101 IV was designated as a Qualified Infectious Disease Product under the GAIN Act, making it eligible for an additional five years of market exclusivity.

Further, we seek trademark protection in the United States and internationally where available and when appropriate. We have filed for trademark protection in several countries for the Cidara trademark, which we use in connection with our pharmaceutical research and development services and our pharmaceutical compounds. We currently have registered trademarks for the Cidara mark in the United States, the European Union, and Australia and pending trademark applications in Canada. We also currently have a pending trademark application for Cloudbreak in the United States.

Competition

The biopharmaceutical industry is characterized by intense and dynamic competition to develop new technologies and proprietary therapies. Any product candidates that we successfully develop and commercialize will have to compete with existing therapies and new therapies that may become available in the future. We believe that CD101 IV, CD201, and any other Cloudbreak development candidate we may pursue in the future, paralleled with our scientific and development expertise in the field of anti-infectives, provide us with competitive advantages over our peers. However, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical, and biotechnology companies, as well as from generic drug manufacturers, academic institutions, governmental agencies and public and private research institutions.

CD101 IV will primarily compete with antifungal classes for the treatment of candidemia, which include polyenes, azoles and echinocandins. The approved branded therapies for this indication include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.) and Mycamine (micafungin, marketed by Astellas Pharma US, Inc.). There may be generics of the current echinocandins available at the time of CD101 market approval, which will create added competition. In addition, there are other generic products approved for candidemia, marketed by companies

such as Baxter Healthcare Corporation, Mylan Inc. and Glenmark Generics Inc., among others. In addition to approved therapies, we expect that CD101 IV will compete with product candidates that we are aware of in clinical development by third parties, such as SCY-078 (being developed by Scynexis, Inc.).

CD201 will compete against approved and investigational agents for the treatment of bacterial infections. We intend to develop other product candidates from our Cloudbreak immunotherapy platform for the treatment of invasive fungal, bacterial or viral infections. We are aware of a number of approved and investigational therapies in these areas.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. These same competitors may invent technology that competes with our Cloudbreak immunotherapy platform.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical study sites and subject enrollment for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We expect any treatments that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, convenience of administration and delivery, price, the level of generic competition and the availability of reimbursement from government and other third-party payers.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, we expect that our therapeutic products, if approved, will be priced at a significant premium over competitive generic products and our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, import and export of pharmaceutical products, such as those we are developing.

United States Drug Approval Process

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and untitled letters, product recalls, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- contract manufacturing expenses, primarily for the production of clinical supplies;
- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug, or IND, which must become effective before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug for each indication;
- submission to the FDA of a new drug application, or NDA;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current good manufacturing practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Preclinical Studies and IND

Preclinical studies include laboratory evaluation of product chemistry and formulation, as well as *in vitro* and animal studies to assess the potential for adverse events, and in some cases, to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations for safety/toxicology studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, to the FDA as part of an IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time, the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination at www.clinicaltrials.gov. Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

- Phase 1: The drug is initially introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness.
- Phase 2: The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- Phase 3: The drug is administered to an expanded patient population in adequate and well-controlled clinical trials to generate sufficient data to statistically confirm the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and, more frequently, if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more

indications. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, which fees are typically increased annually.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission before accepting them for filing to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review of NDAs. Under these goals, the FDA has committed to review most such applications for non-priority products within 10 months, and most applications for priority review products, that is, drugs that the FDA determines represent a significant improvement over existing therapy, within six months from filing. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drugs or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and integrity of the clinical data submitted.

The testing and approval process requires substantial time, effort and financial resources, and each may take many years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to develop our product candidates and secure necessary governmental approvals, which could delay or preclude us from marketing our products.

After the FDA's evaluation of the NDA and inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the NDA. Even if the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including Risk Evaluation and Mitigation Strategies, or REMs, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track Designation

The FDA is required to facilitate the development and expedite the review of drugs that are intended for the treatment of a serious or life-threatening condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the fast track program, the sponsor of a new product candidate may request the FDA to designate the product for a specific indication as a fast track product concurrent with or after the submission of the IND for the product candidate. The FDA must determine if the product candidate qualifies for fast track designation within 60 days after receipt of the sponsor's request.

In addition to other benefits, such as the ability of the sponsor to use surrogate endpoints in the evaluation of the pivotal clinical trials and have more frequent interactions with the FDA, the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review is available if the applicant provides and the FDA approves a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Priority Review

Under FDA policies, a product candidate may be eligible for priority review, or review generally within a six-month time frame from the time a complete application is received. Products regulated by the FDA's Center for Drug Evaluation and Research, or CDER, are eligible for priority review if they provide a significant improvement compared to marketed products in the treatment, diagnosis or prevention of a disease. A fast track designated product candidate would ordinarily meet the FDA's criteria for priority review.

Accelerated Approval

Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments based upon a surrogate endpoint that is reasonably likely to predict clinical benefit. In clinical trials, a surrogate endpoint is a measurement of laboratory or clinical signs of a disease or condition that substitutes for a direct measurement of how a patient feels, functions or survives. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval trials, or confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough Therapy Designation

Under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." 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 product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally defined as a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Qualified Infectious Disease Products

In response to the growing unmet medical need in the area of serious bacterial infections, the Food and Drug Administration Safety and Innovation Act became law in July 2012 and included the Generating Antibiotic Incentives Now Act, or the GAIN Act. The GAIN Act is intended to provide incentives, including, for example, access to expedited FDA review for approval and five years of potential market exclusivity extension, for the development of new, qualified infectious disease products, or QIDP, including antibacterial or antifungal drugs intended to treat serious or life-threatening infections that are resistant to treatment, or that treat qualifying resistant pathogens identified by the FDA. A sponsor must request QIDP designation for a new drug before an NDA is submitted and, if designated as a QIDP and approved, is eligible for an additional five years of exclusivity beyond any period of exclusivity to which it would have otherwise been entitled. In addition, a QIDP receives NDA priority review and Fast Track designation.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act, or the BPCA, certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA (a Written Request) relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

In addition, the Pediatric Research Equity Act, or PREA, requires a sponsor to conduct pediatric studies for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration. Under PREA, original NDAs, biologics license applications and supplements thereto, must contain a pediatric assessment unless the sponsor has received a deferral or waiver. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which an orphan drug designation has been granted. The required assessment must assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor or FDA may request a deferral of pediatric studies for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug or biologic is ready for approval for use in adults before pediatric studies are complete or that additional safety or effectiveness data needs to be collected before the pediatric studies begin. After April 2013, the FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or submit a request for approval of a pediatric formulation.

Other Regulatory Requirements

Any drug manufactured or distributed by us pursuant to FDA approvals is subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval.

The FDA may impose a number of post-approval requirements, including REMs, as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks or imposition of distribution or other restrictions under a REMs program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- consent decrees, injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Additional Provisions

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws restrict our business activities, including certain marketing practices. These laws include, without limitation, anti-kickback laws, false claims laws, data privacy and security laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal healthcare program 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, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that are alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal healthcare program anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal healthcare program anti-kickback statute has been violated. Additionally, the intent standard under the federal healthcare program anti-kickback statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal healthcare program anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, prohibit any person or entity from, among other things, 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 have a false claim paid. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal healthcare program anti-kickback statute, the Affordable Care Act amended the intent standard for certain healthcare fraud under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

Additionally, the federal Physician Payments Sunshine Act, created under the Affordable Care Act, and its implementing regulations, require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value provided to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and

applicable manufacturers and group purchasing organizations to report annually certain ownership and investment interests held by physicians and their immediate family members.

The majority of states also have statutes or regulations similar to the aforementioned federal fraud and abuse laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments or other transfers of value provided to physicians and other health care providers and entities or marketing expenditures.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to potentially significant criminal and civil and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, as well as contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage and Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients and providers are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of therapies in which our products are used. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product candidates will be made on a plan by plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. Additionally, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Healthcare Reform

Current and future legislative proposals to further reform healthcare or reduce healthcare costs may result in lower reimbursement for our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could significantly reduce our revenues from the sale of our products.

For example, implementation of the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers, and significantly impacted the pharmaceutical industry. The Affordable Care Act, among other things, established an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, and provided incentives to programs that increase the federal government's comparative effectiveness research. Since its enactment there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to it in the future.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2025 unless additional congressional action is taken. Additionally, in January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. More recently, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing,

review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations changed or what the effect of such changes, if any, may be.

Employees

As of February 28, 2017, we had 60 employees, 22 of whom hold Ph.D. or M.D. degrees, 41 of whom were engaged in research and development activities and 19 of whom were engaged in business development, finance, information systems, facilities, human resources or administrative support. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Facilities

We lease a 29,638 square foot facility in San Diego, California for administrative and research and development activities. Our lease expires on December 31, 2018 and we have two individual two-year extension option rights. We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Corporate Information

We were incorporated in Delaware as K2 Therapeutics, Inc. in December 2012. In July 2014, we changed our name to Cidara Therapeutics, Inc. Our principal executive offices are located at 6310 Nancy Ridge Drive, Suite 101, San Diego, California 92121, and our telephone number is (858) 752-6170. Our corporate website address is www.cidara.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering in April 2015, (b) in which we have total annual gross revenue of at least $1 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period. References to “emerging growth company” in this Annual Report have the meaning associated with it in the JOBS Act.

In March 2016, we formed a wholly owned subsidiary, Cidara Therapeutics UK Limited, in England for the purpose of developing our product candidates in Europe.

Legal Proceedings

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, as well as the other information in this report and in our public filings, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time.

Risks Related to Drug Discovery, Development and Commercialization

We are very early in our development efforts, which may not be successful.

We have completed two Phase 1 clinical trials of CD101 IV, and we are currently enrolling a Phase 2 clinical trial of CD101 IV in candidemia. We are also conducting IND enabling studies of CD201, our Cloudbreak development candidate to treat infections caused by multidrug-resistant Gram-negative pathogens. Because of the early stage of our development efforts, we are still in the process of determining the overall clinical development path for our current and future product candidates. As a result, the timing and costs of the regulatory paths we will follow and marketing approvals remain uncertain. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our early-stage product candidates. The success of CD101 IV, CD201, and any other product candidates we may develop will depend on many factors, including the following:

- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials;
- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and technologies;
- launching commercial sales of the product candidates, if and when approved, whether alone or selectively in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payers;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not accomplish one or more of these goals in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials could occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial. For example, we recently announced that the efficacy results of our Phase 2 clinical trial of CD101 topical were not sufficiently positive to continue development of that program.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For example, the historically observed high rate of correlation for clinical efficacy for antifungals, antibacterials and other anti-infectives based on preclinical data may not apply for our current or future product candidates, and any of the potential benefits that we anticipate for human clinical use may not be realized.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or in a given country;
- regulators may require that trials or studies be conducted that were unforeseen in order to obtain marketing authorization;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, modify planned clinical trial designs or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- enrollment in these clinical trials may be slower than we anticipate, clinical sites may drop out of our clinical trials or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks due to serious and unexpected side effects;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the FDA or comparable foreign regulatory authorities could require that we perform more studies than, or evaluate clinical endpoints other than, those that we currently expect; and
- the supply of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be delayed or insufficient, or the quality of such materials may be inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to complete clinical trials of our product candidates or other testing successfully or in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;
- be subject to significant restrictions on reimbursement from public and/or private payers; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, could allow our competitors to bring products to market before we do, could increase competition from generics of the same class, and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

We may not be successful in our efforts to use and expand our Cloudbreak immunotherapy platform to build a pipeline of product candidates.

A key element of our strategy is to use and expand our Cloudbreak immunotherapy platform to build a pipeline of development candidates and progress these through clinical development for the treatment of a wide variety of infectious diseases, including bacterial, fungal and/or viral infections. In September 2016, we selected a lead Cloudbreak development candidate, CD201, which is a novel, bispecific antimicrobial immunotherapy being developed for the treatment of multidrug-resistant Gram-negative bacterial infections, including those caused by pathogens harboring the mcr-1 gene. We have not yet identified any other development candidates from the Cloudbreak platform. CD201 and other potential development candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and eventually commercialize products based on our Cloudbreak immunotherapy platform, our ability to obtain product revenues in future periods could be limited, which could result in significant harm to our financial position and adversely affect our share price.

If we experience delays or difficulties in enrolling patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States. In addition, some of our competitors may have ongoing or new clinical trials for product candidates that would treat the same indications as our product candidates or be used in the same patients, and therefore patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment is also affected by other factors, including:

- severity of the disease under investigation;
- availability, safety and efficacy of approved medications or other investigational medications being studied clinically for the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- delays or failures in maintaining an adequate supply of quality drug product for use in clinical trials; and
- changing treatment patterns that may reduce the burden of disease which our product candidates address.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse effects or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit our development of some or all of our product candidates.

All of our programs are in preclinical development or are in early stages of clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. For example, the pharmacokinetic properties, such as a longer half-life or less frequent dosing regimen, that differentiate CD101 IV from other echinocandins could have side effects that we have not anticipated and the consequences of such side effects could be more severe than has been seen with other echinocandins that have shorter half-lives or, or more frequent dosing regimens, or are dosed at lower concentrations than we expect for CD101 IV. Further, the treatment advantages that we are predicting for CD101 IV, such as lower healthcare costs resulting from an ability to administer CD101 IV once-weekly or the predicted ability of CD101 IV to be effective against resistant strains of fungal pathogens, may not be realized. For CD201, the bispecific mechanism of action, including the use of the immune system, may lead to side effects that are not anticipated based on the preclinical work we have conducted to date.

In the biotechnology industry, many agents that initially show promise in early stage testing may later be found to cause side effects that prevent further development of the agent. In addition, fungal and bacterial infections can occur in patients with co-morbidities and weakened immune systems, and there may be adverse events and deaths in our clinical trials that are attributable to factors other than investigational use of our product candidates.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential than opportunities we pursue. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community for us to achieve commercial success. If our product candidates do not achieve an adequate level of acceptance, we may not generate sufficient product revenue to become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- the terms of any approvals, and the size of the markets in the countries in which approvals are obtained;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory agency;
- our ability to offer any approved products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies or dosing regimens;
- the willingness of physicians to prescribe these therapies and, in the case of CD101 IV, transition to a once-weekly dosing regimen from traditional once-daily dosing;
- the strength of marketing and distribution support;
- the success of competing products and the marketing efforts of our competitors;
- sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

If, in the future, we are unable to establish sales and marketing capabilities or to selectively enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties.

There are risks involved both with establishing our own sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians or to achieve adequate numbers of prescriptions for any future products; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenues to us may be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to market and sell our products effectively, including by failing to devote the necessary resources and attention. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Regulatory incentives to develop drugs for treatment of infectious diseases have increased interest and activity in this area and will lead to increased competition for clinical investigators and clinical trial subjects, as well as for future prescriptions, if any of our product candidates are successfully developed and approved. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the indications on which we are focusing our product development efforts. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

CD101 IV will primarily compete with antifungal classes for the treatment of systemic fungal infections such as candidemia and invasive candidiasis, which include polyenes, azoles and echinocandins. The approved branded therapies for this indication include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.) and Mycamine (micafungin, marketed by Astellas Pharma US, Inc.). There may be generics of the current echinocandins available at the time of CD101 market approval, which will create added competition. In addition, there are other generic products approved for candidemia, marketed by companies such as Baxter Healthcare Corporation, Mylan Inc. and Glenmark Generics Inc., among others. In addition to approved therapies, we expect that CD101 IV will compete with product candidates that we are aware of in clinical development by third parties, such as SCY-078 (being developed by Scynexis, Inc.).

CD201 will compete against approved and investigational agents for the treatment of bacterial infections. We intend to develop other product candidates from our Cloudbreak immunotherapy platform for the treatment of invasive bacterial, fungal or viral infections. We are aware of a number of approved and investigational therapies in these areas.

Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products sooner than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater name recognition, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These same competitors may invent technology that competes with our CD101 program or our Cloudbreak immunotherapy platform.

These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. In the United States, new and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for a drug in a particular country, but then be subject to price regulations that delay its commercial launch, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to commercialize and generate revenue from one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health programs, private health insurers, integrated delivery networks, and other third-party payors. Third-party payers decide which medications they will pay for and establish reimbursement levels. A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payers have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payers are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used, may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Commercial third-party payers often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded programs and private payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any product candidates we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and we will face an even greater risk if we commercially sell any products that receive marketing approval. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs and distraction of management to defend any related litigation;
- the initiation of investigations by regulatory bodies;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and

- the inability to commercialize any products we may develop.

Although we have product liability insurance for our clinical trials, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue or expand our clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees in our workplace, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, chemical, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may not be successful in our efforts to identify, discover, in-license or acquire potential product candidates.

In September 2016, we selected a lead Cloudbreak development candidate, CD201, which is a novel, bispecific antimicrobial immunotherapy being developed for the treatment of multidrug-resistant bacterial infections, including those caused by pathogens harboring the mcr-1 gene. We have not yet identified any other development candidates from the Cloudbreak platform. Our Cloudbreak immunotherapy platform and other drug discovery efforts may not be successful in identifying additional molecules that could be developed as drug therapies. Our research programs may initially show promise in identifying such potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons. In particular, our research methodology used may not be successful in identifying compounds with sufficient potency or bioavailability to be potential product candidates. In addition, our potential product candidates may, on further study, be shown to have harmful side effects or other negative characteristics.

Research programs to identify new product candidates require substantial technical, financial and human resources. We may choose to focus our efforts and resources on potential product candidates that ultimately prove to be unsuccessful. If we are unable to identify, in-license or acquire suitable compounds for preclinical and clinical development, we will not be able to generate product revenue, which would harm our financial position and adversely impact our stock price. To date, we have not in-licensed any such compounds.

Risks Related to Our Dependence on Third Parties

We intend to continue to rely on third parties to conduct our clinical trials and to conduct some aspects of our research and preclinical testing, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as contract research organizations, contract manufacturers of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory agencies require us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at www.clinicaltrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

We have no experience manufacturing product candidates on a clinical or commercial scale and will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our product candidates for preclinical studies and clinical trials and for commercial supply of any of these product candidates for which we obtain marketing approval. We do not have a long-term supply agreement with any third-party manufacturers, and we purchase our required drug supply on a purchase order basis.

We may be unable to establish agreements with third-party manufacturers for preclinical, clinical or commercial supply on terms favorable to us, or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current U.S. Good Manufacturing Practice requirements, or cGMPs, or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our product candidates or approved products, could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations.

Any product that we may develop may compete with other product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers, including a failure that may not relate specifically to our product candidate or approved product, could delay clinical development or marketing approval or adversely impact our ability to generate commercial sales. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We currently rely, and expect to continue to rely, on third parties to release, label, store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties, including a failure that may not relate specifically to our product candidate or approved product, could delay or otherwise adversely impact clinical development or marketing approval of our product candidates or commercialization of our drugs, producing additional losses and depriving us of potential revenue.

Moreover, our manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of supply of our product candidates or approved products.

We do not have alternate manufacturing plans in place at this time. If we need to change to other manufacturers, the FDA and comparable foreign regulators may have to approve these manufacturers' facilities and processes prior to our use,

which would require new testing and compliance inspections. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for production. This would result in delays and costs, and in the case of approved products, the potential loss of revenue.

We may seek to selectively establish collaborations, and, if we are unable to establish them on commercially reasonable terms or at all, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We do not currently have any such collaborations.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

Those factors may include:

- the design or results of preclinical studies or clinical trials;
- the likelihood of approval by the FDA or similar regulatory authorities outside the United States;
- the potential market for the subject product candidate;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

To the extent we enter into any collaborations, we may depend on collaborators for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.

We may selectively seek third-party collaborators for the development and commercialization of our product candidates. Our likely potential collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We do not currently have any such arrangements and if we enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates pose many risks to us, including that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or products if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to one or more product candidates or products may not commit sufficient resources to the marketing and distribution of such drugs;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential litigation;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or products or that result in costly litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under circumstances identified in our collaboration agreements if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our ability to generate revenue under any of our collaboration agreements is adversely impacted by any of these risks, our share of the revenues generated by the product, if approved, under the terms of the collaboration could be insufficient to allow us to achieve or maintain profitability, or the product may be less valuable to us than if we had not entered into the collaboration.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are unable to take full advantage of regulatory programs designed to expedite drug development or provide other incentives, our development programs may be adversely impacted.

There are a number of incentive programs administered by the FDA and other regulatory bodies to facilitate development of drugs in areas of unmet medical need. CD101 IV received the designations as a Qualified Infectious Disease Product, or QIDP, a fast track product, and an orphan drug in the U.S. Our product candidates may not qualify for or maintain designations under additional incentive programs under any of the FDA's existing or future programs to expedite drug development in areas of unmet medical need. Our inability to fully take advantage of these incentive programs may require us to run larger trials, incur delays, lose marketing exclusivity for which we would otherwise be eligible, and incur greater expense in the development of our product candidates.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, release, safety, efficacy, regulatory filings, recordkeeping, labeling, storage, distribution, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. For example, in order to commence clinical trials of our product candidates in the United States, we must file an IND and obtain FDA agreement to proceed. The FDA may place our development program on clinical hold and require further preclinical testing prior to allowing our clinical trials to proceed.

We must obtain marketing approval in each jurisdiction in which we market our products. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not submitted a marketing application or received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process, testing and release, and inspection of manufacturing facilities and personnel by the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the United States and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries 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 preclinical or other studies, changes in the manufacturing process or facilities, and clinical trials. Moreover, approval by the FDA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions, but a failure to obtain marketing approval in one jurisdiction may adversely impact the likelihood of approval in other jurisdictions. In addition, varying interpretations of the data obtained from preclinical testing, manufacturing and product testing and clinical trials could delay, limit or prevent marketing approval of a product candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements for product facilities, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and related recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not comply with these restrictions, we may be subject to enforcement actions.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes and facilities, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on such products, manufacturers or manufacturing processes or facilities;
- restrictions on the labeling, marketing, distribution or use of a product;
- requirements to conduct post-approval clinical trials, other studies, or other post-approval commitments;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Our relationships with customers, health care professionals and third-party payers will be subject to applicable healthcare laws, which could expose us to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm and diminished profits and future earnings.

Healthcare professionals and third-party payers will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with customers, healthcare professionals and third-party payers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell

and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, among others:

- the federal healthcare anti-kickback statute, which prohibits persons and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal false claims laws, which impose criminal and civil penalties, including civil whistleblower or qui tam actions under the federal Civil False Claims Act, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA, as amended by HITECH, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute enacted under HIPAA, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act, which require, among other things, certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business activities, including sales or marketing arrangements and claims involving healthcare items or services including, in some states, those reimbursed by non-governmental third-party payers, including private insurers, and some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments or other transfers of value provided to physicians and other health care providers and entities or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Interpretations of standards of compliance under these laws and regulations are rapidly changing and subject to varying interpretations, and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act and subsequent regulations revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. Since its enactment there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to it in the future. Although the full effect of the Affordable Care Act remains uncertain, the

law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We expect that additional healthcare reform measures will be adopted within and outside the United States in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. The continuing efforts of third-party payors to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability, and the level of taxes that we are required to pay.

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to CD101 IV, CD201 or our other product candidates are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to CD101 IV, CD201 and our other product candidates. Any involuntary disclosure to or misappropriation by third parties of our proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain, and our commercial success will depend on our ability to obtain patents and maintain adequate protection for CD101 IV, CD201 and other product candidates in the United States and other countries. We currently hold issued U.S. utility and foreign patents, and multiple pending U.S. utility patent applications, pending U.S. provisional patent applications, and pending international, foreign national and regional counterpart patent applications covering various aspects of CD101 IV, CD201, our Cloudbreak immunotherapy platform, and other technology. The patent applications may fail to result in issued patents in the United States or in foreign countries or jurisdictions. Even if the applications do successfully issue, third parties may challenge the patents.

Further, the existing and/or future patents, if any, may be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by the patent and patent applications we own with respect to CD101 IV or CD201 or the patents we pursue related to any of our other product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize CD101 IV, CD201 and our other product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced, although a patent term extension or supplementary protection certificate may be available in certain jurisdictions and having varied scope to compensate for some of the lost patent term. In addition, we do not know whether:

- we were the first to make the inventions covered by each of our pending patent applications or our issued patents;
- we were the first to file patent applications for these inventions;
- others will independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our patents, once issued, will be valid or enforceable or will issue with claims sufficient to protect our products, or will be challenged by third parties;
- any patents issued to us will provide us with any competitive advantages;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will have an adverse effect on our business.

In addition, patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable in one or more jurisdictions, processes for which patents are difficult to enforce and any other elements of our drug discovery program that involve proprietary know-how, information and technology that is not covered by patents. Although we require all of our employees, consultants, advisers and third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or used in an unauthorized manner or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

There also may be challenges or other disputes concerning the inventorship, ownership, or right to use our intellectual property. For example, our consultants and advisors may have obligations to assign certain inventions and/or know-how that they develop to third-party entities in certain instances, and these third parties may challenge our ownership or other rights to our intellectual property, which would adversely affect our business.

An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. We may encounter significant problems in protecting, enforcing, and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of the intellectual property related to our technologies to third parties, or are otherwise unable to protect, enforce or defend our intellectual property, we will not be able to establish or, if established, maintain a competitive advantage in our markets, which could materially adversely affect our business, operating results and financial condition.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO, and various foreign or jurisdictional governmental patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm to pay these fees due to foreign patent agencies. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process.

We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Such noncompliance events are outside of our direct control for (1) non-U.S. patents and patent applications owned by us, and (2) if applicable in the future, patents and patent applications licensed to us by another entity. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents with claims to materials, methods of manufacture or methods for treatment related to the use or manufacture of CD101 IV, CD201 and/or our other product candidates. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. If any third-party patents were held by a court

of competent jurisdiction to cover the CD101 or CD201 manufacturing process, any molecules formed during the CD101 or CD201 manufacturing process or the final CD101 or CD201 products for any use thereof, the holders of any such patents may be able to block our ability to commercialize CD101 IV or CD201, as applicable, unless we obtained a license under the applicable patent or patents, or until such patents expire. These same issues and risks arise in connection with any other product candidates we develop as well. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, or at all. Any inability to obtain such a license under the applicable patents on commercially reasonable terms, or at all, would have a material adverse effect on our ability to commercialize CD101 IV, CD201 or any of our other product candidates until such patents expire.

In addition, third parties may obtain patents in the future and claim that our product candidates and/or the use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products, which may be impossible and/or require substantial time and monetary expenditure. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of CD101 IV, CD201 or any of our other product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would not be able to further develop and commercialize such product candidates, which could harm our business significantly.

We may be required to file lawsuits or take other actions to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our current or future patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our asserted patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Pursuit of these claims would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference proceedings or derivative proceedings provoked by third parties or brought by the USPTO may be necessary to determine the entitlement to patent protection with respect to our patents or patent applications. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or patent office proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Issued patents covering our product candidates and technologies could be found invalid or unenforceable if challenged in court or the USPTO.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technologies, the defendant could counterclaim that the patent covering our product candidate or our technology, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or our technologies. The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art and that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. If a defendant were to prevail on a

legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection directed to our product candidates or technologies. Such a loss of patent rights could have a material adverse impact on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and are therefore costly, time-consuming and inherently uncertain. In addition, the United States has implemented wide-ranging patent reform legislation, including patent office administrative proceedings that offer broad opportunities to third parties to challenge issued patents. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, the USPTO, and foreign governmental bodies and tribunals, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held in 2013 that certain claims to DNA molecules are not patentable, and lower courts have since been applying this case in the context of other types of biological subject matter. We cannot predict how future decisions by the courts, the U.S. Congress, the USPTO, or foreign governmental bodies or tribunals may impact the value of our patent rights.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any of our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of any of our current or future patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if any of our patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors, and academic or research institutions. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' 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 cost and be a distraction to our management and employees.

Risks Related to Our Financial Position and Need for Additional Capital

We are an early stage biotechnology company that has incurred significant operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. Our net loss was $48.2 million and $32.2 million for the 2016 and 2015 fiscal years, respectively. As of December 31, 2016, we had an accumulated deficit of $93.7 million. To date, we have financed our operations primarily through private placements of convertible preferred stock and convertible notes, our initial public offering of our common stock, or our IPO, our October 2016 term loan facility with Pacific Western Bank, or Pacific Western, and our October 2016 follow-on public offering of common stock. We have devoted substantially all of our financial resources and efforts to research and development. We are currently enrolling a Phase 2 clinical trial of CD101 IV, and we recently commenced IND enabling studies of CD201. We expect that it will be many years, if ever, before we receive regulatory approval and have a product candidate available for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- submit INDs to the FDA and equivalent filings to other regulatory authorities, and seek approval of our clinical protocols by institutional review boards, or IRBs, at clinical trial sites;
- advance CD101 IV through clinical development;
- continue the preclinical development of CD201 and any other product candidates. from our Cloudbreak immunotherapy platform or otherwise, and advance one or more of such product candidates into clinical trials;
- identify additional lead candidates and advance them into preclinical and clinical development;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish or contract for a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;
- maintain, expand and enforce our intellectual property portfolio;
- hire additional manufacturing, clinical, regulatory, quality assurance and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support product development; and
- acquire or in-license other product candidates and technologies.

To become and remain profitable, we must develop and eventually commercialize one or more products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding to advance the development of our product candidates. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our drug development and discovery programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of and seek marketing approval for our product candidates, initially CD101 IV

and CD201, and any other product candidates that we seek to develop. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution of the approved product. Furthermore, we expect to incur additional costs associated with operating as a public company. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates and Cloudbreak platform;
- the costs, timing and outcome of any regulatory review of our product candidates;
- the costs and timing of commercialization activities, including manufacturing, marketing, sales and distribution, for any product candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations, when and if necessary, on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential development candidates and conducting preclinical studies and clinical trials are time consuming, expensive and uncertain processes that take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales for any of our current or future product candidates. In addition, our product candidates, if approved, may not achieve commercial success.

Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need substantial additional funding in connection with our continuing operations and to achieve our goals. Since December 6, 2012 (inception) through December 31, 2016, our operations have been financed primarily by gross proceeds of approximately $188.8 million from the issuance of convertible debt securities, the sale of shares of convertible preferred stock, the sale of shares of our common stock in our IPO, our October 2016 term loan facility with Pacific Western, and our October 2016 follow-on public offering of common stock. As of December 31, 2016, we had cash, cash equivalents, and short-term investments of $104.6 million. Based on our current operating plans, we expect that our existing cash, cash equivalents and marketable securities and anticipated interest income will enable us to fund our operating expenses and capital expenditure requirements through at least the next twelve months. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts, or to make reductions in spending, extend payment terms with suppliers, or liquidate or grant rights to assets where possible. Any of these actions could materially harm our business, results of operations and future prospects. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional financing due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings, as well as potentially entering into collaborations, strategic alliances and licensing arrangements or receiving government grants or contracts. Other than our controlled equity sales agreement with Cantor Fitzgerald & Co. and our term loan facility with Pacific Western, each of which is subject to the fulfillment of specified conditions, we do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and may be secured by all or a portion of our assets. There can be no assurances that we will be able to enter into contracts with or receive grants from the United States government to support our programs. The process of obtaining government grants and contracts is lengthy and uncertain and we will have to compete with other companies and institutions for each grant or contract. United States government grants and contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. If we receive a United States government grant or contract, we would be required to comply with numerous laws and regulations relating to the formation, administration and performance of the grant or contract, which can make it more difficult for us to retain our rights under our such grant or contract and result in increased costs. If we raise funds by entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or

through collaborations, strategic alliances, licensing arrangements or government programs when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our short operating history may make it difficult for you to evaluate the success of our business to date and assess our future viability.

We were founded in December 2012 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential development and product candidates, undertaking preclinical studies and conducting clinical trials. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials required for regulatory approval of our product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes many years to develop one new product from the time it is discovered to when it is commercially available. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had product candidates in advanced clinical trials.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors that may alter or delay our plans. We will need to continue to transition from a company with a research focus to a company capable of supporting development activities and, if a product candidate is approved, a company with commercial activities. We may not be successful in any step of such a transition.

The terms of our term loan facility place restrictions on our operating and financial flexibility, and failure to comply with covenants or to satisfy certain conditions of the agreement governing the debt facility may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our common stock to decline.

In October 2016, we entered into a loan and security agreement with Pacific Western, or the loan agreement, under which we borrowed $10.0 million and may borrow up to an additional $10.0 million on or prior to April 3, 2018, subject to certain terms and conditions set forth therein, including our achievement of certain milestones.

The outstanding principal balance under the loan agreement is secured by a security interest in substantially all of our assets, other than intellectual property, which is subject to a double negative pledge. The loan agreement requires us to comply with a number of customary affirmative and restrictive covenants, including covenants that limit our ability to, among other things: transfer any part of our business or property; merge or consolidate with another entity or otherwise experience a change in control; incur additional indebtedness; encumber the collateral securing the loan; declare or pay any cash dividend or make distributions on our capital stock; repurchase or redeem any class of stock or other equity interest; acquire, own or make investments; and make certain capitalized expenditures over a specified threshold, in each case subject to exceptions. In addition, the loan agreement contains an operating covenant, which requires us to achieve positive data from a Phase 2 clinical trial of CD101 Topical or CD101 IV on or before March 31, 2018. Subsequent operating covenants will be reset in 2018. The loan agreement also includes standard events of default, including a provision that Pacific Western could declare an event of default upon the occurrence of any event that it interprets as having a material adverse effect on (i) our operations, business or financial condition and subsidiaries taken as a whole; (ii) our ability to perform or pay the secured obligations under the loan agreement and related agreements; or (iii) the collateral pledged to Pacific Western under the loan agreement. Upon such determination, Pacific Western could declare all obligations under the loan agreement immediately due and payable. Although, in and of itself, the occurrence of adverse results or delays in any clinical study or the denial, delay or limitation of approval of or taking of any other regulatory action by the United States Food and Drug Administration or another governmental entity will not constitute a material adverse effect under the loan agreement, Pacific Western may determine that such an event together with contemporaneous events or circumstances constitutes a material adverse effect upon our business, operations, properties, assets, or financial condition or upon our ability to perform or pay the secured obligations under the loan agreement. If we default under the facility, Pacific Western may accelerate all of our repayment obligations. At such time, we may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required. If we are unable to access funds to meet those obligations or to renegotiate the loan agreement, Pacific Western could take control of and may sell our pledged assets. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If our assets were liquidated, Pacific Western's right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Pacific Western of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness under the loan

agreement. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our senior management team and to attract, retain and motivate qualified personnel.

We are highly dependent upon our senior management team, as well as the other principal members of our research and development teams. All of our executive officers are employed "at will," meaning we or they may terminate the employment relationship at any time. We maintain "key person" insurance for our Chief Executive Officer but not for any of our other executives or employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing, regulatory, quality assurance, and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisers, including scientific, regulatory, quality assurance, and clinical advisers, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisers may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We expect to expand our operations, and may encounter difficulties in managing our growth, which could disrupt our business.

We expect to expand the scope of our operations, particularly in the areas of drug development, manufacturing, clinical, regulatory affairs, quality assurance, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. We may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We may engage in acquisitions that could disrupt our business, cause dilution to our stockholders or reduce our financial resources.

In the future, we may enter into transactions to acquire other businesses, products or technologies and our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may fail to strengthen our competitive position, and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Risks Related to Ownership of our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this report, these factors include:

- the commencement, timing, enrollment or results of the current and planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter, "complete response" letter, or a request for additional information;
- adverse results, suspensions, terminations, or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our contract manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, government grants or contracts or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial fungal infection, bacterial infection or other target markets;
- our ability to successfully enter new markets or develop additional product candidates;
- actual or anticipated variations in quarterly operating results;
- our cash position and our ability to raise additional capital and the manner and terms on which we raise it;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports or other media coverage about us or our industry, or our therapeutic approaches in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patent rights, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Global Market and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. You may not realize any return on your investment in

us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, and 5% stockholders and their affiliates currently beneficially own a significant percentage of our outstanding voting stock. These stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company through 2020, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (a) December 31, 2020, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1 billion, (c) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (d) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

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, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We will incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The NASDAQ Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment and the current level of government intervention and regulatory reform may lead to substantial new

regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to result in substantial legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. These costs could decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations could make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We had 16,773,232 shares of common stock outstanding as of December 31, 2016. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and make it more difficult for you to sell shares of our common stock. In addition, shares of common stock that are either issuable upon the exercise of outstanding options or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales, and new investors could gain rights, preferences and privileges senior to our existing stockholders.

Pursuant to our 2015 Equity Incentive Plan, or the 2015 EIP, our management is authorized to grant stock options to our employees, directors and consultants. The number of shares of our common stock reserved for issuance under the 2015 EIP will automatically increase on January 1 of each year through and including January 1, 2025, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Additionally, the number of shares of our common stock reserved for issuance under our 2015 Employee Stock Purchase Plan, or the ESPP, will automatically increase on January 1 of each year through and including January 1, 2025, by the lesser of 1% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or 490,336 shares. Unless our board of directors elects not to increase the number of shares available for future grant each year under the 2015 EIP and the ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall.

We have broad discretion in the use of working capital and may not use it effectively.

Our management will have broad discretion in the application of our working capital. Because of the number and variability of factors that will determine our use of our working capital, its ultimate use may vary substantially from its currently intended use. Our management might not apply our working capital in ways that ultimately increase the value of your investment. We expect to use our working capital to fund research and development activities and general operating expenses. The failure by our management to apply this working capital effectively could harm our business. Pending its

use, we may invest our working capital 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 our working capital in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Because we have an even number of members of our board of directors, deadlocks may occur in our board of directors' decision-making process, which may delay or prevent critical decisions from being made.

Since we currently have an even number of directors, deadlocks may occur when such directors disagree on a particular decision or course of action. Our amended and restated certificate of incorporation and amended and restated bylaws do not contain any mechanisms for resolving potential deadlocks. While our directors are under a duty to act in the best interest of our company, any deadlocks may impede the further development of our business in that such deadlocks may delay or prevent critical decisions regarding our development.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated

bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our most recent private placements, our IPO, our October 2016 follow-on public offering of common stock and other transactions that have occurred since our inception in 2012, we may or may not have experienced an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2016, we had U.S. net operating loss carryforwards of approximately $79.5 million, which begin to expire in 2033, which could be limited if we experience an "ownership change."

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

Our operations are vulnerable to interruption by natural disasters, power loss, terrorist activity and other events beyond our control, the occurrence of which could materially harm our business.

Businesses located in California have, in the past, been subject to electrical blackouts as a result of a shortage of available electrical power, and any future blackouts could disrupt our operations. We are vulnerable to a major earthquake, wildfire, inclement weather and other natural and man-made disasters, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster and do not have an applicable recovery plan in place. We carry only limited business interruption insurance that would compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us in excess of insured amounts could cause our business to materially suffer.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

We lease a 29,638 square foot facility in San Diego, California for administrative, research and development activities. Our lease currently expires in December 2018, subject to our option to renew for up to two additional two-year terms. We believe that our facility is sufficient to meet our needs and that suitable additional space will be available as and when needed.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is traded on The NASDAQ Global Market under the symbol "CDTX." The following table sets forth the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market for the periods indicated.

	High	Low
Year ended December 31, 2015		
Second quarter ended June 30, 2015 (beginning April 15, 2015)	$ 19.13	$ 13.34
Third quarter ended September 30, 2015	$ 15.48	$ 11.23
Fourth quarter ended December 31, 2015	$ 18.07	$ 12.03
Year ended December 31, 2016		
First quarter ended March 31, 2016	$ 17.29	$ 9.48
Second quarter ended June 30, 2016	$ 15.91	$ 9.51
Third quarter ended September 30, 2016	$ 12.95	$ 10.23
Fourth quarter ended December 31, 2016	$ 11.85	$ 8.65

Holders of Record

As of February 28, 2017, there were approximately 24 holders of record for our common stock.

Dividend Policy

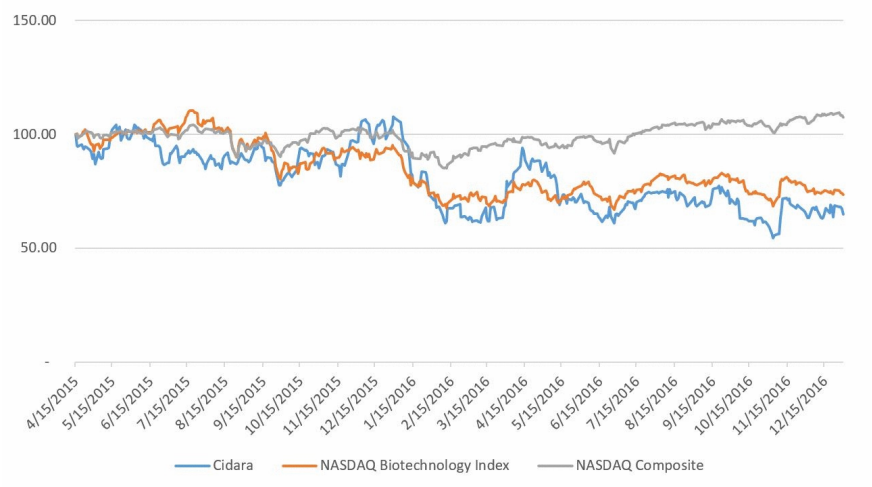
We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. In addition, the terms of our loan agreement with Pacific Western restrict our ability to declare or pay any cash dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock, subject to certain limited exceptions. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12 of this Annual Report.

Performance Graph

The following graph shows a comparison from April 15, 2015 (the date our common stock commenced trading on The NASDAQ Global Market) through December 31, 2016 of the cumulative total return for our common stock, the NASDAQ Biotechnology Index (NBI) and the NASDAQ Composite Index (IXIC). The graph assumes an initial investment of $100 on April 15, 2015. The comparisons in the graph are not intended to forecast or be indicative of possible future performance of our common stock.



Use of Proceeds

On April 14, 2015, our Registration Statements on Form S-1 (file Nos. 333-202740 and 333-203434) were declared effective by the SEC for our initial public offering of common stock, which was completed on April 20, 2015.

We received approximately $69.3 million in net proceeds from our initial public offering. Through December 31, 2016, we used $1.3 million of the net proceeds from the offering to fund our ongoing research and development activities. We intend to use the remaining proceeds to fund our ongoing and future clinical development of CD101 IV; the preclinical development, IND-enabling studies and early clinical trials of CD201 and/or any other Cloudbreak development candidates; research and discovery efforts related to the expansion of our Cloudbreak immunotherapy platform; and working capital, including general operating expenses. Pending such uses, we plan to continue investing the unused proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

Item 6. Selected Financial Data.

The selected financial data set forth below is derived from our audited consolidated financial statements and may not be indicative of future operating results. The following selected financial data should be read in conjunction with the consolidated financial statements and notes thereto and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of our future results. Amounts are in thousands, except share and per share data.

Statement of Operations Data

(In thousands, except share and per share data)	Year ended December 31, 2016	2015	2014
Operating expenses:			
Research and development	$ 35,699	$ 23,475	$ 6,710
Cost of in-process research and development acquired	—	—	1,607
General and administrative	12,737	8,838	3,306
Total operating expenses	48,436	32,313	11,623
Loss from operations	(48,436)	(32,313)	(11,623)
Other income (expense):			
Interest income (expense), net	271	120	(88)
Change in fair value of convertible notes payable	—	—	(183)
Total other income (expense)	271	120	(271)
Net loss	$ (48,165)	$ (32,193)	$ (11,894)
Net loss per common share, basic and diluted	$ (3.32)	$ (3.25)	$ (14.51)
Weighted average shares outstanding used to compute net loss per share, basic and diluted	14,488,987	9,920,382	819,868

Balance Sheet Data

	December 31, 2016	2015	2014
Cash, cash equivalents, and short-term investments	$ 104,619	$ 107,514	$ 22,796
Working capital	96,489	102,244	19,800
Total assets	106,962	109,974	24,350
Convertible preferred stock	—	—	32,548
Accumulated deficit	(93,662)	(45,497)	(13,304)
Total stockholders' equity (deficit)	88,179	103,912	(11,445)

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

You should read the following discussion and analysis together with "Item 6. Selected Financial Data" and our consolidated financial statements and related notes included elsewhere in this Annual Report.

Forward-Looking Statements

The following discussion contains forward-looking statements that involve risks and uncertainties. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Annual Report. See "Special Note Regarding Forward-Looking Statements."

Overview

We are a biotechnology company focused on the discovery, development and commercialization of novel anti-infectives for the treatment of diseases that are inadequately addressed by current standard of care therapies. We are developing a balanced pipeline of product and development candidates, with an initial focus on serious fungal and bacterial infections. Our lead product candidate is CD101 IV, an intravenous formulation of a novel echinocandin. CD101 IV is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections. In addition, we are developing CD201, our bispecific antimicrobial immunotherapy, for the treatment of multidrug-resistant bacterial infections. CD201 is the first development candidate selected from our proprietary Cloudbreak™ platform, which is designed to create compounds that direct a patient's immune system to attack and eliminate bacterial, fungal or viral pathogens.

CD101 IV

CD101 IV is a novel molecule in the echinocandin class of antifungals. We are developing CD101 IV for the treatment and

prevention of systemic *Candida* infections. These infections include candidemia and invasive candidiasis, fungal infections associated with high mortality rates. We are currently conducting a Phase 2 clinical trial of CD101 IV called the STRIVE study. We plan to enroll at least 90 patients with *Candida* bloodstream infections and invasive forms of candidiasis and expect topline results from this trial in the fourth quarter of 2017.

Cloudbreak Immunotherapy Platform and CD201

We continue to advance our Cloudbreak immunotherapy platform, which we believe has broad potential applications across a wide spectrum of infectious diseases, including bacterial, fungal and viral infections. We believe that our Cloudbreak immunotherapy platform is a fundamentally new approach for the treatment of infectious disease. To date, we have generated preclinical, *in vivo* proof of concept data in both our Cloudbreak antibacterial program and our Cloudbreak antifungal program. In September 2016, we selected a lead Cloudbreak development candidate, CD201.

CD201 is a novel, bispecific antimicrobial immunotherapy being developed for the treatment of multidrug-resistant Gram-negative bacterial infections, including those caused by pathogens harboring the mcr-1 plasmid.

FINANCIAL OPERATIONS OVERVIEW

Revenues

To date, we have not generated any revenues. In the future, we may generate revenue from a combination of license fees and other upfront payments, research and development payments, milestone payments, product sales, government and other third-party funding, and royalties in connection with strategic alliances. We expect that any revenue we generate will fluctuate from quarter-to-quarter as a result of the timing of our achievement of preclinical, clinical, regulatory and commercialization milestones, if at all, the timing and amount of payments relating to such milestones and the extent to which any of our products are approved and successfully commercialized. If we are unable to fund our development costs, or we are unable to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues and our results of operations and financial position would be adversely affected.

Research and development expenses

To date, our research and development expenses have related primarily to preclinical development of our CD101 and CD201 product candidates and our Cloudbreak immunotherapy technology platform, as well as clinical development of CD101 IV and CD101 topical. Research and development expenses consist of wages, benefits and stock-based compensation for research and development employees, as well as the cost of scientific consultants, facilities and overhead expenses, laboratory supplies, manufacturing expenses, and preclinical and clinical trial costs. We accrue clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies or activities within studies and other events.

Research and development costs are expensed as incurred and costs incurred by third parties are expensed as the contracted work is performed. We accrue for costs incurred as the services are being provided by monitoring the status of the study or project and the invoices received from our external service providers. We adjust our accruals as actual costs become known.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase over the next several years as we continue to conduct preclinical and clinical studies, expand our research and development pipeline and progress our product candidates through clinical trials. However, it is difficult to determine with certainty the duration, costs and timing to complete our current or future preclinical programs and clinical trials of our product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;

- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidates.

Research and development expenses by major program or category were as follows (in thousands):

	Year ended December 31,		
	2016	2015	2014
CD101 IV	$ 11,230	$ 7,753	$ 2,170
CD101 topical	7,604	3,830	233
Cloudbreak immunotherapy platform	2,915	2,249	1,374
Cost of in-process research and development acquired	—	—	1,607
Personnel costs	10,084	6,752	1,305
Other research and development expenses	3,866	2,891	1,628
Total research and development expenses	$ 35,699	$ 23,475	$ 8,317

We typically deploy our employees, consultants and infrastructure resources across our programs. Thus, some of our research and development expenses are not attributable to an individual program but are included in other research and development expenses as shown above.

In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

In February 2017, we reported results from our Phase 2 clinical trial of CD101 topical, which was designed to evaluate gel and ointment topical formulations of CD101 in women with moderate-to-severe VVC. The study found that while the gel and ointment topical formulations of CD101 tested in the study were well tolerated, both formulations were similar in efficacy to each other but lower in clinical and mycological cure rates compared to oral fluconazole. As a result, we have discontinued the CD101 topical development program for VVC.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal, business development, commercial planning, and support functions. Other general and administrative expenses include facility and overhead costs not otherwise included in research and development expenses, consultant expenses, travel expenses and professional fees for auditing, tax, legal, and other services. We expect that general and administrative expenses will increase in the future as we expand our operating activities and incur additional costs associated with operating as a publicly traded company. These increases will likely include legal fees, accounting fees, directors' and officers' liability insurance premiums and costs associated with investor relations.

Other income (expense), net

Other income (expense) consists primarily of interest income and expense, and various income or expense items of a non-recurring nature. We earn interest income from interest-bearing accounts and money market funds for cash and cash equivalents and marketable securities and for our short-term investments. Interest expense represents interest payable related to term loans, convertible notes payable and the amortization of debt issuance costs. We recorded periodic gains and losses from changes in fair value of convertible notes payable until their conversion into preferred stock in May 2014.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon financial statements that we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses, and related disclosures. On an on-going basis, we evaluate these estimates, including those related to preclinical and clinical trial accruals and share-based compensation. Estimates are based on historical experience, information received from third parties and on various other

assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. The items in our financial statements requiring significant estimates and judgments are as follows:

Preclinical and Clinical Trial Accruals

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our accrued expenses for preclinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by contract research organizations, or CROs, clinical trial investigational sites and for other clinical trial-related activities. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing for these services, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on other information available to us. If we underestimate or overestimate the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

Stock-based compensation

The Company accounts for stock-based compensation expense related to employee stock options, restricted stock grants, and employee stock purchase plan rights by estimating the fair value on the date of grant. For awards subject to time-based vesting conditions, stock-based compensation expense is recognized ratably over the requisite service period of the awards, net of estimated forfeitures. The Company accounts for stock options granted to non-employees using the fair value approach. These option grants are subject to periodic revaluation over their vesting terms.

The Company estimates the fair value of stock option awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the risk-free interest rate, (b) the expected volatility of our stock, (c) the expected term of the award, and (d) the expected dividend yield. Due to the lack of an adequate history of a public market for the trading of our common stock and a lack of adequate company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours, including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We compute the historical volatility data using the daily close prices for the selected companies' shares during the equivalent period of the calculated expected term of our stock-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our common stock price becomes available. We have estimated the expected life of our employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The risk-free interest rates for periods within the expected life of the option are based on the yields of zero-coupon U.S. treasury securities. See Note 8 of the Notes to the Financial Statements for additional information.

RESULTS OF OPERATIONS

Comparison of the years ended December 31, 2016 and 2015

The following table summarizes our results of operations for the years ended December 31, 2016 and 2015 (in thousands):

	Year ended December 31,		
	2016	2015	Change
Research and development	$ 35,699	$ 23,475	12,224
General and administrative	12,737	8,838	3,899
Other income (expense), net	271	120	151

Research and development expenses

Research and development expenses were $35.7 million for the year ended December 31, 2016 compared to $23.5 million for the year ended December 31, 2015. Expenses increased in 2016 as we initiated and conducted our Phase 2 clinical trials for CD101 IV and CD101 topical. In addition, we continued preclinical development activities on our

Cloudbreak platform, including CD201. Personnel costs were greater than they were in the prior year due to increases in headcount to support these activities.

General and administrative expenses

General and administrative expenses were $12.7 million for the year ended December 31, 2016 compared to $8.8 million for the year ended December 31, 2015. The increase in general and administrative expenses was primarily related to personnel costs, legal fees for corporate and intellectual property matters, and market research costs.

Other Income (Expense)

Other income for the year ended December 31, 2016 and 2015 relates to income generated from cash held in interest-bearing investments. In October 2016, we entered into a loan agreement under which we drew a $10.0 million term loan. The cash and non-cash interest associated with this loan partially offset the interest income earned on our balance of cash and investments.

Comparison of the year ended December 31, 2015 and 2014

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014 (in thousands):

	Year ended December 31,		
	2015	2014	Change
Research and development	$ 23,475	$ 6,710	16,765
Cost of in-process research and development acquired	—	1,607	(1,607)
General and administrative	8,838	3,306	5,532
Other expense, net	120	(271)	391

Research and development expenses

Research and development expenses were $23.5 million for the year ended December 31, 2015 compared to $6.7 million for the year ended December 31, 2014. The increase in research and development expenses was due primarily to the expansion of activities associated with our CD101 and Cloudbreak platforms. We acquired the intellectual property for CD101 in May 2014 and commenced development activities CD101 IV and CD101 topical. We conducted two Phase 1 clinical trials for CD101 IV in 2015 and continued preclinical development of CD101 topical in preparation for its Investigational New Drug, or IND, filing. In addition, we expanded early-stage research and preclinical development for our Cloudbreak program. Finally, we began to hire employees in the third quarter of 2014 to support the research and development activities associated with our programs.

In-process research and development

In May 2014, we entered into an asset purchase agreement with Seachaid Pharmaceuticals, or Seachaid, whereby we purchased the intellectual property for CD101. In exchange for the intellectual property, we issued 703,092 shares of common stock to the shareholders of Seachaid, with a fair value of $1.6 million, as consideration for the assets acquired.

General and administrative expenses

General and administrative expenses were $8.8 million for the year ended December 31, 2015 compared to $3.3 million for the year ended December 31, 2014. The increase in general and administrative expenses was primarily related to personnel costs and public company operating costs, including audit and tax fees, insurance premiums, and investor and public relations fees.

Other Income (Expense)

Other income, net, for the year ended December 31, 2015 relates primarily to income generated from cash held in interest-bearing investments. Other expense for the year ended December 31, 2014 related primarily to the change in fair value of convertible notes payable which were marked to their estimated fair values until their conversion into Series A convertible preferred stock in May 2014. In addition, the convertible notes payable accrued interest at 8% while they were outstanding.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have received $188.8 million in gross proceeds to fund our operations, primarily through private placements of convertible preferred stock, convertible notes, public offerings of common stock and term loan draws.

As of December 31, 2016, we had $85.4 million in cash and cash equivalents and $19.3 million in short-term investments. The following table shows a summary of our cash flows for the years ended December 31, 2016, 2015 and 2014 (in thousands):

	Year ended December 31,		
	2016	2015	2014
Net cash provided by (used in):			
Operating activities	$ (39,771)	$ (25,959)	$ (7,710)
Investing activities	25,482	(46,088)	(991)
Financing activities	37,094	111,813	31,312
Net increase in cash and cash equivalents	$ 22,805	$ 39,766	$ 22,611

Operating activities

Net cash used in operating activities was $39.8 million for the year ended December 31, 2016 compared to $26.0 million and $7.7 million for the years ended December 31, 2015 and 2014, respectively. The increase in net cash used in operating activities was attributable to a net loss of $48.2 million for the year ended December 31, 2016 compared to net losses of $32.2 million and $11.9 million for the years ended December 31, 2015 and 2014, respectively. For all periods presented, the primary use of cash was to fund increased levels of research and development activities for our product candidates, which activities and uses of cash we expect to continue to increase for the foreseeable future.

Investing activities

Our primary investing activities during the years ended December 31, 2016 and 2015 consisted of purchases and maturities of short-term investments. For the years ended December 31, 2016 and 2015, we purchased approximately $69.6 million and $54.9 million, respectively, of short-term investments and received proceeds of $95.5 million and $10.0 million, respectively, from the maturity of short-term investments. We invest cash in excess of our immediate operating requirements with staggered investment duration or maturity to optimize our return on investment while satisfying our liquidity needs. Net cash used for the purchase of property and equipment was $0.4 million, $1.2 million, and $1.0 million for the years ended December 31, 2016, 2015, and 2014, respectively.

Financing activities

Net cash provided by financing activities was $37.1 million for the year ended December 31, 2016 compared to $111.8 million and $31.3 million for the years ended December 31, 2015 and 2014, respectively. During the year ended December 31, 2016, net proceeds from the sale of common stock and issuance of the term loan were $26.6 million and $9.9 million, respectively. During the year ended December 31, 2015, net proceeds from the sale of our Series B convertible preferred stock and our initial public offering were $41.9 million and $69.5 million, respectively. During the year ended December 31, 2014, net proceeds from the sale of our Series A convertible preferred stock and the issuance of convertible notes were $29.9 million and $0.9 million, respectively.

Operating Capital Requirements

To continue to fund operations, we will need to raise additional capital. We may obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings, through government funding or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts, or to make reductions in spending, extend payment terms with suppliers, or liquidate or grant rights to assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm our business, results of operations and future prospects. Management performed an analysis of the Company's ability to continue as a going concern. Although it is difficult to predict future liquidity requirements, we believe, based on our current operating plans, that our existing cash, cash equivalents and marketable securities, access to capital under our Loan Agreement with Pacific Western Bank and anticipated interest income will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next twelve months. However, our ability to successfully transition to profitability will be dependent upon

achieving a level of product sales adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

The following is a summary of our long-term contractual obligations as of December 31, 2016 (in thousands):

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Minimum lease payments required under operating lease of laboratory and office space	$ 1,470	$ 724	$ 746	$ —	$ —
Principal under Term Note, excluding accrued interest	10,000	—	6,667	3,333	—
Total minimum contractual obligations	$ 11,470	$ 724	$ 7,413	$ 3,333	$ —

Off-Balance Sheet Arrangements

As of December 31, 2016, we did not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our cash and cash equivalents without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

The market risk inherent in our financial instruments and in our financial position is the potential loss arising from adverse changes in interest rates. We generally hold our cash in checking and savings accounts and invest excess capital in money market funds, certificates of deposit, corporate debt, and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. To minimize our exposure to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum average maturity of our investments does not exceeded 12 months. If a 10% change in interest rates had occurred on December 31, 2016, this change would not have had a significant impact on the fair value of our investment portfolio as of that date.

Item 8. Consolidated Financial Statements and Supplementary Data.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Cidara Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Cidara Therapeutics, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cidara Therapeutics, Inc. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California

March 15, 2017

CIDARA THERAPEUTICS, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 85,367	$ 62,562
Short-term investments	19,252	44,952
Prepaid expenses and other current assets	779	704
Total current assets	105,398	108,218
Property and equipment, net	1,374	1,684
Other assets	190	72
Total assets	$ 106,962	$ 109,974
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,909	$ 3,095
Accrued liabilities	3,338	1,415
Accrued compensation and benefits	2,662	1,464
Total current liabilities	8,909	5,974
Term loan, less debt issuance costs	9,794	—
Other long-term liabilities	80	88
Total liabilities	18,783	6,062
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding at December 31, 2016 and 2015, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2016 and 2015; 16,837,126 and 16,773,232 shares issued and outstanding, respectively, at December 31, 2016; 13,942,520 and 13,786,285 shares issued and outstanding, respectively, at December 31, 2015	2	1
Additional paid-in capital	181,840	149,416
Accumulated other comprehensive loss	(1)	(8)
Accumulated deficit	(93,662)	(45,497)
Total stockholders' equity	88,179	103,912
Total liabilities and stockholders' equity	$ 106,962	$ 109,974

See accompanying notes.

CIDARA THERAPEUTICS, INC.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)	Years ended December 31, 2016	2015	2014
Operating expenses:			
Research and development	$ 35,699	$ 23,475	$ 6,710
Cost of in-process research and development acquired	—	—	1,607
General and administrative	12,737	8,838	3,306
Total operating expenses	48,436	32,313	11,623
Loss from operations	(48,436)	(32,313)	(11,623)
Other income (expense):			
Interest income (expense), net	271	120	(88)
Change in fair value of convertible notes payable	—	—	(183)
Total other income (expense)	271	120	(271)
Net loss	$ (48,165)	$ (32,193)	$ (11,894)
Other comprehensive income (loss):			
Unrealized gain (loss) on short-term investments	7	(8)	—
Comprehensive loss	$ (48,158)	$ (32,201)	$ (11,894)
Basic and diluted net loss per share	$ (3.32)	$ (3.25)	$ (14.51)
Shares used to compute basic and diluted net loss per share	14,488,987	9,920,382	819,868

See accompanying notes.

CIDARA THERAPEUTICS, INC.

Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except share data)	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance, December 31, 2013	—	$ —	—	$ —	366,552	$ —	$ 12	$ (1,410)	$ —	$ (1,398)
Issuance of Series A convertible preferred stock, net of issuance costs of $159	89,360,118	29,866	—	—	—	—	—	—	—	—
Issuance of Series A convertible preferred stock upon conversion of convertible notes payable	8,165,963	2,682	—	—	—	—	—	—	—	—
Issuance of common stock for in-process research and development	—	—	—	—	703,092	—	1,607	—	—	1,607
Vesting of restricted shares	—	—	—	—	61,913	—	5	—	—	5
Issuance of common stock for exercise of stock options	—	—	—	—	1,181	—	3	—	—	3
Stock-based compensation	—	—	—	—	—	—	232	—	—	232
Net loss	—	—	—	—	—	—	—	(11,894)	—	(11,894)
Balance, December 31, 2014	97,526,081	32,548	—	—	1,132,738	—	1,859	(13,304)	—	(11,445)
Issuance of Series B convertible preferred stock, net of issuance costs of $99	—	—	94,533,183	41,921	—	—	—	—	—	—
Conversion of Series A and Series B convertible preferred upon initial public offering	(97,526,081)	(32,548)	(94,533,183)	(41,921)	7,561,380	1	74,468	—	—	74,469
Public offering of common stock, net of issuance costs	—	—	—	—	4,800,000	—	69,271	—	—	69,271
Stock-based compensation	—	—	—	—	—	—	3,033	—	—	3,033
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	19,164	—	225	—	—	225
Vesting of restricted shares	—	—	—	—	249,465	—	499	—	—	499
Issuance of common stock for exercise of stock options	—	—	—	—	23,538	—	61	—	—	61
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	(8)	(8)
Net loss	—	—	—	—	—	—	—	(32,193)	—	(32,193)
Balance, December 31, 2015	—	—	—	—	13,786,285	1	149,416	(45,497)	(8)	103,912
Public offering of common stock, net of issuance costs	—	—	—	—	2,752,637	1	26,621	—	—	26,622
Stock-based compensation	—	—	—	—	—		4,344	—	—	4,344
Vesting of restricted shares	—	—	—	—	90,423	—	197	—	—	197
Issuance of common stock for exercise of stock options	—	—	—	—	83,353	—	525	—	—	525
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	58,616	—	562	—	—	562
Issuance of warrants in connection with term loan	—	—	—	—	—	—	175	—	—	175
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	7	7
Net loss	—	—	—	—	—	—	—	(48,165)	—	(48,165)
Balance, December 31, 2016	—	$ —	—	$ —	16,771,314	$ 2	$ 181,840	$ (93,662)	$ (1)	$ 88,179

See accompanying notes.

CIDARA THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(In thousands)	Years ended December 31, 2016	2015	2014
Operating activities:			
Net loss	$ (48,165)	$ (32,193)	$ (11,894)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	732	461	179
Stock-based compensation	4,344	3,033	232
Non-cash interest expense	17	—	66
Amortization of discount or premium on short-term investments	(176)	(42)	—
Change in fair value of convertible notes payable	—	—	183
Amortization of debt issue costs	5	22	23
Deferred rent	(8)	54	34
Purchase of in-process research and development	—	—	1,607
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(76)	(487)	(204)
Accounts payable and accrued liabilities	1,913	2,143	1,746
Accrued compensation	1,760	1,050	414
Other assets	(117)	—	(96)
Net cash used in operating activities	(39,771)	(25,959)	(7,710)
Investing activities:			
Purchases of short-term investments	(69,617)	(54,918)	—
Maturities of short-term investments	95,500	10,000	—
Purchases of property and equipment	(401)	(1,170)	(991)
Net cash provided by (used in) investing activities	25,482	(46,088)	(991)
Financing activities:			
Proceeds form issuance of common stock, net of offering costs	26,622	69,505	—
Proceeds from issuance of Series A convertible preferred stock, net of offering costs	—	—	29,866
Proceeds from issuance of Series B convertible preferred stock, net of offering costs	—	41,921	—
Proceeds from issuance of Term Loan, net of offering costs	9,947	—	—
Proceeds from issuance of convertible notes payable, net of offering costs	—	—	930
Proceeds from exercise of stock options	525	387	749
Deferred initial public offering costs	—	—	(233)
Net cash provided by financing activities	37,094	111,813	31,312
Net increase in cash and cash equivalents	22,805	39,766	22,611
Cash and cash equivalents at beginning of year	62,562	22,796	185
Cash and cash equivalents at end of year	$ 85,367	$ 62,562	$ 22,796
Non-cash investing activity:			
Property and equipment acquired but not yet paid	$ 21	$ 113	$ 51
Non-cash financing activities:			
Deferred initial public offering costs	$ —	$ 234	$ 146
Conversion of Series A convertible preferred stock to common stock upon initial public offering	$ —	$ 32,548	$ —
Conversion of Series B convertible preferred stock to common stock upon initial public offering	$ —	$ 41,921	$ —
Conversion of convertible notes payable and accrued interest to Series A convertible preferred shares	$ —	$ —	$ 2,682
Issuance of warrants to purchase common stock upon execution of term loan	$ 175	$ —	$ —
Vesting of early exercised stock options	$ 197	$ 499	$ —
Purchase of shares pursuant to Employee Stock Purchase Plan	$ 562	$ —	$ —

See accompanying notes.

1. THE COMPANY AND BASIS OF PRESENTATION

Description of Business

Cidara Therapeutics, Inc., or the Company, was originally incorporated in Delaware in December 2012 as K2 Therapeutics, Inc., and its name was changed to Cidara Therapeutics, Inc. in July 2014. The Company is a biotechnology company focused on the discovery, development and commercialization of novel anti-infectives. The Company's initial product portfolio is comprised of proprietary product candidates for the treatment of serious fungal and bacterial infections. In March 2016, the Company formed a wholly-owned subsidiary, Cidara Therapeutics UK Limited, in England for the purpose of developing its product candidates in Europe.

Basis of Presentation

The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced net losses and negative cash flows from operating activities since its inception. At December 31, 2016, the Company had an accumulated deficit of $93.7 million. The Company expects to continue to incur net losses into the foreseeable future. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. The Company plans to continue to fund its losses from operations and capital funding needs through debt and equity financing, through government funding or through collaborations or partnerships with other entities. Debt or equity financing or collaborations and partnerships with other entities may not be available on a timely basis on terms acceptable to the Company, or at all. If the Company is not able to secure adequate additional funding, the Company may be forced to delay, reduce or eliminate its research and development programs or future commercialization efforts, or to make reductions in spending, extend payment terms with suppliers, liquidate or grant rights to assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Basis of Consolidation—The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates—The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. The Company evaluates its estimates and assumptions on an ongoing basis. The most significant estimates in the Company's consolidated financial statements relate to estimating the fair value of the Company's common shares used to account for share-based compensation and certain accruals, including those related to preclinical and clinical activities. Although the estimates are based on the Company's knowledge of current events, comparable companies, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Segment Information—Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents—The Company considers all short-term investments purchased with a maturity of three months or less when acquired to be cash equivalents.

Investments Available-for-Sale— Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization of premiums and accretion of discounts is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income (expense). The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income. Securities with maturity dates of 12 months or less from the date of purchase are classified as short-term investments and securities with maturity dates of more than 12 months are classified as long-term investments.

Property and Equipment— We carry our property and equipment at cost, which consists of lab equipment, computer equipment and software, office equipment, furniture and fixtures and leasehold improvements. Property and equipment is depreciated using the straight-line method over the estimated useful lives (generally three to seven years). Leasehold improvements are amortized over the lesser of their useful life or the remaining lease term, including any renewal periods that are deemed to be reasonably assured. Repair and maintenance costs are expensed as incurred.

Concentration of Credit Risk—The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. Periodically, the Company maintains deposits in government insured financial institutions in excess of government insured limits. The Company invests its cash balances in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to significant credit risk.

Patent Costs— The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the accompanying statements of operations.

Income Taxes—The Company follows the Financial Accounting Standards Board ("FASB") *Accounting Standards Codification* ("ASC") 740, *Income Taxes*, or ASC 740, in reporting deferred income taxes. The ASC 740 requires a company to recognize deferred tax assets and liabilities for expected future income tax consequences of events that have been recognized in the Company's consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates in the years in which the temporary differences are expected to reverse. Valuation allowances are provided if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions pursuant to ASC 740, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Research and Development Costs—Research and development expenses consist of wages, benefits and stock-based compensation charges for research and development employees, scientific consultant fees, facilities and overhead expenses, laboratory supplies, manufacturing expenses, and preclinical and clinical trial costs. The Company accrues clinical trial expenses based on work performed which relies on estimates of total costs incurred based on patient enrollment, completion of studies, and other events.

Costs incurred in purchasing technology assets and intellectual property are charged to research and development expense if the technology has not been conclusively proven to be feasible and has no alternative future use.

Comprehensive Loss—Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. The Company's only component of other comprehensive loss is unrealized gains (losses) on short-term marketable securities. Comprehensive gains (losses) have been reflected in the statements of operations and comprehensive loss and as a separate component of the statements of convertible preferred stock and stockholders' equity (deficit) for all periods presented.

Stock-based Compensation— The Company accounts for stock-based compensation expense related to employee stock options, restricted stock grants, and employee stock purchase plan rights by estimating the fair value on the date of grant using the Black-Scholes option pricing model. For awards subject to time-based vesting conditions, stock-based compensation expense is recognized ratably over the requisite service period of the awards. The Company accounts for stock options granted to non-employees using the fair value approach. These option grants are subject to periodic revaluation over their vesting terms.

Net Loss Per Share—Basic net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Dilutive common stock equivalents are comprised of convertible preferred stock, convertible notes payable, unvested restricted common stock subject to repurchase, and options outstanding under the Company's stock option plan. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding.

The following table sets forth the outstanding potentially dilutive securities that have been excluded in the calculation of diluted net loss per share because to do so would be anti-dilutive (in common stock equivalent shares):

	December 31,	
	2016	2015
Common stock options issued and outstanding	2,295,393	1,437,583
Common stock warrants	17,331	—
Common stock subject to repurchase	63,894	156,235
Total	2,376,618	1,593,818

Fair Value of Financial Instruments— The Company follows authoritative guidance with respect to fair value reporting issued by the FASB for financial assets and liabilities, which defines fair value, provides guidance for measuring fair value and requires certain disclosures. The guidance does not apply to measurements related to share-based payments. The guidance discusses valuation techniques such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The guidance establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels.

The Company's financial instruments consist of cash and cash equivalents, marketable securities, prepaid expenses, accounts payable, accrued liabilities and long-term debt. Fair value estimates of these instruments are made at a specific point in time based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, prepaid expenses, accounts payable, and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The fair value of short-term investments is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The Company believes that the fair value of long-term debt approximates its carrying value.

Recently Issued Accounting Standards— During 2014, the FASB issued Accounting Standards Update ("ASU") 2014-15, "*Presentation of Financial Statements—Going Concern,*" which requires management to assess an entity's ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. The update is effective for annual reporting periods ending after December 15, 2016 and interim periods thereafter. The Company adopted ASU 2014-15 in the fourth quarter of 2016. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

During 2015, the FASB issued ASU 2015-03, "*Interest - Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*," which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The updated guidance is effective or interim and annual periods beginning after December 15, 2015. The Company adopted ASU 2015-03 in 2016. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

During 2015, the FASB issued 2015-17, "*Income Taxes: Balance Sheet Classification of Deferred Assets*," which requires reporting entities to classify deferred income taxes as non-current on the consolidated balance sheets and simplifies the presentation of deferred income taxes. The updated guidance is effective for annual reporting periods beginning after December 15, 2016, and early adoption is permitted. The Company early adopted ASU 2015-17 in the fourth quarter of 2016. the adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

During 2016, the FASB issued ASU 2016-09, "*Compensation – Stock Compensation: Improvements to Employee Share-Based Payment Accounting*," which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The updated guidance is effective for interim and annual periods beginning after December 15, 2016, and early adoption is permitted. The Company early adopted ASU 2016-09 in the fourth quarter of 2016. The adoption of this guidance did not have a material impact on the Company's consolidated financial statements.

During 2014, the FASB issued ASU 2014-09, "Revenue from Contracts with Customers," which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. ASU 2015-09 outlines a five-step process for revenue recognition that focuses on transfer of control, as opposed to transfer of risk and rewards, and also requires enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenues and cash flows from contracts with customers. Although the Company does not have any revenue contracts, in the event the Company signs a collaboration or other revenue generating contract during 2017 we would anticipate early adopting this standard using the full retrospective method of adoption so that, in the event we enter into any revenue contracts, the contracts will be accounted for under the new guidance from inception of the contract.

During 2016, the FASB issued ASU 2016-01, "*Recognition and Measurement of Financial Assets and Financial Liabilities*," which eliminates the requirement for public companies to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet. The standard also requires public entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes. Furthermore, the standard requires presentation of assets and liabilities by measurement category and form of financial asset on the balance sheet or accompanying notes to the financial statements. The updated guidance is effective for interim and annual periods beginning after December 15, 2017, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

During 2016, the FASB issued ASU 2016-02, "*Leases*," which requires that lease arrangements longer than 12 months result in an entity recognizing an asset and liability. The updated guidance is effective for interim and annual periods beginning after December 15, 2018, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

During 2016, the FASB issued ASU 2016-15, "*Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments,*" which addresses the presentation and classification of certain cash receipts and payments in the statement of cash flows. The updated guidance is effective for interim and annual reporting periods beginning after December 15, 2017, and early adoption is permitted. The adoption of this guidance is not expected to have a material impact on the Company's consolidated financial statements.

3. SHORT-TERM INVESTMENTS

The following table summarizes the available-for-sale securities held at December 31, 2016 and 2015 (in thousands):

As of December 31, 2016	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper	$ 19,253	$ 1	$ (2)	$ 19,252
Total	$ 19,253	$ 1	$ (2)	$ 19,252

As of December 31, 2015	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Certificates of deposit	$ 20,000	$ —	$ —	$ 20,000
Commercial paper	24,960	—	(8)	24,952
Total	$ 44,960	$ —	$ (8)	$ 44,952

All available-for-sale securities held at December 31, 2016 and 2015 mature in less than one year. Unrealized gains and losses on available-for-sale securities are included as a component of other comprehensive loss. The securities in unrealized loss positions have not been in a continuous unrealized loss position for 12 months or longer. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases which may be at maturity. The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value.

4. FAIR VALUE MEASUREMENTS

The Company follows ASC 820-10, *Fair Value Measurements and Disclosures*, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions, which reflect those that a market participant would use.

At December 31, 2016 and 2015, the Company held commercial paper, which is valued using observable market inputs including reported trades, broker/dealer quotes, bids and/or offers, and securities of money market funds, which invested in short-term U.S. Treasury securities, the prices of which were available from quoted prices in active markets.

At December 31, 2015, the Company held certificates of deposit, which are valued at cost.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The following tables summarize the Company's financial instruments measured at fair value on a recurring basis (in thousands):

	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
December 31, 2016				
Assets:				
Cash equivalents and money market funds	$ 84,830	$ 84,830	$ —	$ —
Commercial paper	19,252	—	19,252	—
Total assets at fair value	$ 104,082	$ 84,830	$ 19,252	$ —
December 31, 2015				
Assets:				
Cash equivalents and money market funds	$ 12,353	$ 12,353	$ —	$ —
Certificates of deposit included in cash and cash equivalents	50,000	—	50,000	—
Certificates of deposit included in short-term investments	20,000	—	20,000	—
Commercial paper	24,952	—	24,952	—
Total assets at fair value	$ 107,305	$ 12,353	$ 94,952	$ —

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following (in thousands):

	December 31,	
	2016	2015
Laboratory equipment	$ 1,771	$ 1,438
Leasehold improvements	425	425
Computer hardware and software	295	242
Office equipment	111	111
Furniture and fixtures	142	105
	2,744	2,321
Less accumulated depreciation and amortization	(1,370)	(637)
Total	$ 1,374	$ 1,684

Depreciation and amortization of property and equipment of $732,000 and $461,000 were recorded for the years ended December 31, 2016 and 2015, respectively.

6. DEBT

Term Loans

On October 3, 2016, the Company entered into a loan and security agreement, (the "Loan Agreement"), with Pacific Western Bank, as the collateral agent and a lender (the "Lender"), pursuant to which the Lender agreed to lend to the Company up to $20.0 million in a series of term loans. Contemporaneously, the Company borrowed $10.0 million from the Lender (the "Term A Loan").

Under the terms of the Loan Agreement, including the Company's achievement of specified milestones in the Loan Agreement (the "Milestones"), the Company may, at its sole discretion through April 3, 2018, borrow from the

Lender up to an additional $10.0 million (the "Term B Loan", and together with Term A Loan, the "Term Loans"). The Loan Agreement also includes an operating covenant which requires the Company to achieve the Milestones on or before March 31, 2018. The milestone event for the Term B Loan is the achievement of positive data from a Phase 2 clinical trial of CD101 Topical or CD101 IV.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of the Company's current and future assets, other than its intellectual property, which is subject to a double negative pledge.

The Term Loans mature on October 3, 2020 (the "Maturity Date"). Payments under the Term Loans will be interest-only through April 2, 2018, which will be extended by six months if the Term B milestone event is achieved. The interest-only period will be followed by 30 equal monthly payments of principal and interest; provided that there will be 24 equal monthly payments if the Term B milestone amount is achieved. The Term Loans will bear interest at a variable annual rate equal to the greater of (i) 4.5% or (ii) the Lender's prime interest rate plus 1.0%. At December 31, 2016, the Term Loans bear interest at 4.75%.

The Company may prepay the borrowed amounts, provided that the Company will be obligated to pay a prepayment fee equal to (i) 2.0% of the applicable principal amount of the Term Loan if the prepayment occurs before the first anniversary of the applicable funding date, and (ii) 1.0% of the applicable principal amount of the Term Loan if the prepayment occurs after the first anniversary of the funding date of such Term Loan but on or prior to the second anniversary of the funding date of such Term Loan.

Pursuant to the Loan Agreement, on October 3, 2016, the Company issued to the Lender a warrant to purchase an aggregate of up to 17,331 shares of the Company's common stock at an exercise price of $11.54 per share. If the Company borrows additional amounts under the Loan Agreement, it will, in connection with any such borrowing, issue the Lender an additional warrant to purchase that number of shares of the Company's common stock as is equal to 2.0% of the additional principal amount borrowed divided by the exercise price. The exercise price shall be equal to the 30-day average closing price of the Company's common stock, calculated as of the date immediately prior to the date of such additional borrowing. The warrants are immediately exercisable and will expire ten years from the date of the grant.

While any amounts are outstanding under the Loan Agreement, the Company is subject to a number of affirmative and restrictive covenants, including covenants regarding dispositions of property, business combinations or acquisitions, incurring additional indebtedness and transactions with affiliates, among other customary covenants. The Company is also restricted from paying dividends or making other distributions or payments on its capital stock, subject to limited exceptions.

Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Loan Agreement, the breach of certain of its other covenants under the Loan Agreement, including the receipt of positive Phase 2 clinical data from either the CD101 topical or CD101 IV programs by March 31, 2018, or the occurrence of a material adverse change, the collateral agent will have the right, among other remedies, to declare all principal and interest and other amounts due to the Lender under the Loan Agreement immediately due and payable.

As of December 31, 2016, future principal payments due under the Term A Loan are as follows (in thousands):

Year ended:		
December 31, 2017	$	—
December 31, 2018		2,667
December 31, 2019		4,000
December 31, 2020		3,333
Total future principal payments due under the Term A Loan	$	10,000

The fair value of the warrants to purchase common stock issued in connection with Term Loan A was estimated on the date of issuance using the Black-Scholes valuation model and recorded to additional paid-in capital. The fair value of the warrants on the date of issuance as well as the debt issue costs incurred in connection with the entry into the Loan Agreement are presented as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet and will be amortized utilizing the effective interest method over the term of the loan. Amortization of the fair value of the warrants and debt issue costs was $17,000 and $5,000, respectively, and each was recognized as a component of interest expense for the year ended December 31, 2016.

7. STOCKHOLDERS' EQUITY

Preferred Stock— Under the amended and restated certificate of incorporation, the Company's board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. The Company had 10,000,000 shares of preferred stock authorized and no shares of preferred stock issued or outstanding at December 31, 2016.

Common Stock—The Company had 200,000,000 shares of common stock authorized as of December 31, 2016. Holders of outstanding shares of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the holders of common stock. Subject to the rights of the holders of any class of the Company's capital stock having any preference or priority over common stock, the holders of common stock are entitled to receive dividends that are declared by the Company's board of directors out of legally available funds. In the event of a liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in the net assets remaining after payment of liabilities, subject to prior rights of preferred stock, if any, then outstanding. The common stock has no preemptive rights, conversion rights, redemption rights or sinking fund provisions, and there are no dividends in arrears or default. All shares of common stock have equal distribution, liquidation and voting rights, and have no preferences or exchange rights.

On October 13, 2016, the Company completed a public offering of common stock in which it sold 2,752,637 shares of its common stock at an offering price of $10.10 per share. The Company raised net proceeds of approximately $26.6 million, after deducting underwriting discounts and commissions and offering expenses.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows (in common stock equivalent shares):

	Years ended December 31,	
	2016	2015
Common stock warrants	17,331	—
Stock options issued and outstanding	2,295,393	1,437,583
Authorized for future stock awards under the Company's option plans	1,404,933	1,788,396
Awards available under the ESPP	306,813	226,004
Total	4,024,470	3,451,983

8. EQUITY INCENTIVE PLANS

2015 Equity Incentive Plan

In March 2015, the Company's board of directors and stockholders approved and adopted the 2015 Equity Incentive Plan ("2015 EIP"). Under the 2015 EIP, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, and other awards to individuals who are employees, officers, directors, or consultants of the Company. The number of shares of stock available for issuance under the 2015 EIP will be automatically increased each January 1 by 4% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number as determined by the Company's board of directors.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2015 EIP. Stock options granted by the Company generally vest over a three- or four-year year period. Certain stock options are subject to acceleration of vesting in the event of certain change of control transactions. The stock options may be granted for a term of up to 10 years from the date of grant. The exercise price for stock options granted under the 2015 EIP must be at a price no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided that for an incentive stock option granted to an employee who at the time of grant owns stock representing more than 10% of the voting power of all classes of stock of the Company, the exercise price shall be no less than 110% of the estimated value on the date of grant.

2015 Employee Stock Purchase Plan

In March 2015, the Company's board of directors and stockholders approved and adopted the 2015 Employee Stock Purchase Plan ("ESPP"). In addition, the number of shares of stock available for issuance under the ESPP will be automatically increased each January 1 by the lesser of (i) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, or (ii) 490,336 shares.

The ESPP allows substantially all employees to purchase the Company's common stock through a payroll deduction at a price equal to 85% of the lower of the fair market value of the stock as of the beginning or the end of each purchase period. An employee's payroll deductions under the under the ESPP are limited to 15% of the employee's eligible compensation. During the year ended December 31, 2016, 58,616 shares were issued pursuant to the ESPP.

Restricted Stock

The Company permits early exercise of certain stock options. Any unvested shares are restricted and subject to repurchase by the Company until the conditions for vesting are met. At December 31, 2016 and 2015, the liabilities for the cash received from the early exercise of stock options were $144,000 and $341,000, respectively, and were classified in accrued liabilities on the balance sheet. The Company reduces the liability as the underlying shares vest in accordance with the vesting terms outlined in the stock option agreements which, generally, is 4 years. At December 31, 2016, 63,894 unvested shares were subject to repurchase by the Company.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Total Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2015	1,437,583	$ 6.19	8.94	$ 15,774
Options granted	947,025	10.16		
Options exercised	(83,353)	6.30		
Options canceled	(5,862)	5.97		
Outstanding at December 31, 2016	2,295,393	$ 7.82	8.20	$ 6,774
Vested and expected to vest at December 31, 2016	2,295,393	$ 7.82	8.20	$ 6,774
Exercisable at December 31, 2016	878,658	$ 7.05	8.15	$ 3,444

The following table summarizes the Black-Scholes option pricing model assumptions used to estimate the fair value of stock options granted to employees under our equity incentive plans and the shares purchasable under our 2015 ESPP during the periods presented:

	For the years ended December 31,	
	2016	2015
2015 EIP		
Risk-free interest rate	1.14% - 2.09%	1.53% - 1.91%
Expected dividend yield	0%	0%
Expected volatility	80% - 82%	78% - 80%
Expected term (years)	5.50 - 6.08	5.00 - 6.08
2015 ESPP		
Risk-free interest rate	0.48% - 1.08%	0.35% - 0.94%
Expected dividend yield	0%	0%
Expected volatility	80% - 107%	65% - 101%
Expected term (years)	0.50 - 2.00	0.50 - 2.00

Stock-based compensation expense recognized for stock options and the ESPP has been reported in the statements of operations and comprehensive loss as follows (in thousands):

	Years ended December 31,	
	2016	2015
Research and development	$ 2,005	$ 1,586
General and administrative	2,339	1,447
Total	$ 4,344	$ 3,033

The weighted-average grant date fair value of stock options granted to employees during the year ended December 31, 2016 was $6.99 per share. The total grant date fair value of stock options that vested during the year ended December 31, 2016 was $3.6 million. As of December 31, 2016, total unrecognized share-based compensation expense related to unvested employee stock options of the Company was approximately $7.8 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 2.14 years.

As of December 31, 2016, total unrecognized compensation expense related to the Company's ESPP was approximately $0.6 million. This unrecognized compensation cost is expected to be recognized over approximately 1.9 years.

9. INCOME TAXES

The Company accounts for income taxes under ASC 740. Deferred income tax assets and liabilities are determined based upon differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse.

The following table provides a reconciliation between income taxes computed at the federal statutory rate of 34% and the provision for income taxes (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Federal income taxes at 34%	$ (16,334)	$ (10,946)	$ (4,044)
State income tax, net of federal benefit	(1)	(1,821)	(672)
Tax effect on nondeductible expenses	1,650	341	132
Research credits	(3,538)	(676)	(265)
Rate change	267	—	—
Change in valuation allowance	14,996	13,084	4,849
Reserve for uncertain tax positions	2,883	—	—
Other	77	18	—
Income tax expense	$ —	$ —	$ —

Significant components of the Company's net deferred tax assets are as follows (in thousands):

	Years Ended December 31,	
	2016	2015
Deferred tax assets:		
Net operating losses	$ 27,309	$ 15,646
Research credits	3,646	987
Intangibles	466	590
Other	2,030	1,231
Total deferred tax assets	33,451	18,454
Less valuation allowance	(33,451)	(18,454)
Income tax expense	$ —	$ —

At December 31, 2016, the Company had federal and state net operating loss carryforwards of approximately $79.5 million and $39.1 million, respectively. The federal and state loss carryforwards begin to expire in 2033, unless previously utilized. The Company also has federal research and development and orphan drug credit carryforwards totaling $4.3 million and state research and development credit carryforwards totaling $0.9 million. The federal research and development credit and orphan drug credit carryforwards begin to expire in 2033, unless previously utilized. The state research and development credit carryforwards begin to expire in 2018.

Management assesses the available positive and negative evidence to estimate if sufficient future taxable income will be generated to use the existing deferred tax assets. Based on the weight of all evidence, including a history of operating

losses, management has determined that it is more likely than not that the net deferred tax assets will not be realized. A valuation allowance of $33.5 million and $18.5 million as of December 31, 2016 and 2015, respectively, has been established to offset the deferred tax assets as realization of such assets is uncertain.

Future utilization of the Company's net operating loss and research and development credits carryforwards to offset future taxable income may be subject to an annual limitation, pursuant to Internal Revenue Code (IRC) Sections 382 and 383, as a result of ownership changes that may have occurred or that could occur in the future. An ownership change occurs when a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards.

The Company recognizes a tax benefit from an uncertain tax position when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. Income tax positions must meet a more likely than not recognition at the effective date to be recognized. At December 31, 2016 and 2015, the unrecognized tax benefits recorded were approximately $4.6 million and $0.4 million, respectively. Approximately $3.2 million of the unrecognized tax benefits would reduce our annual effective tax rates, if recognized, subject to the valuation allowances. The Company does not anticipate a significant change in the unrecognized tax benefits within the next 12 months.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits for 2016, 2015 and 2014 is as follows (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Balance as of the beginning of the year	$ 356	$ 108	$ 6
Increases related to current year tax positions	921	248	102
Increases related to prior year tax positions	3,365	—	—
Balance as of the end of the year	$ 4,642	$ 356	$ 108

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by the United States and state jurisdictions where applicable. There are currently no pending income tax examinations. The Company's tax years from inception in 2012 are subject to examination by the federal and state tax authorities due to the carryforward of unutilized net operating losses and research and development credits. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company has not recognized interest or penalties since inception.

10. COMMITMENTS AND CONTINGENCIES

Litigation—From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company at December 31, 2016 which will have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position, or results of operations. Litigation, however, is subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm the Company's business.

Lease Obligations—In June 2014, the Company entered into an operating lease agreement for laboratory and office space in San Diego, California. Amendments for additional space were entered into in February 2015, March 2015 and August 2015. The lease expires in December 2018 with options for two individual two-year extensions. The lease is subject to charges for common area maintenance and other costs, and base rent is subject to 3% annual increases every July. Rent expense is being recorded on a straight-line basis over the life of the lease.

Future minimum payments required under the lease as of December 31, 2016 are summarized as follows (in thousands):

2017	$	724
2018		746
Total minimum lease payments	$	1,470

Rent expense was $733,000 and $581,000 for the years ended December 31, 2016 and 2015, respectively.

Contractual Obligations—The Company enters into contracts in the normal course of business with vendors for research and development activities, manufacturing, and professional services. These contracts generally provide for termination either on or within 30 days of notice.

11. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2016				
Operating expenses	$ 9,885	$ 11,862	$ 12,336	$ 14,353
Other income (expense)	96	107	109	(41)
Net loss	(9,789)	(11,755)	(12,227)	(14,394)
Basic and diluted net loss per share	$ (0.71)	$ (0.85)	$ (0.88)	$ (0.88)
Shares used to compute basic and diluted net loss per share	13,807,825	13,871,938	13,910,145	16,352,046
2015				
Operating expenses	$ 6,732	$ 6,446	$ 9,207	$ 9,928
Other income (expense)	(5)	32	33	60
Net loss	(6,737)	(6,414)	(9,174)	(9,868)
Basic and diluted net loss per share	$ (5.92)	$ (0.59)	$ (0.67)	$ (0.72)
Shares used to compute basic and diluted net loss per share	1,138,911	10,957,150	13,674,568	13,731,519

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our chief executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2016, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2016.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, with the participation of our principal executive officer and principal financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in its 2013 Internal Control — Integrated Framework. Based on this assessment, our management has concluded that, as of December 31, 2016, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our registered public accounting firm due to a transition period established by the JOBS Act that is applicable to emerging growth companies.

Changes in Internal Control over Financial Reporting

During the fourth quarter of 2016, we implemented a new enterprise resource planning (ERP) system by transitioning our corporate operations, including general ledger, procurement, and payment functions. We have accordingly modified our existing internal controls infrastructure to adapt to our new ERP system as we take advantage of the increased functionality of the new system. We believe that the new ERP system and related chagnes to processes and the design of our internal controls will enhance our internal control over financial reporting while providing us with the ability to scale our business. We believe we have taken the necessary steps to monitor and maintain appropriate internal control over financial reporting during the fourth quarter of 2016 and we will continue to evaluate the operating effectiveness of related key controls during subsequent periods.

There were no other changes in our internal control over financial reporting that occurred during our latest fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below will be set forth in the section headed “Election of Directors” and “Executive Officers” in our Proxy Statement for our 2017 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days after the fiscal year ended December 31, 2016, and is incorporated herein by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at http://www.cidara.com under the Corporate Governance section of our Investor Relations page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals that is required to be disclosed pursuant to SEC rules and regulations, the name of such person who is granted the waiver and the date of the waiver. The information contained on, or that can be accessed through, our website is not part of this Annual Report, and the inclusion of our website address in this Annual Report is an inactive textual reference only

Item 11. Executive Compensation.

The information required by this item will be set forth in the section headed “Executive and Director Compensation” in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth under the headings “Equity Benefit Plans” and “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement and is incorporated herein by reference.

The information required by Item 201(d) of Regulation S-K will be set forth in the section headed “Executive and Director Compensation” in our Proxy Statement and is incorporated herein by reference.

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

The information required by this item will be set forth in the section headed “Certain Relationships and Related Party Transactions” in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the section headed “Principal Accountant Fees and Services” in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

1. ***Financial Statements***—We have filed the following documents in Item 8of this Annual Report:

2. ***Financial Statement Schedules***—All other schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

3. ***Exhibits***—For a list of exhibits filed with this Annual Report, refer to the exhibit index following the signature page on this Annual Report. The exhibits listed in the Exhibit Index are filed or incorporated by reference as part of this Annual Report.

SIGNATURES

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

Cidara Therapeutics, Inc.

Date: March 15, 2017

By: /s/ Jeffrey Stein, Ph.D.

Jeffrey Stein, Ph.D.

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Stein, Ph.D. and Matthew Onaitis, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or either of them, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Jeffrey Stein, Ph.D. **Jeffrey Stein, Ph.D.**	President and Chief Executive Officer *(Principal Executive Officer)*	March 15, 2017
/s/ Matthew Onaitis, J.D. **Matthew Onaitis, J.D.**	Chief Financial Officer and General Counsel *(Principal Financial Officer)*	March 15, 2017
/s/ Marc J.S. Wilson **Marc J.S. Wilson**	Vice President, Finance and Accounting *(Principal Accounting Officer)*	March 15, 2017
/s/ Scott M. Rocklage, Ph.D **Scott M. Rocklage, Ph.D**	Chairman of the Board of Directors	March 15, 2017
/s/ Daniel D. Burgess **Daniel D. Burgess**	Member of the Board of Directors	March 15, 2017
/s/ Timothy R. Franson, M.D. **Timothy R. Franson, M.D.**	Member of the Board of Directors	March 15, 2017
/s/ Robert J. Perez **Robert J. Perez**	Member of the Board of Directors	March 15, 2017
/s/ Theodore R. Schroeder **Theodore R. Schroeder**	Member of the Board of Directors	March 15, 2017

Exhibit Index

Exhibit Number	Description
1.2(1)	Controlled Equity Offering℠ Sales Agreement by and between the Registrant and Cantor Fitzgerald & Co., dated May 19, 2016.
3.1(2)	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2(2)	Amended and Restated Bylaws of the Registrant, as currently in effect.
4.1(3)	Form of Common stock Certificate of the Registrant.
4.2(3)	Second Amended and Restated Investor Rights Agreement, by and among the Registrant and certain of its stockholders, dated February 10, 2015.
4.3(4)	Form of Warrant to Purchase Common Stock issued to Pacific Western Bank.
10.1+(3)	Form of Indemnity Agreement by and between the Registrant and its directors and officers.
10.2+(3)	2015 Equity Incentive Plan and Form of Grant Notice, Stock Option Agreement and Notice of Exercise thereunder.
10.3+(3)	2015 Employee Stock Purchase Plan.
10.4+(3)	2013 Stock Option and Grant Plan and Form of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder, as amended.
10.5+(5)	Form of Amended and Restated Employment Agreement by and between the Registrant and its executive officers, dated September 19, 2016.
10.6(6)	Consulting and Independent Contractor Agreement by and between the Registrant and Dirk Thye, M.D., dated September 2, 2016.
10.7(4)	Loan and Security Agreement by and between Registrant and Pacific Western Bank, dated October 3, 2016.
10.8(3)	Asset Purchase Agreement by and between Registrant and Seachaid Pharmaceuticals, Inc., dated May 30, 2014.
10.9(3)	Addendum to Asset Purchase Agreement by and between Registrant and Seachaid Pharmaceuticals, Inc. dated September 23, 2014 and deemed effective as of May 30, 2014.
10.10(3)	Standard Industrial/Commercial Multi-Tenant Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated June 9, 2014.
10.11(3)	First Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated June 9, 2014.
10.12(3)	Second Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated February 15, 2015.
10.13(7)	Third Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated July 1, 2015.
21.1*	List of subsidiaries of the Registrant.
23.1*	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

Exhibit Number	Description
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Registrant’s Registration Statement on Form S-3 (File No. 333-211472), filed on May 19, 2016.

(1) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed on April 24, 2015.

(2) Incorporated by reference to the Registrant’s Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015.

(3) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed on October 3, 2016.

Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q, filed on November 10, 2016.

(4) Incorporated by reference to the Registrant’s Current Report on Form 8-K, filed on September 1, 2016.

(5) Incorporated by reference to the Registrant’s Quarterly Report on Form 10-Q, filed on November 16, 2015.

† Indicates management contract or compensatory plan.

* Filed herewith.

Exhibit 21.1

Cidara Therapeutics, Inc. Subsidiaries

The following is a list of subsidiaries of the Company, doing business under the name stated.

Name	Country or State of Incorporation
Cidara Therapeutics UK Limited	United Kingdom

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-211472) of Cidara Therapeutics, Inc., and

(2) Registration Statements (Form S-8 Nos. 333-203434 and 333-210263) pertaining to the 2013 Stock Option and Grant Plan, the 2015 Equity Inventive Plan, and the 2015 Employee Stock Purchases Plan of Cidara Therapeutics, Inc.;

of our report dated March 15, 2017, with respect to the consolidated financial statements of Cidara Therapeutics, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2016.

/s/ Ernst & Young LLP

San Diego, California

March 15, 2017

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey Stein, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Cidara Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2017

By: /s/ Jeffrey Stein, Ph.D.

Jeffrey Stein, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew Onaitis, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cidara Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2017

By: /s/ Matthew Onaitis

Matthew Onaitis
Chief Financial Officer and General Counsel
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cidara Therapeutics, Inc. (the "Company") for the period ending December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof and to which this certification is attached as an exhibit (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 15, 2017

By: /s/ Jeffrey Stein, Ph.D.

Jeffrey Stein, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cidara Therapeutics, Inc. (the "Company") for the period ending December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof and to which this certification is attached as an exhibit (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 15, 2017

By: /s/ Matthew Onaitis

Matthew Onaitis
Chief Financial Officer and General Counsel
(Principal Financial Officer)