

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, 2018

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  
(State or Other Jurisdiction of  
Incorporation or Organization)

46-1537286  
(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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES  NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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, a smaller reporting company, or an emerging growth company.

|                         |                                     |                         |                                     |
|-------------------------|-------------------------------------|-------------------------|-------------------------------------|
| Large accelerated filer | <input type="checkbox"/>            | Accelerated filer       | <input checked="" type="checkbox"/> |
| Non-accelerated filer   | <input type="checkbox"/>            | Small reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input checked="" type="checkbox"/> |                         |                                     |

If an emerging growth company, indicate by check mark if the Registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the 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, 2018, was approximately \$139.5 million.

The number of shares of Registrant's common stock outstanding as of February 20, 2019 was 27,816,014.

#### **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 2018 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, 2018.

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CIDARA THERAPEUTICS, INC.

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**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 ability to obtain and maintain intellectual property protection for our product candidates;
- our ability to use our Cloudbreak platform to identify development candidates, or to expand our Cloudbreak 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.**

**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 pipeline of product and development candidates, with an initial focus on serious fungal infections. Our lead product candidate is rezafungin acetate, an intravenous formulation of a novel echinocandin. Rezafungin is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections.

In addition, our proprietary Cloudbreak® platform is designed to discover compounds that directly kill pathogens and also direct a patient's immune system to attack and eliminate pathogens. Currently, we are using our Cloudbreak platform to develop antibody-drug conjugates, or ADCs, for viral infections, including influenza, and bacterial infections.

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 \$4.2 billion global systemic antifungal market in which there is high unmet need, high mortality rate and few new agents in development.

**Rezafungin**

Rezafungin is a novel molecule in the echinocandin class of antifungals. We are developing rezafungin for the treatment and prevention of serious, invasive fungal infections. These infections include candidemia and invasive candidiasis, which are fungal infections associated with high mortality rates.

*STRIVE clinical trial*

In March 2018, we reported topline results from Part A of our global, randomized Phase 2 clinical trial of rezafungin, called the STRIVE trial. In STRIVE Part A, patients were randomized to one of two rezafungin arms or to the caspofungin arm. In the two rezafungin arms of the trial, patients received either 400 mg of rezafungin administered intravenously once weekly for two to four weeks (Group 1) or 400 mg for the first week followed by 200 mg once weekly for one to three weeks, for a total of two to four weeks (Group 2). In the comparator arm (Group 3), patients received daily caspofungin administered intravenously according to the approved prescribing information, with an optional step down to oral fluconazole. STRIVE Part A met its primary objectives related to tolerability and safety of rezafungin in the treatment of candidemia/invasive candidiasis, and rezafungin was generally well-tolerated at both dosing regimens.

Data from this trial indicated that a 400mg / 200mg dosing regimen of rezafungin had a higher rate of Clinical Cure by PI Assessment at Day 14 (86%) and a lower All Cause Mortality at Day 30 (3%) when compared with once daily Caspofungin (71% and 11%, respectively).

**Cloudbreak Platform**

We believe our Cloudbreak platform is a fundamentally new approach for the treatment of infectious disease, and may have broad potential applications across a wide spectrum of infectious diseases, including viral and bacterial infections. The lead program is focused on the treatment and prevention of the influenza virus. We have generated preclinical, *in vivo* proof of concept data in both our Cloudbreak antiviral and antibacterial programs.

## CIDARA THERAPEUTICS, INC.

### 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 rezafungin to commercialization.** We plan to leverage the favorable regulatory environment for anti-infectives to expedite the development of rezafungin.
- **Develop our Cloudbreak antiviral program in influenza.** We expect to nominate a development candidate for influenza in the first quarter of 2019. We will also continue to establish intellectual property related to the Cloudbreak 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 in the United States, addressing the relatively small base of well-defined customers for the treatment and prevention of serious infections 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.

### Rezafungin

We acquired rezafungin, a novel echinocandin antifungal agent, in 2014. We believe rezafungin has the potential to be differentiated from other echinocandins and other classes of antifungal agents based on its prolonged half-life, high C<sub>max</sub>, 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.

Rezafungin is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections.

### Overview of Systemic Fungal Infections and the Antifungal Market

Fungal infections pose significant medical challenges in both the hospital and outpatient settings. While fungi are ubiquitous in our environment, they are usually harmless for people with a normal immune system. 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 \$4.2 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 invasive fungal infections are caused by two fungi, *Candida* and *Aspergillus*. We estimate that approximately 97,000 Americans may die from invasive fungal infections each year. Approximately 90 percent of all reported fungal related deaths result from a few common fungi, including *Candida*, *Aspergillus* and *Pneumocystis*. Systemic *Candida* infections include candidemia and invasive candidiasis. In a 2014 study in the New England Journal of Medicine, candidemia was shown to be the most common cause of healthcare-acquired bloodstream infections in the United States.

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 crude mortality rate of 35% within 12 weeks of diagnosis. By contrast, the CDC reports that the mortality rate due to methicillin-resistant staphylococcus aureus, or MRSA, infections is 13%. Further, it is estimated that each case of candidemia results in an additional 23 days of hospitalization and over \$68,000 in additional 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 drug development, including a previously challenging regulatory environment that necessitated large and costly clinical trials. As a result of this regulatory environment and other factors, the number of antifungals in development has decreased, while anti-microbial resistance has increased.

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 changes in a drug's effect on the body when taken together with a second drug, or drug-drug interactions.

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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 candidemia and invasive candidiasis.

The currently 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 intravenous 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 approximately 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 an 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.

The U.S. Centers for Disease Control and Prevention, or CDC, reports that certain species of *Candida* are becoming increasingly resistant to available antifungals, such as 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 United States. In a recent study of cancer patients with *Candida* infections from MD Anderson Cancer Center, patient prognosis was inversely correlated with a patient's fungal infection's 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<sub>max</sub> 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<sub>max</sub> or AUC, maximize the antifungal therapeutic benefit of these drugs.

When a fungus starts to develop resistance to a drug, the minimum inhibitory concentration, or 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<sub>max</sub> 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. Additionally, the EU label for caspofungin requires higher doses in obese patients. A recent analysis found that micafungin, the market leader in the United States, achieves 85% - 88% target attainment [against *C. glabrata* MIC<sub>97</sub> of 0.06 mg/L] when given at the higher dosing regimen of 200 mg followed by 150 mg, daily but achieves only 10% - 50% with its approved dose of 100 mg once daily. These factors suggest the pharmacokinetics of the currently approved echinocandins are not optimal.

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, while improving pharmacokinetic characteristics to enable enhanced efficacy and convenience.

### ***Our Solution—Rezafungin for the Treatment and Prevention of Serious Fungal Infections***

Due to its novel chemical structure, rezafungin has a prolonged half-life, a high C<sub>max</sub> and a high AUC. In addition, rezafungin was tested *in vitro* against 27 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. Rezafungin was also tested *in vitro* against 100 isolates of *Candida auris*, a highly resistant emerging strain, including eight isolates that were resistant to other echinocandins, and showed equivalent or better potency (up to 64-fold) than the currently available echinocandins against the echinocandin-resistant strains.

These factors are in contrast to all other echinocandins, and we believe they can allow rezafungin to be developed as a once-weekly intravenous therapy for the treatment and prevention of systemic fungal infections. We are developing rezafungin 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 rezafungin 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 echinocandin followed by an oral azole solely to enable earlier hospital discharge, rezafungin would enable extended single-agent intravenous 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 intravenous echinocandin can potentially discharge appropriate patients earlier and thereby reduce hospital

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costs, which we believe may account for over 80% of the overall treatment cost of candidemia. Furthermore, early discharge from the hospital setting may reduce the risk for contracting nosocomial infections. For patients discharged on an intravenous echinocandin, once-weekly rezafungin could eliminate significant outpatient infusion costs for once-daily intravenous echinocandin therapy.

- **Improved compliance.** A once-weekly treatment of rezafungin could facilitate compliance by eliminating the need for patients to return to a hospital or outpatient center for a daily dose of an intravenous 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 or trimethoprim-sulfamethoxazole prophylactic therapy due to drug interactions or poor tolerability. We expect that once weekly rezafungin therapy could provide for better prophylactic therapy on an inpatient and outpatient basis, particularly for these patients.

The FDA has granted rezafungin designations for orphan drug and Qualified Infectious Disease Product, or QIDP for the treatment of candidemia and invasive candidiasis. 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 may enable more frequent interactions with the 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 rezafungin with a total of 12 years of potential marketing exclusivity to be granted at the time of FDA approval. 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. We have also received QIDP and Fast Track designations for rezafungin for prophylactic use. We plan to seek orphan drug designation for rezafungin for prophylactic use in the United States and Europe.

### **Rezafungin Clinical Results**

#### **STRIVE Part A**

In March 2018, we reported topline results from Part A of our global, randomized Phase 2 clinical trial of rezafungin, called the STRIVE trial.

STRIVE is an international, multicenter, double-blind clinical trial evaluating the safety, tolerability and efficacy of once-weekly dosing of rezafungin compared to once-daily dosing of caspofungin in patients with candidemia and/or invasive candidiasis. In Part A, patients were randomized to one of two rezafungin arms or to the caspofungin arm. In the two rezafungin arms of the trial, patients received either 400 mg of rezafungin administered intravenously once weekly for two to four weeks (Group 1) or 400 mg for the first week followed by 200 mg once weekly for one to three weeks, for a total of two to four weeks in total (Group 2). In the comparator arm (Group 3), patients received daily caspofungin administered intravenously according to the approved prescribing information, with an optional step down to oral fluconazole. The STRIVE trial results we reported include efficacy data from 92 treated patients (the microbiological intent-to-treat, or MITT, population) and safety and tolerability results from 104 patients, from 31 trial sites in North America and Europe. The trial was not statistically powered to demonstrate superiority or non-inferiority and therefore comparisons of efficacy are directional.

STRIVE Part A met its primary objectives related to tolerability and safety of rezafungin in the treatment of candidemia/invasive candidiasis. Topline efficacy data are summarized in Table 1. Overall success is defined as eradication of *Candida* from the blood or infected organ, plus clinical cure, which is defined as resolution of clinical signs of infection which were present at baseline. Additionally, clinical response is assessed by the principal investigator based on the clinical and microbiological resolution of disease.



**CIDARA THERAPEUTICS, INC.**

**Table 1: Overall Response, High APACHE II Score Response, and Principal Investigator (PI) Assessment of Clinical Response at Day 14 and All-Cause Mortality in the mITT Population<sup>a</sup>**

|  | <b>Group 1:<br/>Rezafungin once weekly 400<br/>mg</b> | <b>Group 2:<br/>Rezafungin once weekly<br/>400mg Week 1/200mg</b> | <b>Group 3:<br/>Caspofungin once daily<br/>70 mg Day 1/50 mg</b> |
|--|---|---|--|
|  | <b>n (%)</b>  |   |  |
| Overall Success (Day 14)                             | 19/26 (73%)   | 22/28 (79%)   | 18/26 (69%)  |
| Invasive Candidiasis Patients                        | 1/2 (50%)   | 5/5 (100%)  | 1/3 (33%)  |
| Response: High APACHE II Score Patients              | 6/10 (60%)  | 8/10 (80%)  | 7/12 (58%)   |
| Clinical Cure (Day 14) by PI Assessment <sup>b</sup> | 25/32 (78%)   | 24/28 (86%)   | 20/28 (71%)  |
| All Cause Mortality (Day 30) <sup>c</sup>            | 5/33 (15%)  | 1/31 (3%)   | 3/28 (11%)   |

<sup>a</sup>Excludes indeterminate responses (inability to assess outcome due to missing data point(s)).

<sup>b</sup>Outcome that most closely approximates the primary outcome in prior candidemia/invasive candidiasis clinical trials.

<sup>c</sup>Primary outcome measure for FDA for planned Phase 3 ReSTORE trial to assess rezafungin in treatment of candidemia and/or invasive candidiasis.

Rezafungin was generally well-tolerated at both dosing regimens. Treatment Emergent Adverse Events, or TEAEs, were observed in most patients, with an incidence of 88.6 percent in Group 1, 94.4 percent in Group 2, and 81.8 percent in Group 3.

The rates of severe adverse events were 37.1 percent, 27.8 percent, and 39.4 percent, respectively. There were six adverse events leading to study drug discontinuation across all study groups: four in Group 1, one in Group 2 and one in Group 3. Two of the six adverse events were considered possibly related to study drug, one in Group 1 and one in Group 3.

There were two serious adverse events possibly related to study drug: one in Group 2 and one in Group 3, and both patients fully recovered. There were no deaths related to study drug, and there were no concerning trends in System Organ Class groups or specific adverse events.

*Phase 1 SAD / MAD Trials*

In November 2015, we obtained data from our single ascending dose, or SAD, study of rezafungin. 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 rezafungin in healthy subjects. Results demonstrated that rezafungin was well tolerated in all dose cohorts after single doses of 50 mg, 100 mg, 200 mg, and 400 mg. Rezafungin 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, or 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 rezafungin in healthy subjects. Results demonstrated that rezafungin was well tolerated in all dose cohorts after multiple doses of 100 mg, 200 mg, and 400 mg. Rezafungin exhibited a pharmacokinetic profile consistent with preclinical data and supportive of once-weekly dosing.

For both Phase 1 SAD and MAD trials, there were no serious adverse events, or SAEs, severe 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.

The clinical results of these Phase 1 trials demonstrated that a single dose of rezafungin is sufficient drug exposure for a period of seven days. In contrast, a single dose of anidulafungin provides sufficient drug exposure for only one day. Rezafungin has the potential to be safely developed as a once-weekly intravenous drug for the effective and convenient treatment and prevention of serious, invasive fungal infections in the inpatient or outpatient settings.

In addition, rezafungin demonstrated a C<sub>max</sub> and an AUC significantly higher than other approved echinocandins. Based on the higher drug exposure demonstrated by rezafungin early in the course of therapy and high, sustained tissue concentration at the site of infection, we believe that rezafungin 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.

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### *Phase 1 DDI Study*

In May 2018, we obtained data from our Phase 1 Drug-Drug Interaction study, or DDI study, to evaluate the potential effects of rezafungin on other drugs. We evaluated the pharmacokinetics, or PK, of several drug combinations with and without rezafungin. The results suggested no clinically significant drug-drug interactions with any of the drugs tested including: tacrolimus, repaglinide, metformin, rosuvastatin, pitavastatin, caffeine, efavirenz, midazolam and digoxin. Together with *in vitro* experiments, we do not expect drug-drug interactions for rezafungin via common drug metabolism or transport pathways.

### *Phase 1 QT Trial*

In March 2018 we announced the results of our definitive Phase 1 QT clinical trial of rezafungin. The QT clinical trial was a Phase 1, single-center, randomized, comparative study of the effect of single-ascending doses of rezafungin, intravenous placebo, and a single oral dose of moxifloxacin (positive control) in healthy adult subjects. The primary objective was to assess the effects of rezafungin on QT interval. Secondary objectives included assessments of other cardiac conduction parameters, including PR intervals, QRS intervals and heart rate. The results of the trial indicated that rezafungin in single intravenous doses up to 1400 mg had no significant effect on QT prolongation or on any of the other cardiac conduction parameters tested.

### **Clinical Development Plan**

Based on the STRIVE Part A trial results, we have initiated our ReSTORE Phase 3 clinical trial of rezafungin, and continue to discuss with regulatory authorities our plans for the design and initiation of our second Phase 3 trial, the ReSPECT Phase 3 clinical trial.

- Phase 3 ReSTORE Treatment Trial: A single, global, randomized, double-blind, controlled Phase 3 pivotal clinical trial in patients with candidemia and/or invasive candidiasis. The design is similar to the STRIVE trial, except that the only rezafungin dosing regimen that will be studied is 400 mg for the first week followed by 200 mg once weekly for up to four weeks in total, in comparison to caspofungin in a 1:1 randomization regime. The primary efficacy outcome for the FDA is all-cause mortality at day 30, and the primary efficacy outcome for the EMA is global response (clinical, radiological, and mycological response) at day 14. We expect this trial to enroll approximately 184 mITT patients. This trial began in the third quarter of 2018 and we expect to produce topline results in mid-2020.

With the expected size of the ReSTORE trial, we estimate that the total number of patients exposed to our selected dose and duration of rezafungin treatment will be less than the target safety database of 300 patients. For this reason, as well as to maintain enrollment momentum before the start of the Phase 3 trial, we are continuing enrollment at several STRIVE trial sites. This continuation of the STRIVE trial, which we call STRIVE Part B, will evaluate the 400mg/400mg and 400mg/200mg doses selected from the initial portion of the STRIVE trial in comparison to caspofungin in a 1:1 randomization regime. We expect to announce topline results of Part B in mid-2019.

- Phase 3 ReSPECT Prophylaxis (Prevention) Trial: A single, global, randomized, double-blind, controlled Phase 3 pivotal clinical trial in patients undergoing allogeneic blood and marrow transplant to assess rezafungin in a 90-day prophylaxis regimen to prevent infections due to *Candida*, *Aspergillus* and *Pneumocystis*. Subject to approval of the Phase 3 trial by the U.S. and E.U. regulatory authorities, rezafungin will be dosed once weekly and compared to a regimen containing two drugs (an azole and Bactrim) dosed once daily for 90 days. The primary efficacy outcome for the FDA is expected to be fungal-free survival at day 90. The primary efficacy outcome for the EMA is expected to be prophylaxis success at day 90. We expect this trial to enroll approximately 462 patients. We plan to conduct an interim futility analysis after primary endpoint data is available for approximately 50% of the trial's subjects, which we expect to be in mid-2020. Based on these considerations and assuming the successful outcome of ongoing discussions with regulatory authorities, we anticipate commencing the trial in the first half of 2019 and to announce topline results in the first quarter of 2021.

We also plan to conduct a trial with the NIH to evaluate safety, tolerability, and pharmacokinetics for a subcutaneous formulation of rezafungin. We expect to commence this trial in the first half of 2019.

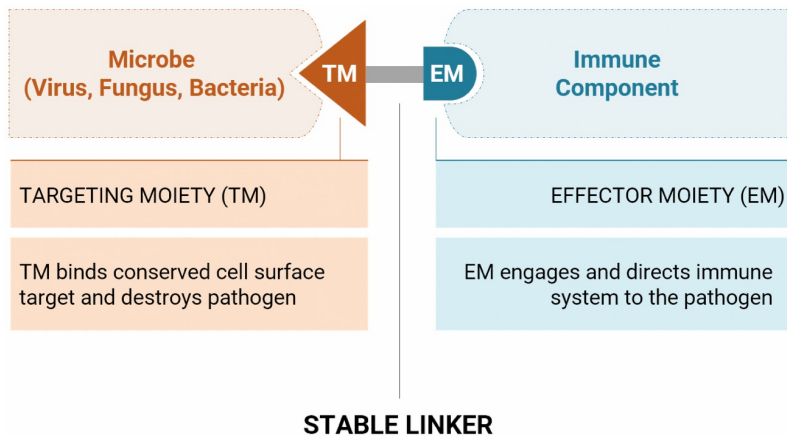
### **Cloudbreak Platform**

We believe that our Cloudbreak platform is a fundamentally new approach for the treatment of infectious disease that, in a single molecule, pairs potent antimicrobials with agents that direct the immune system to destroy microbial pathogens. The design of the Cloudbreak platform recognizes that infectious disease is often due to a temporary deficiency in the function of the immune system to address potentially life-threatening infections. Our Cloudbreak molecules are designed to address this deficiency by directly acting against the pathogen while recruiting components of the patient's immune

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system to the site of infection, enabling more effective treatment. Similar to the way that immunotherapy has the potential to transform the treatment of cancer by redirecting the immune system to destroy cancer cells, we believe that our Cloudbreak 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 incorporate both small and large molecule approaches. In either case, the Cloudbreak candidates would attack pathogens via two routes consisting of a targeting moiety, or TM, that binds a conserved cell surface target and an effector moiety, or EM, that engages and directs the immune system. The coupling of the TM to the EM results in a bispecific molecule with intrinsic antimicrobial activity that can also 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 antimicrobial activity that bind conserved targets on the surface of the pathogen;
- 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 and prevention of infectious diseases.

We have generated preclinical *in vitro* and *in vivo* proof of concept data in both our Cloudbreak antiviral and antibacterial programs. Below we discuss the results of our Cloudbreak antiviral program for influenza.

### Cloudbreak Antiviral Program

Influenza, or flu, is a respiratory infection caused by influenza viruses. The flu virus can cause mild to severe illness, and at times can lead to death. Young children, adults older than 65 years, pregnant women and immunocompromised patients are more prone to infection, but even healthy people are at risk of infection with seasonal flu. In 2017, the CDC estimated that between 291,000 and 646,000 people worldwide die from influenza each year.

In the U.S., the CDC estimated that during the 2017-18 flu season almost 50 million people became ill from the flu, resulting in approximately one million hospitalizations and \$10.4 billion per year in direct medical expenses and an additional \$16.3 billion per year in lost earnings. The CDC also estimated that almost 80,000 people died during the 2017-18 flu season, which makes it one of the most severe in recent history.

The primary preventive measure to protect against flu is the seasonal vaccine. However, in recent years the efficacy of the vaccine has varied, with recent studies estimating that the flu vaccine reduces the risk of flu illness by between 38% and 62%, depending on the virus strain and age and health of the recipient, among other factors. In years when the seasonal vaccine results in sub-optimal protection, more patients are at higher risk for serious complications resulting from the flu. Vulnerable patient populations must then rely upon therapeutic options.

Older antiviral medications, such as amantadine and rimantadine, are no longer recommended for use because of high levels of resistance. Currently, four antiviral drugs are recommended by the CDC for treating the flu:

- oseltamivir phosphate (Tamiflu®)

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- zanamivir (Relenza®)
- peramivir (Rapivab®)
- baloxavir marboxil (Xofluza™)

The above list includes neuraminidase inhibitors and the recently approved cap-dependent endonuclease inhibitor, baloxavir. These molecules have one or more of the following limitations: short half-life; high susceptibility to resistance; multi-dose regimens; and dosing route limitations. The current therapies should be administered within 48 hours of symptom onset to be effective.

### *Pre-Clinical Studies of CB-012 for Flu*

We plan to develop novel ADCs that provide a direct and sustained antiviral effect and engage the immune system for additional potency. We have run multiple studies to test the efficacy of CB-012, one of several potential Cloudbreak flu antivirals we are evaluating, and initial results indicate it may have efficacy in both the treatment and prophylaxis settings.

### *In Vitro Studies Measuring CB-012 Potency Against Multiple Flu Strains*

We evaluated CB-012 *in vitro* for its ability to inhibit viral replication in a human epithelial cell line versus a range of seasonal and pandemic Influenza A strains, including H1N1, H3N2 and H5N1, as well as Influenza B. CB-012 showed potent activity against all of the strains tested, including influenza B, which is less sensitive to oseltamivir phosphate.

### *In Vivo Studies Measuring CB-012 Potency Against Multiple Flu Strains in Lethal Infection Models*

We evaluated CB-012 *in vivo* in lethal mouse models of H1N1 and H3N2 compared to oseltamivir phosphate. CB-012 provided 100% protection against both H1N1 and H3N2 using single, low doses, while oseltamivir phosphate required twice daily dosing for 5 days to protect 100% and 80% of mice from death in the H1N1 and H3N2 models, respectively. CB-012 was able to provide the same protection as oseltamivir phosphate in these models at approximately 1/500th to 1/1000th the cumulative dose.

In both studies, we also measured the average body weights of the mice over time to support the survival data with CB-012. The CB-012 dosed mice maintained stable body weights over the 14 day course of the experiment demonstrating the potency of CB-012 at low doses and the potency and tolerability of CB-012 at high doses. The mice dosed with oseltamivir phosphate showed approximately 10% loss of body weight upon discontinuation of treatment after the five-day treatment cycle, suggesting that the influenza virus was not eradicated upon cessation of treatment. Body weights for the mice dosed with oseltamivir phosphate recovered as their immune system overcame the disease.

Additional pre-clinical toxicity studies in rats indicate the potential for a broad safety margin for CB-012 with no signs of acute or chronic toxicity at over 100-fold the efficacious dose in prophylactic efficacy models.

### *In Vivo Study Evaluating CB-012 as a Long-Acting Prophylactic Agent Against Flu*

We tested mean plasma concentrations of CB-012 in mice and based on the long half life we observed, we evaluated CB-012 *in vivo* in a lethal mouse model of H1N1 by administering CB-012 to the mice 28 days before we administered the flu challenge. CB-012 provided 100% protection from mortality across a broad range of dose levels, demonstrating its potential suitability as a long-acting prophylactic agent.

### *In Vivo Study Measuring CB-012 Treatment Window Against Flu*

We evaluated CB-012 and oseltamivir phosphate *in vivo* in a lethal mouse model of H1N1 by challenging the mice with flu and then administering antiviral treatment at different time periods after challenge. CB-012 and oseltamivir phosphate both provided 100% protection against flu when dosed up to 24 hours post-infection. However, when anti-viral treatment was administered at 48- and 72-hours post-infection, a single dose of CB-012 was more effective at reducing mortality than multiple doses of oseltamivir phosphate, even though the single dose of CB-012 was substantially lower than the cumulative dose of oseltamivir phosphate.

### *Potential Advantages of Cloudbreak Antibody-Drug Conjugates*

Based on our pre-clinical studies and the inherent mode of action, the ADCs we are evaluating may offer several potential advantages over vaccines, small molecule antiviral treatments, and monoclonal antibodies.

**Long-acting:** A single dose may provide months of protection from flu, with antibody-like half-life.

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**Broad Coverage:** While estimates of the efficacy of the flu vaccine have ranged from 10% to 60% for the past 14 flu seasons, the ADCs may provide broad coverage against seasonal and pandemic Influenza A and seasonal Influenza B viruses, including oseltamivir phosphate-resistant viruses.

**Potent TM Activity:** ADCs may protect immune-compromised patients who cannot mount a sufficient immune response to a vaccine.

**Superior Resistance Profile:** ADCs are expected to be less prone to resistance because they target highly conserved regions of the virus and have bi-functional modality. For example, H3N2 is poorly covered by the seasonal flu vaccine due to the fact that it rapidly mutates. According to the CDC, vaccine efficacy rates are less than 30% against H3N2.

**Manufacturing:** ADCs may be more reliable to manufacture than the current vaccine manufacturing processes.

### *Cloudbreak Antibacterial Program*

In May 2018, we and Rutgers University were awarded a five year, \$5.5 million partnership grant from the U.S. National Institute of Allergy and Infectious Diseases, or the NIAID. The grant will fund continued research and development of our Cloudbreak antibacterial program to identify novel immunotherapy agents for the treatment and prevention of serious and life-threatening multi-drug resistant Gram-negative bacterial infections in high-risk populations. We began work under this grant in July 2018 but have not recognized any potential reimbursements for the year ended December 31, 2018 as the subaward agreement between us and Rutgers University has not yet been executed.

### **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 rezafungin, any 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 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 as necessary to ensure sufficient commercial quantities of each product.

### **Intellectual Property**

The proprietary nature of, and protection for, rezafungin, our ADCs, our Cloudbreak 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 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 rezafungin, any other product candidates and technology in the United States and abroad. As of February 28, 2019, our patent portfolio included 13 families of patents and patent applications related to various aspects of rezafungin, and nine families of patent applications related to our Cloudbreak platform.

For our issued patents related to rezafungin, we expect the last to expire in 2033, excluding any additional term for patent term adjustments or applicable patent term extensions.

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With respect to our Cloudbreak platform, any patents that result from our currently pending applications would be expected to expire between 2037 and 2039, 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 product candidates where appropriate.

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

In addition to the orphan drug designation, rezafungin 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, and we have a registered trademark for the Cloudbreak mark in the United States for our pharmaceutical preparations for the treatment or prevention of infectious diseases.

### 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 rezafungin and any Cloudbreak development candidates we 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.

Rezafungin will primarily compete with antifungal classes for the treatment of 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 will be generic versions of one or more of the current echinocandins available at the time of rezafungin regulatory 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 rezafungin will compete with product candidates that we are aware of in clinical development by third parties, such as SCY-078, which is being developed by Scynexis, Inc.

We expect that any antiviral drug candidates developed through our Cloudbreak antiviral program for influenza will compete against approved and investigational agents for the treatment of viral influenza infections, including neuraminidase inhibitors such as Tamiflu, Relenza, and Peramivir, and endonuclease inhibitors such as Xofluza. We intend to develop other product candidates through our Cloudbreak platform for the treatment of invasive 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 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 payors.

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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 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 payors 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 application, 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.

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### *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](http://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 fee, and the sponsor of an approved NDA is also subject to annual program fees, which 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.

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.



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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 of 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.

### *Breakthrough Therapy Designation*

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.

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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 and 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 Generating Antibiotic Incentives Now Act, or 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. If designated as a QIDP and approved, the drug 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, or a Written Request, relating to the use of the active moiety of the drug in children. The FDA may issue a Written Request for studies on unapproved or approved indications, but it may not issue a Written Request 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.

### **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 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

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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. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. 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 hand. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, but 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 federal 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 civil and 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

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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 their 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, which include certain healthcare providers, health plans and healthcare clearinghouses, 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, 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, marketing expenditures, or drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives.

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, civil and administrative penalties, damages, fines, disgorgement, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, 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,

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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, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the Affordable Care Act, and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been enacted. The Tax Cuts and Jobs Act of 2017, or Tax Act, includes a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the Affordable Care Act, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, and also increased, effective January 1, 2019, the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent to 70 percent. In July 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace Affordable Care Act will impact Affordable Care Act.

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, including the BBA, will remain in effect through 2027 unless additional congressional action is taken. Additionally, in January 2013, the President 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.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. At the federal level there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal healthcare program anti-kickback statute discount safe harbor for the purpose of reducing the cost of drug

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products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

### **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 15, 2019, we had 68 total employees, all of whom were full-time employees, and 21 of whom hold Ph.D. or M.D. degrees, 50 of whom were engaged in research and development activities and 18 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, 2021 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.

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 \$1.07 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, or (2) the date on which we have

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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.

We formed wholly-owned subsidiaries, Cidara Therapeutics UK Limited, in England, and Cidara Therapeutics (Ireland) Limited, in Ireland, in March 2016 and October 2018, respectively, 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.

### **Available Information**

We make available free of charge on or through our internet website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. We also regularly post copies of our press releases as well as copies of presentations and other updates about our business on our website. Our website address is [www.cidara.com](http://www.cidara.com). The information contained in or that can be accessed through our website is not part of this Annual Report on Form 10-K. Information is also available through the Securities and Exchange Commission’s website at [www.sec.gov](http://www.sec.gov).

### **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 depend heavily on the success of rezafungin, currently in Phase 3 clinical development, and we also are very early in our development efforts from our Cloudbreak programs, neither of which may be successful.***

We have completed four Phase 1 clinical trials of rezafungin, as well as Part A of the STRIVE Phase 2 clinical trial of rezafungin for the treatment of candidemia and invasive candidiasis. We are currently conducting an additional Phase 1 clinical trial of rezafungin, Part B of the STRIVE Phase 2 clinical trial of rezafungin and the ReSTORE Phase 3 clinical trial of rezafungin for treatment of candidemia and invasive candidiasis. Assuming the successful outcome of ongoing discussions with regulatory authorities, we anticipate commencing the ReSPECT Phase 3 clinical trial of rezafungin for prophylaxis in the first half of 2019. We are also conducting preclinical studies of ADCs in our Cloudbreak programs for viral infections and infections caused by multidrug-resistant Gram-negative pathogens. Our assumptions about why rezafungin is worthy of future development, as well as our assumptions about the market for rezafungin or any potential products from our Cloudbreak programs, are based on data primarily collected by other companies. The timing and costs of our preclinical and clinical development programs, and the regulatory paths for marketing approvals for our products 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 product candidates. The success of rezafungin 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;
- agreement with regulatory authorities on study design and other requirements for study initiation;
- 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;

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- 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 payors;
- 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 for rezafungin or any other product candidates are delayed, terminated or suspended, or fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, 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 delay in starting or completing our clinical trials would materially impact our timelines and our ability to complete development of our product candidates in a timely manner or at all. For example, our ability to commence our ReSPECT Phase 3 clinical trial for prophylaxis in the first half of 2019 or at all is dependent on the successful outcome of our ongoing discussions with regulatory authorities.

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, although Part A of the STRIVE Phase 2 clinical trial met its primary objectives related to tolerability and safety of rezafungin in the treatment of candidemia and invasive candidiasis, this does not guarantee success in the ongoing Part B of the STRIVE Phase 2 clinical trial, in our ReSTORE Phase 3 clinical trial for treatment or our planned ReSPECT Phase 3 clinical trial for prophylaxis.

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 do not know whether our planned clinical trials, such as our ReSPECT Phase 3 clinical trial for prophylaxis, will begin on time or whether our ongoing or planned clinical trials will be completed on schedule, or at all. We may experience numerous unforeseen events in preparation for, during, or as a result of our clinical trials that could delay or prevent our ability to commence or complete our clinical trials, which could then delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial on our expected timeline or at all or conduct a clinical trial at a prospective trial site or in a given country;
- regulators may disagree with our interpretation of preclinical data, which may impact our ability to commence our trials on our expected timeline or at all;
- regulators may require that trials or studies be conducted, or sized or otherwise designed in ways, that were unforeseen in order to begin planned studies or 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;



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- 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, institutional review boards or the Data Safety Monitoring Board assembled by us to oversee our rezafungin clinical trials 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;
- 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; and
- we may be required to delay or terminate studies due to financial constraints.

We plan to conduct an interim futility analysis for our ReSPECT Phase 3 clinical trial for prophylaxis after primary endpoint data is available for approximately 50% of the total subjects we intend to enroll. The futility analysis will be conducted based on conditional power. If the conditional power is below a pre-specified cutoff for both primary endpoints, the study may be stopped for futility.

We are also in discussions with regulatory authorities about the final trial design of and other matters related to our ReSPECT Phase 3 clinical trial for prophylaxis. These discussions and potential design changes could lead to delays in the commencement and completion of the ReSPECT trial, or may result in the trial not proceeding at all.

If we are required to conduct additional clinical trials or other tests of our product candidates beyond those that we currently contemplate, if we are unable to complete clinical trials of our product candidates or other tests 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 payors; 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.

***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 or if we do not believe that the number of patients required by such regulatory authorities in any clinical trial can be enrolled in a reasonable timeframe. 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;

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- 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;
- the 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, or to enroll such patients in a timely manner, 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 could 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.***

Because 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, the risk of each of our programs is high. 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 rezafungin from other echinocandins could have side effects that we have not anticipated and the consequences of such side effects could be more severe than have been seen with other echinocandins that have shorter half-lives or more frequent dosing regimens, or are dosed at lower concentrations than we expect for rezafungin.

Further, the treatment advantages that we are predicting for rezafungin, such as lower healthcare costs resulting from an ability to administer rezafungin once-weekly or the predicted ability of rezafungin to be effective against resistant strains of fungal pathogens, may not be realized. For our ADCs, 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 agents. 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. For example, because we believe that an NDA filing for rezafungin for prophylaxis can be supported by one Phase 3 trial in prophylaxis, together with the data from our Phase 3 clinical trial in the treatment of candidemia and invasive candidiasis and the remainder of our rezafungin treatment program, if financial constraints require us to choose between our planned rezafungin treatment and prophylaxis programs, we may be required to choose our treatment program and forego or delay our prophylaxis program.

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 markets for a particular product candidate or opportunity, we may relinquish valuable rights to that product candidate or opportunity 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 or opportunity.

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***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 payors 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 therapies;
- the size of the markets in the countries in which approvals are obtained;
- terms, limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- 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 rezafungin, 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 payor 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. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to 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 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

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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.

We expect that rezafungin will primarily compete with certain antifungal classes of drugs, which include polyenes, azoles and echinocandins. Approved branded echinocandin antifungal therapies include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.), Mycamine (micafungin, marketed by Astellas Pharma US, Inc.). We expect that there will be generics of all of the current echinocandins available at the time of rezafungin 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 rezafungin 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.).

We expect that any influenza product candidates developed through our Cloudbreak antiviral program will compete against approved and investigational agents for the treatment of viral influenza infections, including neuraminidase inhibitors such as Tamiflu, Relenza and Peramivir, and endonuclease inhibitors such as Xofluza. We may develop other product candidates through our Cloudbreak platform for the treatment of other invasive 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 rezafungin program or our Cloudbreak 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.

***Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publicly disclose interim, preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analysis of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. For example, we expect to receive topline data from Part B of our STRIVE Phase 2 clinical trial in mid-2019. The topline data may be reported as positive, however, if the final data materially differs in an adverse manner from the topline data, we may have unnecessarily expended or continued to commit substantial resources to the Phase 3 clinical trials, which costs we may not be able to recover. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. For example, we plan to conduct an interim futility analysis after primary endpoint data is available for approximately 50% of the subjects that we

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intend to enroll in the ReSPECT Phase 3 clinical trial. There can be no guarantee that a favorable utility analysis will result in a favorable final result at the completion of the clinical trial.

Further, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

***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, coverage 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 payors 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 payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payors 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 for commercial success. 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 payors 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 payors 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 payors 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.

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### ***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, and develop potential product candidates through our Cloudbreak platform or otherwise.***

Through our Cloudbreak platform, we are developing ADCs for the treatment of viral infections and multidrug-resistant bacterial infections. We currently do not have any development candidates from the Cloudbreak platform. Our Cloudbreak platform may not be successful in identifying additional molecules that could be developed as drug therapies. In addition, our Cloudbreak platform may initially show promise in identifying 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, bioavailability or efficacy 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 expertise and human resources. For example, we have recently announced preclinical results from our Cloudbreak antiviral program. We have limited

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experience with the use of the Cloudbreak platform applied to viral pathogens. A failure to optimize our expertise using the Cloudbreak platform for the development of our Cloudbreak antiviral program may limit our ability to identify a product candidate and successfully advance this program. Research programs to identify new product candidates also require substantial financial resources. We may choose to expend our financial resources on potential product candidates that ultimately prove to be unsuccessful. If we are unable to develop successful product candidates from our Cloudbreak platform 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.

### **Risks Related to Our Financial Position and Need for Additional Capital**

***We need substantial additional funding to advance the development of rezafungin, as well as other product and development candidates. If we are unable to raise capital, we will be forced to delay, reduce or eliminate our drug development and discovery programs.***

In connection with the preparation of our financial statements for the fiscal year ending December 31, 2018, we performed an analysis of our ability to continue as a going concern. We believe, based on our current business plan, that our existing cash and cash equivalents will be sufficient to fund our obligations through the third quarter of 2019, but will not be sufficient to fund our obligations after the third quarter of 2019. Our ability to execute our operating plan, including continuing the development of rezafungin, beyond the third quarter of 2019 depends on our ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements.

There can be no assurance that additional funds will be available from any source or, if available, will be available on terms that are acceptable to us. For example, investors that participated in our May 2018 registered direct offering may invest \$50 million on a pro rata basis in a second closing triggered by our receipt of topline data from Part B of the STRIVE Phase 2 clinical trial, and, should we choose to proceed with the optional 3<sup>rd</sup> closing, those investors may also invest an additional \$20 million on a pro rata basis, in each case subject to certain conditions; however, investors from the first closing may refuse to participate in the second closing or may decline the option to participate in the optional third closing.

There can also be no assurance that additional funds will be available to us without first obtaining the approval of our stockholders, which can be a difficult and lengthy process with an uncertain outcome. For example, the purchase price at the initial closing of the May 2018 registered direct offering was based on a price of \$4.70 per share of common stock and, due to the rules of The Nasdaq Stock Market regarding stockholder approval requirements, we may not complete the 2<sup>nd</sup> or optional 3<sup>rd</sup> closings at a price below \$4.70 per share of common stock without first obtaining the approval of our stockholders. The subscription agreement for the May 2018 registered direct offering specifies that the purchase price in the second and optional third closings is 75% of the volume weighted average price of our common stock for the five trading days following our announcement of topline data from Part B of the STRIVE clinical trial. Accordingly, if our common stock is trading below \$6.27 at that time, the resulting purchase price for the 2<sup>nd</sup> and 3<sup>rd</sup> closings will be less than \$4.70 per share of our common stock and we will be unable to complete the 2<sup>nd</sup> or 3<sup>rd</sup> closings without first obtaining the approval of our stockholders. As of the date we issued our financial statements for the fiscal year ending December 31, 2018, the price of our common stock was below \$6.27. The stockholder approval process could be lengthy and expensive, and there is no assurance that the stockholders would provide their approval.

Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans which could have a negative effect on our business, operating results and financial condition and our ability to achieve our intended business objectives.

In addition, our expenses may increase in connection with our ongoing activities beyond what is currently expected. Our future capital requirements will depend on many factors, including:

- the costs and timing to complete our Phase 3 ReSTORE and Phase 3 ReSPECT clinical trials;
- the costs, timing and outcome of any regulatory review of rezafungin or future development candidates;
- our ability to establish and maintain collaborations, when and if necessary, on favorable terms, if at all;
- the costs and timing of commercialization activities, including manufacturing, marketing, sales and distribution, for rezafungin or any future 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;
- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates, for the Cloudbreak platform; and
- the extent to which we acquire or in-license other product candidates and technologies.

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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 need substantial additional funding in connection with our continuing operations and to achieve our goals. Since December 6, 2012 (inception) through December 31, 2018, our operations have been financed primarily by gross proceeds of approximately \$269.4 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, our October 2016 follow-on public offering of common stock, our October 2017 private placement of common stock, sales of common stock during the fourth quarter of 2017 and the first quarter of 2018 under our controlled equity sales agreement with Cantor Fitzgerald & Co., which has since been terminated, and our May 2018 registered direct offering of common stock. As of December 31, 2018, we had cash and cash equivalents of \$74.6 million.

If we are unable to raise capital or on attractive terms, we will be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts, make reductions in spending, extend payment terms with suppliers, liquidate or grant rights to assets where possible, or suspend, curtail or terminate planned programs. Any of these actions could materially harm our business, results of operations and future prospects.

### ***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 and/or charitable grants or contracts. In November 2018, we entered into a new controlled equity offering sales agreement with Cantor Fitzgerald & Co. with an aggregate offering price of up to \$35 million. Other than our November 2018 controlled equity offering sales agreement with Cantor Fitzgerald & Co., the term loan facility with Pacific Western and the potential to complete the second and optional third closings of our May 2018 registered direct offering after we announce data from Part B of the STRIVE Phase 2 clinical trial, 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. For instance, your ownership interest will be diluted in the event we complete the 2<sup>nd</sup> and optional 3<sup>rd</sup> closings of the 2018 May registered direct offering. In the event that we proceed with the optional 3<sup>rd</sup> closing of our May 2018 registered direct offering, your ownership interest may be further diluted as certain investors participating in the optional 3<sup>rd</sup> closing will also have the right to purchase an aggregate of up to 2,500,000 shares of our common stock at a purchase price of \$0.125 per share subject to each such warrant at an exercise price of \$6.81 per share. 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 or charitable organizations to support our programs. The process of obtaining 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 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 or by receiving charitable grants, 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 or charitable 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.



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***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, as amended in June 2018 and July 2018, under which we borrowed \$10.0 million, subject to certain terms and conditions set forth therein.

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 Part B of the STRIVE clinical trial of rezafungin on or before July 31, 2019.

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.

In connection with the audit of our 2018 financial statements, we received an unqualified auditor opinion with a going concern explanatory paragraph. Pacific Western provided written confirmation that it has not and will not deem the inclusion of the going concern explanatory paragraph to constitute an event of default under the Loan Agreement as a material adverse effect; however, Pacific Western also specified that it has not made and is not making any determination with respect to the underlying circumstances that prompted the inclusion of such a paragraph in the opinion. In the future, Pacific Western may determine that the underlying circumstances resulting in the receipt of a going concern explanatory note in the auditor opinion for our 2018 financial statements either on their own, or together with contemporaneous events or circumstances, such as a failure to timely secure additional funding, constitute 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.

Additionally, Pacific Western may determine that 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 FDA or another governmental entity may also constitute 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, either on its own or together with contemporaneous events or circumstances, such as our status regarding going concern or a failure to timely secure additional funding.

The Loan Agreement also requires us to timely deliver certain financial statements, reports, and certificates including a requirement to provide audited annual financial statements together with an unqualified audit opinion or a qualified opinion only for going concern so long as our investors provide additional equity as needed or if Pacific Western otherwise provides its consent in writing. In connection with the audit of our 2018 financial statements, we received an unqualified auditor opinion with a going concern explanatory paragraph. Pacific Western provided us with a written acknowledgement that inclusion of the going concern explanatory paragraph in the auditor opinion for our 2018 financial statements satisfies our requirements regarding delivery of an auditor opinion under the Loan Agreement; however, should we in the future receive either a qualified or unqualified opinion with a going concern explanatory paragraph without satisfaction of the additional equity criteria or the consent of Pacific Western required by the Loan Agreement, this may also constitute a default under the facility.

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

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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.

***We have incurred significant operating losses since our inception, and we 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 \$59.0 million and \$55.7 million for our 2018 and 2017 fiscal years, respectively. As of December 31, 2018, we had an accumulated deficit of \$218.7 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, our October 2016 follow-on public offering of common stock, our October 2017 private placement of common stock, sales of common stock during the fourth quarter of 2017 and the first quarter of 2018 under our controlled equity sales agreement with Cantor Fitzgerald & Co., which has since been terminated, and our May 2018 registered direct offering of common stock. We have devoted substantially all of our financial resources and efforts to research and development. We have completed Part A of our STRIVE Phase 2 clinical trial of rezafungin and we are conducting Part B of the STRIVE Phase 2 clinical trial, the ReSTORE Phase 3 clinical trial of rezafungin, Phase 1 and non-clinical studies of rezafungin and preclinical studies of our ADCs, and we are planning to conduct the ReSPECT Phase 3 clinical trial of rezafungin for prophylaxis. 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;
- continue to advance rezafungin through clinical development;
- continue the preclinical development of our ADCs from our Cloudbreak platform or otherwise, and advance one or more of such product candidates into clinical trials;
- seek marketing approvals for rezafungin and other product candidates;
- 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 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.

***Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly

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resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The United Kingdom's referendum to leave the European Union or "Brexit," has and may continue to cause disruptions to capital and currency markets worldwide. The full impact of the Brexit decision, however, remains uncertain. A process of negotiation will determine the future terms of the United Kingdom's relationship with the European Union. During this period of negotiation, our results of operations and access to capital may be negatively affected by interest rate, exchange rate and other market and economic volatility, as well as regulatory and political uncertainty. Brexit may also have a detrimental effect on our customers, distributors and suppliers, which would, in turn, adversely affect our financial condition.

### ***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 late-stage 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.

### **Risks Related to Our Dependence on Third Parties**

#### ***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 in the territories that are the subject of the collaboration;
- 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.

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***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.

***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

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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 authorities 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](http://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 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 or the manufacturers, 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 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.

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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.

### **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. Rezafungin received the designations as a Qualified Infectious Disease Product, or QIDP, a fast track product, and an orphan drug in the U.S. for the treatment of candidemia and invasive candidiasis. Rezafungin also received QIPD and Fast Track designation in the U.S. for the prevention of invasive fungal infections in adults undergoing allogeneic bone marrow transplantation. We plan to seek designation as an orphan drug in the U.S. and Europe for the prophylaxis indication and we also plan to seek orphan drug designation for rezafungin for treatment in Europe. Our product candidates may not qualify for or maintain designations under these or other 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 opportunities that may not otherwise be available to us, 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, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities 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 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 or 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.

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***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 promotional materials and 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. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA 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 payors may 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, the curtailment or restructuring of our operations and diminished future profits and earnings.***

Healthcare professionals and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with customers, healthcare professionals and third-party payors 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 conduct research, 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;

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- 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 CMS information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state and foreign 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 payors, including private insurers, 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, marketing expenditures, or drug pricing, state and local laws that require the registration of pharmaceutical sales representatives, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.
- As of May 25, 2018, the EU General Data Protection Regulation 2016/679, or GDPR replaced the EU General Data Protection Regulation with respect to the processing of personal data in the European Union. The GDPR imposes many requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third-party processors in connection with the processing of the personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. The GDPR includes more stringent operational requirements for processors and controllers of personal data and creates additional rights for data subjects. Additionally, in June 2016, United Kingdom voters approved an exit from the EU, commonly referred to as "Brexit," which could also lead to further legislative and regulatory changes. In March 2017, the United Kingdom began the process to leave the EU by April 2019. While the Data Protection Act of 2018, that "implements" and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful under GDPR. We may incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the United Kingdom privacy laws in connection with any measures we take to comply with them.

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, reputational harm, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could diminish our future profits or earnings. 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.



***We are dependent on information technology systems, infrastructure and data, which exposes us to data security risks.***

We are dependent upon our own or third-party information technology systems, infrastructure and data, including mobile technologies, to operate our business. The multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, disruption of data integrity, malicious intrusion, or random attacks. Likewise, data privacy or security incidents or breaches by employees or others may pose a risk that sensitive data, including our intellectual property, trade secrets or personal information of our employees, patients, customers or other business partners may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. Cyber-attacks could include the deployment of harmful malware, denial-of-service, social engineering and other means to affect service reliability and threaten data confidentiality, integrity and availability. Our business partners face similar risks and any security breach of their systems could adversely affect our security posture. A security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to litigation or other liability under laws and regulations that protect personal data, any of which could disrupt our business and/or result in increased costs or loss of revenue. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have invested, and continue to invest, in the protection of our data and information technology infrastructure, there can be no assurance that our efforts will prevent service interruptions, or identify breaches in our systems, that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, which could result in financial, legal, business or reputational harm to us. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

***We are subject to extensive laws and regulations related to data privacy, and our failure to comply with these laws and regulations could harm our business.***

We are subject to laws and regulations governing data privacy and the protection of personal information. These laws and regulations govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and/or may in the future, be subject. For example, the collection and use of personal health data in the EU is governed by the GDPR. The GDPR, which is wide-ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the EU to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third-party transactions, but also to transfers of information within our company, including employee information. The GDPR and similar data privacy laws of other jurisdictions place significant responsibilities on us and create potential liability in relation to personal data that we or our third party service providers process, including in clinical trials conducted in the United States and EU. In addition, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the United States, the EU and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for

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the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

***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, including cost-containment measures, that could reduce or limit coverage and reimbursement for newly approved drugs, 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 imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may 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, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the Affordable Care Act and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been enacted. The Tax Act includes a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the Affordable Care Act, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans and also increased, effective January 1, 2019, the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent to 70 percent. In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

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.

Further, 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, including the BBA, will remain in effect through 2027 unless additional congressional action is taken. Additionally, in January 2013, the President signed into law the American Taxpayer Relief Act of 2012, which, among other things,

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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.

In addition, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation 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. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal healthcare program anti-kickback statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients with life-threatening diseases or conditions to access certain investigational new drug products that have completed a Phase 1 clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

We expect that additional healthcare reform measures will be adopted within and outside the United States in the future, any of which could add difficulty to the regulatory approval processes for our product candidates or 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 rezafungin, our Cloudbreak compounds or our other product candidates or compounds are not adequate, we may not be able to compete effectively in our markets.***

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to rezafungin and our other product candidates and compounds. 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 markets.

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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 rezafungin, our ADCs and other compounds and 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 rezafungin and our ADCs. 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 rezafungin or our ADCs or the patents we pursue related to any of our other product candidates or compounds is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize the product candidates or compounds. 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 having varied scope may be available in certain jurisdictions 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, 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, inventions 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,

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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 of treatment related to the use or manufacture of rezafungin, our ADCs and/or our other product candidates or compounds. If any third-party patents were held by a court of competent jurisdiction to cover the rezafungin or ADC manufacturing process, any molecules formed during these processes or the final products or any use thereof, the holders of any such patents may be able to block our ability to commercialize the product 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 the affected product 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 management and other 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 one or more of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, or 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

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claims would involve substantial litigation expense and would be a substantial diversion of management and other 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 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 or legal process 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 or 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 and legal processes of some foreign countries do not protect intellectual property to the same extent as federal and

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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, 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 U.S. Government Contracts and Grants**

***If we are unable to generate revenues from partnerships, government funding or other sources of funding, we may be forced to suspend or terminate one or more of our Cloudbreak programs.***

We have been awarded a partnership grant with Rutgers University from the NIAID for our Cloudbreak antibacterial program. This will cover only a portion of our Cloudbreak development expenses for the antibacterial program and will not cover any expenses for the Cloudbreak antiviral program. In order to continue our Cloudbreak programs, we will need to seek funding from partnerships, the government or other sources of funding. There can be no assurances that we will be able to obtain funding from partnerships, or enter into new contracts with the United States government or obtain other sources of funding to support any program resulting from our Cloudbreak platform. The process of completing a partnership or obtaining government contracts is lengthy and uncertain and we will have to compete with other companies and institutions in each instance. Further, with respect to government contracting, changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on supporting the discovery and development of anti-infective products. If we cannot obtain or maintain government or other funding for our Cloudbreak programs, we may be forced to discontinue those programs.

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***Our use of government funding adds uncertainty to our research and commercialization efforts and may impose requirements that increase our costs.***

Contracts funded by the U.S. government and its agencies include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including intellectual property rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor from doing future business with the government;
- control and potentially prohibit the export of products; and
- pursue criminal or civil remedies under the Federal Civil Monetary Penalties Act and the federal civil False Claims Act and similar remedy provisions specific to government agreements.

In addition, government contracts contain additional requirements that may increase our costs of doing business, reduce our profits and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, anti-human-trafficking, non-discrimination, and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with these requirements, we may be subject to potential liability and to termination of our contracts.

***Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018 and ending on January 25, 2019, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If repeated or prolonged government shutdowns occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.



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### ***Our business is subject to audit by the U.S. government and a negative audit could adversely affect our business.***

United States government agencies routinely audit and investigate government contractors and recipients of Federal grants. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. BU also has the right to audit our activities under our CARB-X Subaward Agreement.

Government agencies also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a specific contract will not be reimbursed, while such costs already reimbursed must be refunded.

If an audit uncovers improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the United States government.

In addition, we could suffer serious reputational harm if allegations of impropriety were made against us, which could cause our stock price to decrease.

### ***Laws and regulations affecting government contracts make it more expensive and difficult for us to successfully conduct our business.***

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under our government grant contracts. These laws and regulations affect how we conduct business with government agencies. Among the most significant government contracting regulations that affect our business are:

- the Federal Acquisition Regulations, or FAR, and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and include other requirements such as the Anti-Kickback Statute and Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Any changes in applicable laws and regulations could restrict our ability to maintain our existing CARB-X Subaward Agreement and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our results of operations.

## **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

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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 pre-clinical or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial or development program;
- 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 requirements for approvals;
- changes in the structure of healthcare payment systems;
- 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 or acceptable quality;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates successfully, or at all;

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- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- the 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 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, and the expectation of future fundraising activities by us;
- 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 or the expectation of such sales;
- the 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.

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***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 \$1.07 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 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 political environment and the 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 27,816,014 shares of common stock outstanding as of December 31, 2018. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

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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 may 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 warrants 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 believe, based on our current business plan, that our existing cash and cash equivalents will not be sufficient to fund our obligations past the third quarter of 2019. Significant additional capital will be needed to continue our operations as currently planned, beyond the third quarter of 2019, 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, new investors could gain rights, preferences and privileges senior to our existing stockholders and our existing stockholders may be materially diluted by such subsequent sales. For example, current stockholders may be diluted by the completion of the 2<sup>nd</sup> and optional 3<sup>rd</sup> closings of our May 2018 registered direct offering. Investors in the May 2018 registered direct offering may invest \$50 million on a pro rata basis in a second closing triggered by our receipt of topline data from Part B of the STRIVE Phase 2 clinical trial, and, should we choose to proceed with the optional 3<sup>rd</sup> closing, those investors also have the option to invest an additional \$20 million on a pro rata basis at such time, in each case subject to certain conditions. The price at which we would sell common stock in the second and optional third closings would be 75% of the volume weighted average price of our common stock for the five trading days following our announcement of topline data from Part B of the STRIVE Phase 2 clinical trial. Additionally, certain investors in the optional 3<sup>rd</sup> closing also have the right to purchase warrants to purchase an aggregate of up to 2,500,000 shares of our common stock at a purchase price of \$0.125 per share subject to each such warrant. The warrants will be exercisable immediately for cash, at an exercise price of \$6.81 per share and may also be dilutive to our current 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.

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***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.

***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.

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### ***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 capital raising 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, 2018, we had U.S. net operating loss carryforwards of approximately \$179.1 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 2021, 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.

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### 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."

##### Holders of Record

As of February 20, 2019, there were approximately 26 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.

#### Item 6. Selected Financial Data.

As a smaller reporting company, we are not required to provide information typically disclosed under this item.

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

*You should read the following discussion and analysis together with 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 pipeline of product and development candidates, with an initial focus on serious fungal infections. Our lead product candidate is rezafungin acetate, an intravenous formulation of a novel echinocandin. Rezafungin 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 our ADCs for viral infections, including influenza, and bacterial infections as part of our proprietary Cloudbreak® platform. The Cloudbreak platform is designed to discover compounds that directly kill pathogens and also direct a patient's immune system to attack and eliminate pathogens.

##### Rezafungin

Rezafungin is a novel molecule in the echinocandin class of antifungals. We are developing rezafungin for the treatment and prevention of serious, invasive fungal infections. These infections include candidemia and invasive candidiasis, which are fungal infections associated with high mortality rates.



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### *STRIVE clinical trial*

In March 2018, we reported topline results from Part A of our global, randomized Phase 2 clinical trial of rezafungin, called the STRIVE trial. In STRIVE Part A, patients were randomized to one of two rezafungin arms or to the caspofungin arm. In the two rezafungin arms of the trial, patients received either 400 mg of rezafungin administered intravenously once weekly for two to four weeks (Group 1) or 400 mg for the first week followed by 200 mg once weekly for one to three weeks, for a total of two to four weeks (Group 2). In the comparator arm (Group 3), patients received daily caspofungin administered intravenously according to the approved prescribing information, with an optional step down to oral fluconazole. STRIVE Part A met its primary objectives related to tolerability and safety of rezafungin in the treatment of candidemia/invasive candidiasis, and rezafungin was generally well-tolerated at both dosing regimens.

Data from this trial indicated that a 400mg / 200mg dosing regimen of rezafungin had a higher rate of Clinical Cure by PI Assessment at Day 14 (86%) and a lower All Cause Mortality at Day 30 (3%) when compared with once daily Caspofungin (71% and 11%, respectively).

### **Cloudbreak Platform**

We believe our Cloudbreak platform is a fundamentally new approach for the treatment of infectious disease, and may have broad potential applications across a wide spectrum of infectious diseases, including viral and bacterial infections. The lead program is focused on the treatment and prevention of the influenza virus. We have generated preclinical, *in vivo* proof of concept data in both our Cloudbreak antiviral and antibacterial programs.

## **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, other funded research and development agreements, 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 nonclinical, clinical, regulatory and commercialization milestones, 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 nonclinical development of our rezafungin acetate and CD201 product candidates and our Cloudbreak platform, as well as clinical development of rezafungin 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 nonclinical 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.

We have received potential research and development funding through a grant from CARB-X and a partnership grant from the NIAID. We have evaluated the terms of the grants to assess our obligations and the classification of funding received. Amounts received for funded research and development are recognized in the statement of operations as a reduction to research and development expense over the grant period as the related costs are incurred to meet our obligations.

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 nonclinical 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 nonclinical programs and clinical trials of our product candidates.

## CIDARA THERAPEUTICS, INC.

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 authorities;
- 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):

|  | <b>Year ended December 31,</b> |                  |                  |
|--|--------------------------------|------------------|------------------|
|  | <b>2018</b>                    | <b>2017</b>      | <b>2016</b>      |
| Rezafugin                                      | \$ 30,634                      | \$ 24,394        | \$ 11,230        |
| CD101 topical                                  | —                              | 1,385            | 7,604            |
| Cloudbreak platform                            | 3,147                          | 2,915            | 2,915            |
| Personnel costs                                | 12,378                         | 11,022           | 10,084           |
| Other research and development expenses        | 2,983                          | 3,107            | 3,866            |
| <b>Total research and development expenses</b> | <b>\$ 49,142</b>               | <b>\$ 42,823</b> | <b>\$ 35,699</b> |

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 rezafungin topical, which was designed to evaluate gel and ointment topical formulations of rezafungin in women with moderate-to-severe VVC. The study found that while the gel and ointment topical formulations of rezafungin 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 discontinued the rezafungin 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)**

Other income (expense) consists primarily of the change in the fair value of the contingent forward purchase obligation and related issuance costs, interest income and expense, and various income or expense items of a non-recurring nature.

## CIDARA THERAPEUTICS, INC.

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 and the amortization of debt issuance costs.

### **Contingent forward purchase obligation**

On May 21, 2018, we entered into a subscription agreement with certain investors providing for the purchase and sale of up to an aggregate of \$120.0 million of common stock and preferred stock in three closings. The second and optional third closings and warrants related to the optional third closing are triggered by our announcement of topline data from our STRIVE Part B Phase 2 clinical trial of rezafungin. We determined that these closings are classified as liabilities and represent contingent forward purchase obligations. These liabilities are recorded at their estimated fair value initially and on a recurring basis. The liability was initially recorded at \$4.3 million on May 21, 2018, and fair value adjustments resulting in a gain of \$3.9 million were recorded during the year ended December 31, 2018.

### **Beneficial conversion feature**

For the year ended December 31, 2018, we recognized the fair value of an embedded beneficial conversion feature of \$10.3 million on the Series X Convertible Preferred Stock issued in connection with the financing transaction that closed on May 23, 2018.

## **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 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:

### **Subaward Agreement and Partnership Grants**

In March 2017, we entered into a Subaward Agreement with CARB-X, under which CARB-X will reimburse us for qualifying development expenses for our Cloudbreak antibacterial program for CD201. We stopped work under the CARB-X Subaward Agreement in the first quarter of 2018.

In May 2018, we and Rutgers University were awarded a five year, \$5.5 million partnership grant from the NIAID, under which we will be reimbursed for qualifying expenses from our Cloudbreak antibacterial program.

We reflect the costs reimbursed under these agreements as a reduction of our research and development expenses. See Notes 2 and 9 to our financial statements for additional information.

### **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 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.

## CIDARA THERAPEUTICS, INC.

### Stock-based compensation

The Company accounts for stock-based compensation expense related to employee stock options, restricted stock and employee stock purchase plan rights by estimating the fair value on the date of grant.

We estimate 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, and 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.

### Restricted Stock Units

In 2017 and 2018, we granted Restricted Stock Units, or RSUs, and Performance-based RSUs, or PRSUs, to employees. We estimate the fair value of RSUs and PRSUs based on the closing price of the Company's common stock 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. For awards subject to performance-based vesting conditions, we assess the probability of achievement of the individual milestones under the stock-based awards and recognize stock-based compensation expense over the implicit service period commencing once we believe the performance criteria is probable of achievement.

### Stockholder's Equity

On May 21, 2018, we entered into a subscription agreement with certain investors providing for the purchase and sale, in a registered direct offering, of up to an aggregate of \$120.0 million of our common stock and preferred stock in three closings. On May 23, 2018, we completed the first closing, which was comprised of 6,185,987 shares of common stock at an offering price of \$4.70 per share, 445,231 shares of Series X Convertible Preferred Stock at an offering price of \$47.00 per share, and an option fee relating to the third closing paid by the investors for a total of \$0.5 million. In a private placement concurrent with the first closing, we also sold warrants to purchase an aggregate of 12,499,997 shares of common stock at \$0.125 per warrant share. Net proceeds for the first closing and the concurrent private placement were \$49.5 million. We determined that warrants and future closings represented derivative instruments requiring bifurcation under ASC 815. Accordingly, we determined a fair value for each component of the subscription agreement and allocated the expected proceeds across each component on a relative fair value basis. Key estimates within the valuation include the expected timing for completion and estimated probability of success of our STRIVE Part B clinical trial. See Note 7 of the Notes to the Financial Statements for additional information.

## RESULTS OF OPERATIONS

### Comparison of the years ended December 31, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017 (in thousands):

|                             | Year ended December 31, |           | Change |
|-----------------------------|-------------------------|-----------|--------|
|                             | 2018                    | 2017      |        |
| Research and development    | \$ 49,142               | \$ 42,823 | 6,319  |
| General and administrative  | 14,143                  | 12,898    | 1,245  |
| Other income (expense), net | 4,269                   | (7)       | 4,276  |

## CIDARA THERAPEUTICS, INC.

### *Research and development expenses*

Research and development expenses were \$49.1 million for the year ended December 31, 2018 compared to \$42.8 million for the year ended December 31, 2017. The increase in research and development expenses is due to higher clinical expenses associated with start up activities for the rezafungin ReSTORE and ReSPECT studies, as well as higher personnel costs. The increase was partially offset by a decrease in clinical expenses associated with the rezafungin STRIVE clinical trial and a decrease in CD101 topical expenses due to the discontinuation of that program in February 2017.

### *General and administrative expenses*

General and administrative expenses were \$14.1 million for the year ended December 31, 2018 compared to \$12.9 million for the year ended December 31, 2017. The increase in general and administrative expenses was primarily related to higher legal, accounting, and consulting expense.

### *Other income (expense)*

Other income for the year ended December 31, 2018 related primarily to the change in the fair value of the contingent forward purchase obligation and related issuance costs, as well as income generated from cash held in interest-bearing investments. Other income was partially offset by interest expense in connection with our loan from Pacific Western Bank. Other expense for the year ended December 31, 2017 included interest expense incurred in connection with our loan from Pacific Western Bank, offset by income generated from cash held in interest-bearing investments.

### **Comparison of the year ended December 31, 2017 and 2016**

The following table summarizes our results of operations for the years ended December 31, 2017 and 2016 (in thousands):

|                             | Year ended December 31, |           | Change |
|-----------------------------|-------------------------|-----------|--------|
|                             | 2017                    | 2016      |        |
| Research and development    | \$ 42,823               | \$ 35,699 | 7,124  |
| General and administrative  | 12,898                  | 12,737    | 161    |
| Other income (expense), net | (7)                     | 271       | (278)  |

### *Research and development expenses*

Research and development expenses were \$42.8 million for the year ended December 31, 2017 compared to \$35.7 million for the year ended December 31, 2016. The majority of the increase in research and development expense is due to higher clinical expenses associated with the rezafungin STRIVE trial. Increases in rezafungin expenses were partially offset by decreases in CD101 topical expenses due to the discontinuation of that program in February 2017.

### *General and administrative expenses*

General and administrative expenses were \$12.9 million for the year ended December 31, 2017 compared to \$12.7 million for the year ended December 31, 2016. The increase in general and administrative expenses was primarily related to personnel costs.

### *Other Income (Expense)*

Other income (expense) for the years ended December 31, 2017 and 2016 relates to income generated from cash held in interest-bearing investments, offset by the cash and non-cash interest associated with our loan from Pacific Western Bank.

### **LIQUIDITY AND CAPITAL RESOURCES**

Since our inception, we have received \$269.4 million in gross proceeds to fund our operations, primarily through private placements of convertible preferred stock, convertible notes, our initial public offering, our entry into a debt facility in October 2016 with Pacific Western Bank, our October 2016 public offering of common stock, our October 2017 private placement of common stock, sales of common stock under our controlled equity sales agreement, and our May 2018 registered direct offering.

**CIDARA THERAPEUTICS, INC.**

As of December 31, 2018, we had \$74.6 million in cash and cash equivalents. The following table shows a summary of our cash flows for the years ended December 31, 2018, 2017 and 2016 (in thousands):

|  | Year ended December 31, |                    |                  |
|--|-------------------------|--------------------|------------------|
|  | 2018                    | 2017               | 2016             |
| Net cash provided by (used in):                      |                         |                    |                  |
| Operating activities                                 | \$ (56,705)             | \$ (49,909)        | \$ (39,771)      |
| Investing activities                                 | 14,301                  | 4,471              | 25,482           |
| Financing activities                                 | 56,153                  | 20,884             | 37,094           |
| Net increase (decrease) in cash and cash equivalents | <u>\$ 13,749</u>        | <u>\$ (24,554)</u> | <u>\$ 22,805</u> |

*Operating activities*

Net cash used in operating activities was \$56.7 million for the year ended December 31, 2018 compared to \$49.9 million and \$39.8 million for the years ended December 31, 2017 and 2016, respectively. The increase in net cash used in operating activities was attributable to a net loss of \$59.0 million for the year ended December 31, 2018 compared to net losses of \$55.7 million and \$48.2 million for the years ended December 31, 2017 and 2016, 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, 2018, 2017, and 2016 consisted of purchases and maturities of short-term investments. For the years ended December 31, 2018, 2017, and 2016 we purchased approximately \$14.5 million, \$19.5 million, and \$69.6 million, respectively, of short-term investments and received proceeds of \$29.0 million, \$24.3 million, and \$95.5 million, respectively, from the maturity of short-term investments. Net cash used for the purchase of property and equipment was \$0.2 million, \$0.3 million, and \$0.4 million for the years ended December 31, 2018, 2017, and 2016, respectively.

*Financing activities*

Net cash provided by financing activities was \$56.2 million for the year ended December 31, 2018 compared to \$20.9 million and \$37.1 million for the years ended December 31, 2017 and 2016, respectively. During the year ended December 31, 2018, net proceeds from the sale of common stock, Series X Convertible Preferred Stock, and warrants were \$55.9 million. During the year ended December 31, 2017, net proceeds from the sale of common stock was \$20.7 million. 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.

**Operating Capital Requirements**

We performed an analysis of our ability to continue as a going concern. We believe, based on our current business plan, that our existing cash and cash equivalents will be sufficient to fund our obligations through the third quarter of 2019, but will not be sufficient to fund our obligations after the third quarter of 2019. Our ability to execute our operating plan beyond the third quarter of 2019 depends on our ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. We plan to continue to fund our losses from operations through cash and cash equivalents on hand, as well as through future equity offerings, debt financings, other third party funding, and potential licensing or collaboration arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to us. Even if we raise additional capital, we may also be required to modify, delay or abandon some of our plans which could have a material adverse effect on our business, operating results and financial condition and our ability to achieve our intended business objectives. Any of these actions could materially harm our business, results of operations and future prospects.

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

As a smaller reporting company, we are not required to provide information typically disclosed under this item.

**CIDARA THERAPEUTICS, INC.**

**Item 8. Consolidated Financial Statements and Supplementary Data.**

**Report of Independent Registered Public Accounting Firm**

**To the Shareholders and the Board of Directors of Cidara Therapeutics, Inc.**

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Cidara Therapeutics, Inc. (the Company) as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes. In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

**The Company's Ability to Continue as a Going Concern**

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has experienced net losses and negative cash flows from operating activities since its inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

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

San Diego, California

February 28, 2019

**CIDARA THERAPEUTICS, INC.**

**Consolidated Balance Sheets**

|   | <b>December 31, 2018</b> | <b>December 31, 2017</b> |
|---|--------------------------|--------------------------|
| <b>(In thousands, except share and per share data)</b>  |                          |                          |
| <b>ASSETS</b>   |                          |                          |
| Current assets:   |                          |                          |
| Cash and cash equivalents   | \$ 74,562                | \$ 60,813                |
| Short-term investments  | —                        | 14,501                   |
| Accounts receivable   | —                        | 321                      |
| Prepaid expenses and other current assets   | 2,567                    | 2,035                    |
| Total current assets  | 77,129                   | 77,670                   |
| Property and equipment, net   | 712                      | 1,044                    |
| Other assets  | 1,271                    | 321                      |
| Total assets  | \$ 79,112                | \$ 79,035                |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                          |                          |
| Current liabilities:  |                          |                          |
| Accounts payable  | \$ 2,846                 | \$ 2,590                 |
| Accrued liabilities   | 3,883                    | 4,257                    |
| Accrued compensation and benefits   | 2,824                    | 2,571                    |
| Contingent forward purchase obligation  | 411                      | —                        |
| Current portion of term loan  | 9,928                    | 2,667                    |
| Total current liabilities   | 19,892                   | 12,085                   |
| Term loan, less debt issuance costs   | —                        | 7,206                    |
| Other long-term liabilities   | 81                       | —                        |
| Total liabilities   | 19,973                   | 19,291                   |
| Commitments and contingencies   |                          |                          |
| Stockholders' equity:   |                          |                          |
| Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at December 31, 2018 and December 31, 2017:   | —                        | —                        |
| Series X Convertible Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at December 31, 2018 and no shares authorized at December 31, 2017; 445,231 shares issued and outstanding at December 31, 2018; no shares issued and outstanding at December 31, 2017 | —                        | —                        |
| Common stock, \$0.0001 par value; 200,000,000 shares authorized at December 31, 2018 and 2017; 27,816,014 shares issued and outstanding at December 31, 2018; 20,534,993 and 20,525,688 shares issued and outstanding, respectively, at December 31, 2017                   | 3                        | 2                        |
| Additional paid-in capital  | 277,871                  | 209,140                  |
| Accumulated other comprehensive loss  | —                        | (8)                      |
| Accumulated deficit   | (218,735)                | (149,390)                |
| Total stockholders' equity  | 59,139                   | 59,744                   |
| Total liabilities and stockholders' equity  | \$ 79,112                | \$ 79,035                |

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, |             |             |
|--|--------------------------|-------------|-------------|
|  | 2018                     | 2017        | 2016        |
| Operating expenses:  |                          |             |             |
| Research and development   | \$ 49,142                | \$ 42,823   | \$ 35,699   |
| General and administrative   | 14,143                   | 12,898      | 12,737      |
| Total operating expenses   | 63,285                   | 55,721      | 48,436      |
| Loss from operations   | (63,285)                 | (55,721)    | (48,436)    |
| Other income (expense):  |                          |             |             |
| Change in fair value of contingent forward purchase obligation     | 3,851                    | —           | —           |
| Interest income (expense), net                                     | 629                      | (7)         | 271         |
| Other expense  | (211)                    | —           | —           |
| Total other income (expense)                                       | 4,269                    | (7)         | 271         |
| Net loss   | \$ (59,016)              | \$ (55,728) | \$ (48,165) |
| Recognition of beneficial conversion feature                       | (10,329)                 | —           | —           |
| Net loss attributable to common shareholders                       | \$ (69,345)              | \$ (55,728) | \$ (48,165) |
| Basic and diluted net loss per common share                        | \$ (2.76)                | \$ (3.18)   | \$ (3.32)   |
| Shares used to compute basic and diluted net loss per common share | 25,142,976               | 17,500,853  | 14,488,987  |
| Net loss   | \$ (59,016)              | \$ (55,728) | \$ (48,165) |
| Unrealized gain(loss) on short-term investments                    | 8                        | (7)         | 7           |
| Comprehensive loss   | \$ (59,008)              | \$ (55,735) | \$ (48,158) |

See accompanying notes.

**CIDARA THERAPEUTICS, INC.**

**Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity**

| (In thousands, except share data)                                     | Series X Convertible Preferred Stock |             | Common Stock      |             | Additional Paid-In Capital | Accumulated Deficit | Other Comprehensive Loss | Total Stockholders' Equity |
|---|--------------------------------------|-------------|-------------------|-------------|----------------------------|---------------------|--------------------------|----------------------------|
|   | Shares                               | Amount      | Shares            | Amount      |                            |                     |                          |                            |
| <b>Balance, December 31, 2015</b>                                     | —                                    | \$ —        | 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 loss on marketable securities                              | —                                    | —           | —                 | —           | —                          | —                   | 7                        | 7                          |
| Net loss  | —                                    | —           | —                 | —           | —                          | (48,165)            | —                        | (48,165)                   |
| <b>Balance, December 31, 2016</b>                                     | —                                    | —           | 16,771,314        | 2           | 181,840                    | (93,662)            | (1)                      | 88,179                     |
| Sale of common stock, net of issuance costs                           | —                                    | —           | 3,600,178         | —           | 20,771                     | —                   | —                        | 20,771                     |
| Stock-based compensation  | —                                    | —           | —                 | —           | 5,696                      | —                   | —                        | 5,696                      |
| Vesting of restricted shares  | —                                    | —           | 19,055            | —           | 44                         | —                   | —                        | 44                         |
| Issuance of common stock for exercise of stock options                | —                                    | —           | 38,332            | —           | 228                        | —                   | —                        | 228                        |
| Issuance of common stock for restricted share units vested            | —                                    | —           | 2,500             | —           | 18                         | —                   | —                        | 18                         |
| Issuance of common stock under Employee Stock Purchase Plan           | —                                    | —           | 94,309            | —           | 543                        | —                   | —                        | 543                        |
| Unrealized gain on marketable securities                              | —                                    | —           | —                 | —           | —                          | —                   | (7)                      | (7)                        |
| Net loss  | —                                    | —           | —                 | —           | —                          | (55,728)            | —                        | (55,728)                   |
| <b>Balance, December 31, 2017</b>                                     | —                                    | —           | 20,525,688        | 2           | 209,140                    | (149,390)           | (8)                      | 59,744                     |
| Registered Direct Offering, net of offering costs                     | 445,231                              | —           | 6,185,987         | 1           | 45,457                     | —                   | —                        | 45,458                     |
| Beneficial conversion feature of Series X Convertible Preferred Stock | —                                    | —           | —                 | —           | 10,329                     | (10,329)            | —                        | —                          |
| Public offering of common stock, net of issuance costs                | —                                    | —           | 847,937           | —           | 6,440                      | —                   | —                        | 6,440                      |
| Stock-based compensation  | —                                    | —           | —                 | —           | 5,710                      | —                   | —                        | 5,710                      |
| Vesting of restricted shares  | —                                    | —           | 9,305             | —           | 21                         | —                   | —                        | 21                         |
| Issuance of common stock for exercise of stock options                | —                                    | —           | 89,031            | —           | 204                        | —                   | —                        | 204                        |
| Issuance of common stock under Employee Stock Purchase Plan           | —                                    | —           | 158,066           | —           | 570                        | —                   | —                        | 570                        |
| Unrealized loss on marketable securities                              | —                                    | —           | —                 | —           | —                          | —                   | 8                        | 8                          |
| Net loss  | —                                    | —           | —                 | —           | —                          | (59,016)            | —                        | (59,016)                   |
| <b>Balance, December 31, 2018</b>                                     | <u>445,231</u>                       | <u>\$ —</u> | <u>27,816,014</u> | <u>\$ 3</u> | <u>\$ 277,871</u>          | <u>\$ (218,735)</u> | <u>\$ —</u>              | <u>\$ 59,139</u>           |

See accompanying notes.

**CIDARA THERAPEUTICS, INC.**  
**Consolidated Statements of Cash Flows**

| (In thousands)  | Years ended December 31, |             |             |
|---|--------------------------|-------------|-------------|
|   | 2018                     | 2017        | 2016        |
| <b>Operating activities:</b>  |                          |             |             |
| Net loss  | \$ (59,016)              | \$ (55,728) | \$ (48,165) |
| Adjustments to reconcile net loss to net cash used in operating activities: |                          |             |             |
| Depreciation and amortization   | 523                      | 667         | 732         |
| Stock-based compensation  | 5,710                    | 5,714       | 4,344       |
| Non-cash interest expense   | 43                       | 61          | 17          |
| Amortization of discount or premium on short-term investments               | 31                       | (33)        | (176)       |
| Amortization of debt issue costs  | 13                       | 18          | 5           |
| Deferred rent   | 30                       | (29)        | (8)         |
| Change in fair value of contingent forward purchase obligations             | (3,851)                  | —           | —           |
| Contingent forward purchase obligation offering costs                       | 211                      | —           | —           |
| Changes in operating assets and liabilities:                                |                          |             |             |
| Prepaid expenses and other current assets                                   | (211)                    | (1,481)     | (76)        |
| Accounts payable and accrued liabilities                                    | (59)                     | 642         | 1,913       |
| Accrued compensation  | 822                      | 453         | 1,760       |
| Other assets  | (951)                    | (193)       | (117)       |
| Net cash used in operating activities                                       | (56,705)                 | (49,909)    | (39,771)    |
| <b>Investing activities:</b>  |                          |             |             |
| Purchases of short-term investments   | (14,548)                 | (19,523)    | (69,617)    |
| Maturities of short-term investments  | 29,026                   | 24,300      | 95,500      |
| Purchases of property and equipment   | (177)                    | (306)       | (401)       |
| Net cash provided by investing activities                                   | 14,301                   | 4,471       | 25,482      |
| <b>Financing activities:</b>  |                          |             |             |
| Proceeds from Registered Direct Offering, net of offering costs             | 49,509                   | —           | —           |
| Proceeds from issuance of common stock, net of offering costs               | 6,440                    | 20,735      | 26,622      |
| Proceeds from issuance of Term Loan, net of offering costs                  | —                        | —           | 9,947       |
| Proceeds from exercise of stock options                                     | 204                      | 228         | 525         |
| Repurchase of unvested restricted stock                                     | —                        | (79)        | —           |
| Net cash provided by financing activities                                   | 56,153                   | 20,884      | 37,094      |
| Net increase (decrease) in cash and cash equivalents                        | 13,749                   | (24,554)    | 22,805      |
| Cash and cash equivalents at beginning of year                              | 60,813                   | 85,367      | 62,562      |
| Cash and cash equivalents at end of year                                    | \$ 74,562                | \$ 60,813   | \$ 85,367   |
| <b>Supplemental disclosure of cash flows:</b>                               |                          |             |             |
| Interest paid   | \$ 582                   | \$ 511      | \$ —        |
| <b>Non-cash investing activity:</b>   |                          |             |             |
| Property and equipment acquired but not yet paid                            | \$ 14                    | \$ 30       | \$ 21       |
| <b>Non-cash financing activities:</b>                                       |                          |             |             |
| Issuance of warrants to purchase common stock upon execution of term loan   | \$ —                     | \$ —        | \$ 175      |
| Vesting of early exercised stock options                                    | \$ 21                    | \$ 44       | \$ 197      |
| Purchase of shares pursuant to Employee Stock Purchase Plan                 | \$ 570                   | \$ 543      | \$ 562      |
| Receivable for issuance of common stock, net of offering costs              | \$ —                     | \$ 36       | \$ —        |

See accompanying notes.

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements**

## 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 portfolio is comprised of a proprietary product candidate for the treatment and prevention of serious fungal infections. The Company is also conducting research in bacterial and viral infection. The Company formed wholly-owned subsidiaries, Cidara Therapeutics UK Limited, in England, and Cidara Therapeutics (Ireland) Limited, in Ireland, in March 2016 and October 2018, respectively, 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 Company has experienced net losses and negative cash flows from operating activities since its inception. At December 31, 2018, the Company had an accumulated deficit of \$218.7 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.

At December 31, 2018, the Company had cash and cash equivalents of \$74.6 million. Based on the Company's current business plan, management believes that existing cash and cash equivalents will be sufficient to fund the Company's obligations through the third quarter of 2019. The Company's ability to execute its operating plan beyond the third quarter of 2019 depends on its ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. However, the Company's current working capital, anticipated operating expenses and net losses and the uncertainties surrounding its ability to raise additional capital as needed, as discussed below, raise substantial doubt about its ability to continue as a going concern for a period of one year following the date that these financial statements are issued. The consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company plans to continue to fund its losses from operations through cash and cash equivalents on hand, as well as through future equity offerings, debt financings, other third party funding, and potential licensing or collaboration arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. Even if the Company raises additional capital, it may also be required to modify, delay or abandon some of its plans which could have a material adverse effect on the Company's business, operating results and financial condition and the Company's ability to achieve its intended business objectives. 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 subsidiaries. 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 and 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 stock options, the fair value of the Company's contingent forward purchase obligations, and certain accruals, including those related to nonclinical 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 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**— The Company records 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, 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.

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the "Tax Act"), which among other provisions, reduced the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018. Due to the timing of the enactment and the complexity involved in applying the provisions of the Tax Act, the Company made reasonable estimates of the effects and recorded provisional amounts, offset with valuation allowances, in its financial statements as of December 31, 2017. At December 31, 2018, the Company has completed its assessment of the impact of the Tax Cuts and Jobs Act and has reflected the impact in the current year. At December 31, 2018, there were no material changes from the provisional amounts recorded for the year ended December 31, 2017.

**Revenue Recognition**—The Company recognizes revenues when customers obtain control of promised goods or services, in an amount that reflects the consideration which it expects to receive in exchange for those goods or services. The Company recognizes revenues following the five step model prescribed under Accounting Standards Update ("ASU") No. 2014-09 ("ASU 2014-09"): (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) the Company satisfies the performance obligation.

**Grant Funding**—The Company has received research and development funding through a grant from CARB-X, a public-private partnership focused on antibacterials. The Company has also been awarded a partnership grant with Rutgers University from the NIAID. The Company has evaluated the terms of the grants to assess its obligations and the classification of funding received. Amounts billable for funded research and development are recognized in the statement

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

of operations as a reduction to research and development expense over the grant period as the related costs are incurred to meet the Company's obligations.

**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 nonclinical and clinical trial costs. The Company accrues nonclinical and 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 investments. Comprehensive losses have been reflected in the consolidated 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 and employee stock purchase plan rights by estimating the fair value on the date of grant using the Black-Scholes option pricing model. The fair value of Restricted Stock Units (RSUs) and Performance-based RSUs (PRSUs) granted to employees is estimated based on the closing price of the Company's common stock 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. For awards subject to performance-based vesting conditions, the Company assesses the probability of achievement of the individual milestones under the stock-based awards and recognizes stock-based compensation expense over the implicit service period commencing once the Company believes the performance criteria is probable of achievement. The Company accounts for stock options, RSUs, and PRSUs granted to non-employees using the fair value approach. These stock-based awards are subject to periodic revaluation over their vesting terms. The Company recognizes forfeitures related to stock-based compensation as they occur.

**Net Loss Per Share**—Basic net loss per share is calculated by dividing the net loss allocable to common shares 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 allocable to common shares 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 warrants, Series X Convertible Preferred stock, unvested restricted common stock subject to repurchase, and RSUs and options outstanding under the Company's stock option plans. 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,      |                  |
|---|-------------------|------------------|
|   | 2018              | 2017             |
| Common stock warrants                                       | 12,517,328        | 17,331           |
| Series X Convertible Preferred stock                        | 4,452,310         | —                |
| Common stock options, RSUs and PRSUs issued and outstanding | 4,392,671         | 3,099,173        |
| Common stock subject to repurchase                          | —                 | 9,305            |
| <b>Total</b>  | <b>21,362,309</b> | <b>3,125,809</b> |

**Fair Value of Financial Instruments**— The Company follows ASC 820-10 issued by the FASB with respect to fair value reporting for financial assets and liabilities. The guidance 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, contingent forward purchase obligations, 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, accounts receivable, prepaid expenses, accounts payable, and accrued liabilities are generally considered to

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

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 fair value of contingent forward purchase obligations is based on a probability-weighted valuation approach (See Note 4). The Company believes that the fair value of long-term debt approximates its carrying value.

**Recently Issued Accounting Standards**— 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 currently expects that its operating lease commitments will be subject to the new standard and recognized as right-of-use assets and operating lease liabilities upon the adoption of ASU 2016-02, which will increase the total assets and total liabilities that it reports relative to such amounts prior to adoption.

During 2018, the FASB issued ASU 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting," which expanded the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Under the ASU, the guidance on such payments to nonemployees is aligned with the accounting for share-based payments granted to employees, including the measurement of equity-classified awards, which is fixed at the grant date under the new guidance. 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 2018, the FASB issued ASU 2018-13, "Changes to the Disclosure Requirements for Fair Value Measurement," which modifies certain disclosure requirements on fair value measurements. The updated guidance is effective for interim and annual periods beginning after December 15, 2019, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

### 3. SHORT-TERM INVESTMENTS

The Company did not have any available-for-sale securities at December 31, 2018. The following table summarizes the available-for-sale securities held at 2017 (in thousands):

| As of December 31, 2017 | Amortized Cost   | Unrealized Gains | Unrealized Losses | Fair Value       |
|-------------------------|------------------|------------------|-------------------|------------------|
| Corporate debt          | 14,509           | —                | (8)               | 14,501           |
| Total                   | <u>\$ 14,509</u> | <u>\$ —</u>      | <u>\$ (8)</u>     | <u>\$ 14,501</u> |

All available-for-sale securities held at December 31, 2017 had maturities of less than one year. Unrealized gains and losses on available-for-sale securities are included as a component of other comprehensive loss. 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. During the years ended December 31, 2018 and 2017, the Company did not recognize any impairment or gains or losses on sales of available-for-sale securities.

### 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 determined based on assumptions that market participants would use in pricing an asset or liability. The carrying amounts of accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates available to the Company for loans with similar terms, which is considered a Level 2 input as described below, the Company believes that the fair value of long-term debt approximates its carrying value.

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 for 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.

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

The Company classifies investments in money market funds within Level 1 as the prices are available from quoted prices in active markets. Investments in commercial paper, corporate debt and reverse repurchase agreements are classified within Level 2 as these instruments are valued using observable market inputs including reported trades, broker/dealer quotes, bids and/or offers.

As discussed in Note 7, on May 21, 2018, the Company entered into a subscription agreement with certain investors providing for the purchase and sale of up to an aggregate of \$120.0 million of its common stock and preferred stock in three closings. The second and optional third closings and warrants related to the optional third closing, which are triggered by the Company's announcement of topline data of Part B of its STRIVE Phase 2 clinical trial of rezafungin, contain features for subsequent closings that are not solely within the control of the Company and that embody an obligation that the Company must settle by issuing a variable number of shares when the obligation is based predominantly on having a fixed value at inception. In accordance with ASC 480, "Distinguishing Liabilities from Equity," the Company determined that these closings are classified as liabilities and represent contingent forward purchase obligations. These liabilities are required to be recorded at their estimated fair value initially and on a recurring basis. The contingent forward purchase obligations are classified within Level 3 of the fair value hierarchy as the Company is using a probability-weighted valuation approach, utilizing significant unobservable inputs including the probability and estimated timing of achieving positive or negative results associated with Part B of the STRIVE Phase 2 clinical trial and estimated discount rates related to the risk of achievement of the expected equity issuances. The liability was initially recorded at \$4.3 million on May 21, 2018 and fair value adjustments resulting in a gain of \$3.9 million were recorded during the year ended December 31, 2018. The liability was valued at \$0.4 million for the year ended December 31, 2018.

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       |
|---|------------------|------------------|------------------|---------------|
| <b>December 31, 2018</b>                    |                  |                  |                  |               |
| Assets:                                     |                  |                  |                  |               |
| Money market funds                          | \$ 74,077        | \$ 74,077        | \$ —             | \$ —          |
| Total assets at fair value                  | <u>\$ 74,077</u> | <u>\$ 74,077</u> | <u>\$ —</u>      | <u>\$ —</u>   |
| Liabilities:                                |                  |                  |                  |               |
| Contingent forward purchase obligations     | \$ 411           | \$ —             | \$ —             | \$ 411        |
| Total liabilities at fair value             | <u>\$ 411</u>    | <u>\$ —</u>      | <u>\$ —</u>      | <u>\$ 411</u> |
| <b>December 31, 2017</b>                    |                  |                  |                  |               |
| Assets:                                     |                  |                  |                  |               |
| Money market funds                          | \$ 11,556        | \$ 11,556        | \$ —             | \$ —          |
| U.S. Treasury reverse repurchase agreements | 48,000           | —                | 48,000           | —             |
| Corporate debt                              | 15,101           | —                | 15,101           | —             |
| Total assets at fair value                  | <u>\$ 74,657</u> | <u>\$ 11,556</u> | <u>\$ 63,101</u> | <u>\$ —</u>   |



**CIDARA THERAPEUTICS, INC.**

**5. PROPERTY AND EQUIPMENT**

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

|  | December 31,  |                 |
|--|---------------|-----------------|
|  | 2018          | 2017            |
| Laboratory equipment                           | \$ 2,114      | \$ 2,051        |
| Leasehold improvements                         | 425           | 425             |
| Computer hardware and software                 | 455           | 327             |
| Office equipment                               | 119           | 119             |
| Furniture and fixtures                         | 142           | 142             |
|  | <u>3,255</u>  | <u>3,064</u>    |
| Less accumulated depreciation and amortization | (2,543)       | (2,020)         |
| Total  | <u>\$ 712</u> | <u>\$ 1,044</u> |

Depreciation and amortization of property and equipment of \$523,000 and \$667,000 were recorded for the years ended December 31, 2018 and 2017, 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, because the Company achieved positive clinical results from the STRIVE Phase 2 clinical trial of rezafungin by March 31, 2018, the Company could, at its sole discretion through October 3, 2018, borrow from the Lender up to an additional \$10.0 million (the "Term B Loan," and together with the Term A Loan, the "Term Loans"). The Company did not borrow any funds available under the Term B Loan before the draw period ended.

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 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.

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.

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.

On June 13, 2018, the Company and the Lender entered into a First Amendment to the Loan Agreement, which reset the operating covenant to require the Company to achieve positive data from Part B of the STRIVE Phase 2 clinical trial of rezafungin on or prior to July 31, 2019 (the "Milestone").

On July 27, 2018, the Company and the Lender entered into a Second Amendment to the Loan Agreement, which amended, among other things, the interest-only period, the date of maturity (the "Maturity Date") and the interest rate. The Maturity Date is January 3, 2022. Payments under the Term Loans will be interest-only through July 31, 2019, which will be extended to October 31, 2019 if the Milestone is achieved. The interest-only period will be followed by equal monthly payments of principal and interest. The Term Loans will bear interest at a variable annual rate equal to the

## CIDARA THERAPEUTICS, INC.

greater of (i) 4.5% or (ii) the Lender's prime interest rate plus 0.75%. At December 31, 2018, the Term Loans bear interest at 6.25%.

The Company evaluated the First and Second Amendments to evaluate whether the amendments represented modifications or extinguishment of debt. The Company determined that the amendments did not represent a substantial change from the original Loan Agreement and accounted for the amendments as debt modifications. Costs previously deferred under the original terms of the Loan Agreement are amortized into interest expense over the new term of the Second Amendment.

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 data from Part B of the STRIVE Phase 2 clinical trial of rezafungin on or prior to July 31, 2019, 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. The principal payments due under the Loan Agreement have been classified as a current liability at December 31, 2018 due to the considerations discussed in Note 1 and the assessment that the material adverse change clause under the Loan Agreement is not within the Company's control. The Company has not been notified of an event of default by the Lenders as of the date of the filing of this Form 10-K.

As of December 31, 2018, future principal payments due under the Term A Loan are as follows (in thousands):

### Year ended:

|   |    |        |
|---|----|--------|
| December 31, 2019   | \$ | 1,667  |
| December 31, 2020   |    | 4,000  |
| December 31, 2021   |    | 4,000  |
| December 31, 2022   |    | 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 are being amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense for the amortization of the fair value of the warrants and debt issue costs of \$56,000 and \$78,000 for the years ended December 31, 2018 and 2017, respectively, for the amortization of the fair value of the warrants and debt issue costs.

## 7. STOCKHOLDERS' EQUITY

**May 2018 Registered Direct Offering**— On May 21, 2018, the Company entered into a subscription agreement with certain investors providing for the purchase and sale, in a registered direct offering, of up to an aggregate of \$120.0 million of its common stock and preferred stock in three closings. On May 23, 2018, the Company completed the first closing, which was comprised of 6,185,987 shares of common stock at an offering price of \$4.70 per share, 445,231 shares of Series X Convertible Preferred Stock at an offering price of \$47.00 per share, and an option fee relating to the third closing paid by the investors for a total of \$0.5 million. In a private placement concurrent with the first closing (the "First Private Placement"), the Company also sold warrants, at \$0.125 per warrant share, to purchase an aggregate of 12,499,997 shares of common stock. Net proceeds for the first closing and the First Private Placement were \$49.5 million.

The Company performed an analysis to allocate the proceeds from the May 2018 registered direct offering to the offering's various components on a relative fair value basis, including the contingent forward purchase obligations (discussed further in Note 4) as well as the common stock, Series X Convertible Preferred Stock, warrants, and option fee. With respect to the Series X Convertible Preferred Stock, because the adjusted conversion price on the commitment date (following the allocation of proceeds on a fair value basis) was below the fair value of the common stock at the date of issuance, a beneficial conversion feature with a calculated fair value of \$10.3 million existed at the issuance date. The beneficial conversion feature is amortized as a deemed dividend to the preferred holders. As the Series X Convertible Preferred Stock is fully convertible at issuance, the full amortization of the \$10.3 million was recorded at issuance as a one-time deemed dividend on May 23, 2018. This one-time, non-cash deemed dividend impacted net loss attributable to common stockholders and net loss attributable to common stockholders per share for the year ended December 31, 2018.

In the second closing of the offering, the Company may sell up to an additional \$50.0 million in shares of common stock to investors who purchased at least \$1.0 million of shares of common stock in the first closing of the offering at a purchase

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

price per share that is equal to 75% of the volume weighted average price of the common stock for the five trading days following the Company's public release of topline data from Part B of its STRIVE global, randomized Phase 2 clinical trial of rezafungin, provided that the Company will not be obligated to complete the second closing of the offering if the purchase price is less than \$4.70 per share.

In the optional third closing, which would be held five trading days following the second closing, purchasers who fully participate in the second closing may, at their option, purchase up to an additional \$20.0 million of common stock at a purchase price per share equal to the purchase price of the shares purchased at the second closing.

At the Company's option, and prior to the completion of the second or third closing, as applicable, the Company may reduce the aggregate offering size of the such closing by the dollar amount received by the Company from any (i) strategic partnership or other non-dilutive source of funding or (ii) sale of equity securities at a price greater than \$6.81 per share.

If the volume weighted average price of the Company's common stock for the five trading days following the Company's public release of topline data from Part B of its STRIVE global, randomized Phase 2 clinical trial of rezafungin is below \$6.27, the resulting purchase price for the second and third closings will be less than \$4.70 per share and the Company will be unable to complete the second and third closings without first obtaining the approval of our stockholders. As of the date the Company issued financial statements for the fiscal year ending December 31, 2018, the price of the Company's common stock was below \$6.27.

The Company will also offer to each purchaser in the second or third closing the opportunity, in lieu of purchasing common stock, to purchase Series X Convertible Preferred Stock. For each share of Series X Convertible Preferred Stock purchased in the offering in lieu of common stock, the Company will reduce the number of shares of common stock being sold by 10 shares. Each share of Series X Convertible Preferred Stock is convertible into 10 shares of common stock.

As the issuance of the additional closings are outside the control of the Company, the second closing and optional third closing are accounted for as a liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*, which is measured at fair value on a recurring basis. See Note 4 to our financial statements for additional information.

In a private placement to be held concurrently with the optional third closing (the "Second Private Placement"), the Company would sell warrants to purchase up to 2,500,000 shares of Common Stock to the purchasers that participate, at a purchase price of \$0.125 per warrant share (such warrants, together with the warrants sold in the First Private Placement, each, a "Warrant", and collectively, the "Warrants").

The Warrants are exercisable immediately for cash at an exercise price of \$6.81 per share. The Warrants issued in the First Private Placement will expire upon the earliest of (i) five years from the date of the first closing of the offering, (ii) the date that the holder of such Warrant transfers or sells any of the shares of Common Stock purchased by such holder in the first closing of the offering, if such transfer or sale occurs prior to the date that is 120 calendar days following the closing of the first closing of the offering, (iii) the taking of any short position on the Common Stock by the holder of such Warrant prior to the completion of the second closing of the offering, and (iv) the failure by the holder of such Warrant to purchase its pro rata allocation of shares of Common Stock in the second closing of the offering. The Company accounts for the Warrants as equity instruments in accordance with ASC 480, *Distinguishing Liabilities from Equity*.

The Warrants issued in the Second Private Placement will expire five years from the date of the third closing of the offering.

**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 at December 31, 2018.

In May 2018, the Company designated 5,000,000 shares of preferred stock as Series X Convertible Preferred Stock with a par value of \$0.0001 per share. As of December 31, 2018, 445,231 shares of Series X Convertible Preferred Stock were issued and outstanding.

The specific terms of the Series X Convertible Preferred Stock are as follows:

**Conversion:** Each share of Series X Convertible Preferred Stock is convertible at the option of the holder into 10 shares of common stock.

Holder's are not permitted to convert Series X Convertible Preferred Stock into common stock if, after conversion, the holder, its affiliates, and any other person whose beneficial ownership of common stock would be aggregated with the holder's for purposes of Section 13(d) or Section 16 of the Exchange Act, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after the conversion.

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

**Dividends:** Holders of Series X Convertible Preferred Stock are not entitled to receive any dividends except to the extent that dividends are paid on the Company's common stock. If dividends are paid on shares of common stock, holders of Series X Convertible Preferred Stock are entitled to participate in such dividends on an as-converted basis.

**Liquidation:** Upon the liquidation, dissolution, or winding up of the company, each holder of Series X Convertible Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock.

**Voting:** Shares of Series X Convertible Preferred Stock will generally have no voting rights, except as required by law and except that the consent of the holders of a majority of the outstanding Series X Convertible Preferred Stock will be required to amend the terms of the Series X Convertible Preferred Stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X Convertible Preferred Stock, or to increase or decrease (other than by conversion) the number of authorized shares of Series X Convertible Preferred Stock.

The Company evaluated the Series X Convertible Preferred Stock for liability or equity classification under ASC 480, *Distinguishing Liabilities from Equity*, and determined that equity treatment was appropriate because the Series X Convertible Preferred Stock did not meet the definition of the liability instruments defined thereunder as convertible instruments. Specifically, the Series X Convertible Preferred Stock does not meet the criteria for classification as an ASC 480 liability. As such, the Series X Convertible Preferred Stock should be recorded as permanent equity. Additionally, the Series X Convertible Preferred Stock is not redeemable for cash or other assets (i) on a fixed or determinable date, (ii) at the option of the holder, and (iii) upon the occurrence of an event that is not solely within control of the Company.

**Common Stock**—The Company had 200,000,000 shares of common stock authorized as of December 31, 2018. 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.

In October 2017 the Company closed a private placement transaction pursuant to which an aggregate of 3,360,000 shares of common stock were sold at a price of \$6.00 per share. The Company received net proceeds of approximately \$18.9 million after deducting placement agent fees and offering expenses.

In November 2017 the Company began to sell shares of common stock under a controlled equity sales agreement with Cantor Fitzgerald & Co. During the years ended December 31, 2018 and December 31, 2017, the Company sold 847,937 and 240,178 shares of common stock for net proceeds of approximately \$6.4 million and \$1.8 million, respectively, after deducting placement agent fees.

**Common Stock Reserved for Future Issuance**

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

|  | Years ended December 31, |                  |
|--|--------------------------|------------------|
|  | 2018                     | 2017             |
| Common stock warrants                                | 12,517,328               | 17,331           |
| Series X Convertible Preferred stock                 | 4,452,310                | —                |
| Stock options, RSUs and PRSUs issued and outstanding | 4,392,671                | 3,099,173        |
| Authorized for future stock awards                   | 669,873                  | 1,006,307        |
| Awards available under the ESPP                      | 706,242                  | 380,875          |
| Total  | <u>22,738,424</u>        | <u>4,503,686</u> |

## 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, RSUs, 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 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"). 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, (ii) 490,336 shares, or (iii) such lesser number as determined by the Company's board of directors.

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 ESPP are limited to 15% of the employee's eligible compensation. During the year ended December 31, 2018, 158,066 shares were issued pursuant to the ESPP.

### *Restricted Stock*

The Company permits exercise of certain stock options prior to vesting. Any such exercised shares are restricted and subject to repurchase by the Company until the conditions for vesting are met. At December 31, 2018 there was no liability for cash received from the early exercise of stock options. At December 31, 2017, the liabilities for the cash received from the early exercise of stock options was \$21,000 and was 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 are 4 years. At December 31, 2018, there were no shares subject to repurchase by the Company.

### *Restricted Stock Units*

The following table summarizes RSU and PRSU activity during the year ended December 31, 2018:

|                                  | <b>Number of<br/>RSUs and PRSUs</b> |
|----------------------------------|-------------------------------------|
| Outstanding at December 31, 2017 | 227,500                             |
| RSUs and PRSUs granted           | 55,000                              |
| RSUs and PRSUs vested            | (2,500)                             |
| RSUs and PRSUs canceled          | (20,000)                            |
| Outstanding at December 31, 2018 | 260,000                             |

For the year ended December 31, 2018, stock-based compensation expense related to RSUs and PRSUs was approximately \$0.3 million. At December 31, 2018, estimated unrecognized compensation expense related to RSUs and PRSUs granted to employees was approximately \$1.0 million.

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

**Stock Options**

The following table summarizes stock option activity during the year ended December 31, 2018:

|  | Number of<br>Shares | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Remaining<br>Contractual Life<br>in Years | Total Aggregate<br>Intrinsic Value (in<br>thousands) |
|--|---------------------|---------------------------------------|--|--|
| Outstanding at December 31, 2017                 | 3,099,173           | \$ 7.74                               | 8.10   | \$ 2,264   |
| Options granted                                  | 1,436,250           | 4.22                                  |  |  |
| Options exercised                                | (89,031)            | 2.29                                  |  |  |
| Options canceled                                 | (313,721)           | 8.41                                  |  |  |
| Outstanding at December 31, 2018                 | <u>4,132,671</u>    | \$ 6.58                               | 7.41   | \$ 25  |
| Vested and expected to vest at December 31, 2018 | <u>4,132,671</u>    | \$ 6.58                               | 7.41   | \$ 25  |
| Exercisable at December 31, 2018                 | <u>2,423,061</u>    | \$ 7.29                               | 6.74   | \$ 25  |

The intrinsic value of a stock option is the difference between the market price of the common stock at the measurement date and the exercise price of the option.

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, |               |
|-------------------------|----------------------------------|---------------|
|                         | 2018                             | 2017          |
| <b>2015 EIP</b>         |                                  |               |
| Risk-free interest rate | 2.55% - 3.06%                    | 1.87% - 2.23% |
| Expected dividend yield | 0%                               | 0%            |
| Expected volatility     | 83%                              | 79% - 86%     |
| Expected term (years)   | 5.50 - 6.08                      | 5.50 - 6.08   |
| <b>2015 ESPP</b>        |                                  |               |
| Risk-free interest rate | 2.14% - 2.81%                    | 1.05% - 1.77% |
| Expected dividend yield | 0%                               | 0%            |
| Expected volatility     | 77% - 92%                        | 79% - 102%    |
| Expected term (years)   | 0.50 - 2.00                      | 0.50 - 2.00   |

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

|                            | Years ended December 31, |                 |
|----------------------------|--------------------------|-----------------|
|                            | 2018                     | 2017            |
| Research and development   | \$ 2,676                 | \$ 2,428        |
| General and administrative | 3,034                    | 3,286           |
| Total                      | <u>\$ 5,710</u>          | <u>\$ 5,714</u> |

The weighted-average grant date fair value of stock options granted to employees during the year ended December 31, 2018 was \$2.98 per share. The total grant date fair value of stock options that vested during the year ended December 31, 2018 was \$3.6 million. As of December 31, 2018, total unrecognized share-based compensation expense related to unvested employee stock options of the Company was approximately \$5.4 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 2.31 years.

As of December 31, 2018, total unrecognized compensation expense related to the Company's ESPP was approximately \$0.8 million. This unrecognized compensation cost is expected to be recognized over approximately 0.70 years.

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

**Common Stock Warrants**

A summary of warrant activity for the year ended December 31, 2018 is presented below:

|                                  | Warrants          | Weighted Average<br>Exercise Price | Total Intrinsic Value |
|----------------------------------|-------------------|------------------------------------|-----------------------|
| Outstanding at December 31, 2017 | 17,331            | 11.54                              | \$ —                  |
| Issued                           | 12,499,997        | 6.81                               | —                     |
| Exercised                        | —                 | —                                  | —                     |
| Canceled                         | —                 | —                                  | —                     |
| Outstanding at December 31, 2018 | <u>12,517,328</u> | <u>6.82</u>                        | <u>\$ —</u>           |

The intrinsic value of a common stock warrant is the difference between the market price of the common stock at the measurement date and the exercise price of the warrant.

**9. SIGNIFICANT AGREEMENTS AND CONTRACTS**

***Combating Antibiotic Resistant Bacteria Accelerator (CARB-X) Subaward Agreement***

On March 30, 2017, the Company entered into a Cost Reimbursement Research Subaward Agreement (the "Subaward Agreement") with the Trustees of Boston University. Under the Subaward Agreement, the Company is a subawardee under the CARB-X program. CARB-X is a public-private partnership focused on antibacterials, created by the U.S. Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority (BARDA), the NIAID. CARB-X is funded by BARDA and the London-based Wellcome Trust, a global charitable foundation (Wellcome), and administered by the Boston University School of Law.

The subaward was intended to support development of the Company's CD201 product candidate. Under the Subaward Agreement, during an initial phase that began on April 1, 2017 and ends upon acceptance by the U.S. Food and Drug Administration of an initial new drug application, CARB-X would reimburse up to \$3.9 million of qualifying development expenses. If all of the milestones in such initial phase are met, the CARB-X Joint Oversight Committee will evaluate the progress made in such initial phase and determine whether to exercise its option to fund a second stage. During the second stage, CARB-X would reimburse up to \$3.0 million of qualifying development expenses through a Phase 1 clinical trial. Such second stage would be subject to a new subaward agreement.

Under the Subaward Agreement, the Company is reimbursed for direct costs incurred plus allowable indirect costs which consist of fringe benefits and allowable general and administrative expenses. For the year ended December 31, 2018, the Company did not recognize any reductions to research and development expenses for costs eligible for reimbursement under the Subaward Agreement. As of December 31, 2018, there were no billed or unbilled accounts receivable related to reimbursable expenses under the Subaward Agreement.

The Subaward Agreement can be terminated upon the delivery of 30 days written notice to the Company for default or convenience. Upon receipt of a notice of termination, the Company must discontinue contract activities and CARB-X must pay the Company a final settlement based on eligible expenses incurred under the Subaward Agreement.

Based on preclinical studies of CD201 as well as preclinical studies of antibody-drug conjugates (ADCs) from the Cloudbreak program, the Company decided in February 2018 to cease development of CD201 to focus on the more promising ADCs. The Company will no longer be seeking funding under the Subaward Agreement relating to CD201.

***Partnership Grant for the Development of Cloudbreak Antibody-Drug Conjugates***

In May 2018, the Company and Rutgers University were awarded a five year, \$5.5 million partnership grant from the NIAID. The grant will fund continued research and development of the Company's Cloudbreak platform to identify novel immunotherapy agents for the treatment and prevention of serious and life-threatening viral infections and multi-drug resistant Gram-negative bacterial infections in high-risk populations. The Company began work under this grant in July 2018 but has not billed Rutgers University for any work performed to date, nor recognized any potential reimbursements in the statement of operations for the year ended December 31, 2018 as the subaward agreement between the Company and Rutgers University has not yet been executed.



**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

**10. 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 and the provision for income taxes (in thousands):

|  | Years Ended December 31, |             |             |
|--|--------------------------|-------------|-------------|
|  | 2018                     | 2017        | 2016        |
| Federal income taxes at 21% for 2018 and 34% for 2017 and 2016 | \$ (12,393)              | \$ (18,947) | \$ (16,334) |
| State income tax, net of federal benefit                       | —                        | —           | (1)         |
| Tax effect on nondeductible expenses                           | (278)                    | 3,389       | 1,650       |
| Research credits   | (4,737)                  | (8,125)     | (3,538)     |
| Rate change  | —                        | —           | 267         |
| Change in valuation allowance                                  | 16,421                   | 5,133       | 14,996      |
| Reserve for uncertain tax positions                            | 1,184                    | 1,451       | 2,883       |
| Tax Cuts and Jobs Act  | —                        | 17,334      | —           |
| Other  | (197)                    | (235)       | 77          |
| Income tax expense   | <u>\$ —</u>              | <u>\$ —</u> | <u>\$ —</u> |

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

|                           | Years Ended December 31, |                 |
|---------------------------|--------------------------|-----------------|
|                           | 2018                     | 2017            |
| Deferred tax assets:      |                          |                 |
| Net operating losses      | \$ 38,268                | \$ 26,364       |
| Research credits          | 14,007                   | 10,232          |
| Intangibles               | 241                      | 265             |
| Other                     | 2,488                    | 1,722           |
| Total deferred tax assets | <u>55,004</u>            | <u>38,583</u>   |
| Less valuation allowance  | <u>(55,004)</u>          | <u>(38,583)</u> |
| Income tax expense        | <u>\$ —</u>              | <u>\$ —</u>     |

At December 31, 2018, the Company had federal and state net operating loss carryforwards of approximately \$179.1 million and \$132 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 \$17 million and state research and development credit carryforwards totaling \$2.4 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 2029.

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 \$55.0 million and \$38.6 million as of December 31, 2018 and 2017, 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 Tax Cuts and Jobs Act was enacted on December 22, 2017. The Act reduces the US federal corporate tax rate from 35% to 21%, requires companies to pay a one-time transition tax on earnings of certain foreign subsidiaries that were previously tax deferred, and creates new taxes on certain foreign sourced earnings. At December 31, 2017, the Company made a reasonable estimate of the effects on their existing deferred tax balances. At December 31, 2017 the Company



**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements — Continued**

recognized a provisional amount of \$17.3 million which was included as a component of income tax expense from continuing operations offset with valuation allowances. As of December 31, 2018, the Company has completed its assessment of the impact of the Tax Cuts and Jobs Act with no additional impact recorded in the current year.

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, 2018 and 2017, the unrecognized tax benefits recorded were approximately \$16.5 million and \$10.8 million, respectively. Approximately \$13.4 million of the unrecognized tax benefits would reduce the Company's 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 2018, 2017 and 2016 is as follows (in thousands):

|   | Years Ended December 31, |                  |                 |
|---|--------------------------|------------------|-----------------|
|   | 2018                     | 2017             | 2016            |
| Balance as of the beginning of the year         | \$ 10,756                | \$ 4,642         | \$ 356          |
| Increases related to current year tax positions | 1,224                    | 2,149            | 921             |
| Increases related to prior year tax positions   | 4,544                    | 3,965            | 3,365           |
| Balance as of the end of the year               | <u>\$ 16,524</u>         | <u>\$ 10,756</u> | <u>\$ 4,642</u> |

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.

#### 11. 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, 2018 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. On June 29, 2018 the Company entered into a Fourth Amendment to its lease which extended the term of the lease by an additional 36 months and increases base rent to \$70,000 per month effective January 1, 2019. The Company has also been granted an option, exercisable prior to September 30, 2019, to expand its leased premises on the same terms as the current lease, subject to compliance with specified conditions. The lease expires in December 2021 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 January. 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, 2018 are summarized as follows (in thousands):

|                              |                 |
|------------------------------|-----------------|
| 2019                         | 836             |
| 2020                         | 861             |
| 2021                         | 887             |
| Total minimum lease payments | <u>\$ 2,584</u> |

Rent expense was \$776,000 and \$704,000 for the years ended December 31, 2018 and 2017, 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.

**CIDARA THERAPEUTICS, INC.**  
**Notes to Consolidated Financial Statements**

**12. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)**

|   | <u>First Quarter</u> | <u>Second Quarter</u> | <u>Third Quarter</u> | <u>Fourth Quarter</u> |
|---|----------------------|-----------------------|----------------------|-----------------------|
| <b>2018</b>   |                      |                       |                      |                       |
| Operating expenses  | \$ 16,810            | \$ 15,152             | \$ 14,725            | \$ 16,598             |
| Other income (expense)                                      | 61                   | (1,154)               | 1,106                | 4,256                 |
| Net loss  | (16,749)             | (16,306)              | (13,619)             | (12,342)              |
| Basic and diluted net loss per share                        | \$ (0.80)            | \$ (1.13)             | \$ (0.49)            | \$ (0.44)             |
| Shares used to compute basic and diluted net loss per share | 20,894,353           | 23,592,763            | 27,705,472           | 27,780,212            |
| <b>2017</b>   |                      |                       |                      |                       |
| Operating expenses  | \$ 13,398            | \$ 16,615             | \$ 12,249            | \$ 13,459             |
| Other income (expense)                                      | —                    | (30)                  | (8)                  | 31                    |
| Net loss  | (13,398)             | (16,645)              | (12,257)             | (13,428)              |
| Basic and diluted net loss per share                        | \$ (0.80)            | \$ (0.99)             | \$ (0.73)            | \$ (0.69)             |
| Shares used to compute basic and diluted net loss per share | 16,795,366           | 16,831,960            | 16,864,211           | 19,489,375            |

**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, 2018, 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, 2018.

***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. In addition, 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, 2018. 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, 2018, 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***

There were no 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 2019 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days after the fiscal year ended December 31, 2018, 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 8 of this Annual Report:

|  | <u>Page</u> |
|--|-------------|
| <a href="#">Report of Independent Registered Public Accounting Firm</a>                      | 61          |
| <a href="#">Balance Sheets</a>   | 62          |
| <a href="#">Statements of Operations and Comprehensive Loss</a>                              | 63          |
| <a href="#">Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)</a> | 64          |
| <a href="#">Statements of Cash Flows</a>   | 65          |
| <a href="#">Notes to Financial Statements</a>  | 66          |

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 below. The exhibits listed in the Exhibit Index are filed or incorporated by reference as part of this Annual Report.

## Exhibit Index

| Exhibit Number | Description   |
|----------------|---|
| 1.1            | <a href="#"><u>Controlled Equity OfferingSM Sales Agreement, dated as of November 8, 2018, by and between Cidara Therapeutics, Inc. and Cantor Fitzgerald &amp; Co. (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3, filed on November 8, 2018).</u></a>   |
| 3.1            | <a href="#"><u>Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on April 24, 2015).</u></a>  |
| 3.2            | <a href="#"><u>Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on April 24, 2015).</u></a>  |
| 3.3            | <a href="#"><u>Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 21, 2018).</u></a>  |
| 4.1            | <a href="#"><u>Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a>  |
| 4.2            | <a href="#"><u>Form of Warrant to Purchase Common Stock issued to Pacific Western Bank (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on October 3, 2016).</u></a>  |
| 4.3            | <a href="#"><u>Form of Common Stock Purchase Warrant for First Private Placement (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on May 21, 2018)</u></a>   |
| 4.4            | <a href="#"><u>Form of Common Stock Purchase Warrant for Second Private Placement (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on May 21, 2018)</u></a>  |
| 10.1+          | <a href="#"><u>Form of Indemnity Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a>   |
| 10.2+          | <a href="#"><u>2015 Equity Incentive Plan and Form of Grant Notice, Stock Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-203434), filed on April 15, 2015).</u></a>   |
| 10.3+          | <a href="#"><u>2015 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a>  |
| 10.4+          | <a href="#"><u>2013 Stock Option and Grant Plan and Form of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder, as amended (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a>                         |
| 10.5+          | <a href="#"><u>Form of Amended and Restated Employment Agreement by and between the Registrant and its executive officers (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on November 10, 2016).</u></a>  |
| 10.6           | <a href="#"><u>Consulting and Independent Contractor Agreement by and between the Registrant and Dirk Thye, M.D., dated September 2, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 1, 2016).</u></a>   |
| 10.7           | <a href="#"><u>Loan and Security Agreement by and between Registrant and Pacific Western Bank, dated October 3, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on October 3, 2016).</u></a>  |
| 10.8           | <a href="#"><u>Asset Purchase Agreement by and between Registrant and Seachaid Pharmaceuticals, Inc., dated May 30, 2014 (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a>   |
| 10.9           | <a href="#"><u>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 (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a> |
| 10.10          | <a href="#"><u>Standard Industrial/Commercial Multi-Tenant Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated June 9, 2014 (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a>                         |
| 10.11          | <a href="#"><u>First Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated June 9, 2014 (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a>  |
| 10.12          | <a href="#"><u>Second Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated February 15, 2015 (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).</u></a>  |
| 10.13          | <a href="#"><u>Third Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated July 1, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on November 16, 2015).</u></a>  |

|         |   |
|---------|---|
| 10.14*  | <a href="#"><u>Cost Reimbursement Research Subaward Agreement by and between Registrant and the Trustees of Boston University, dated March 30, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on May 10, 2017).</u></a>   |
| 10.15+  | <a href="#"><u>Form of Restricted Stock Unit Award Grant Notice (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on May 10, 2017).</u></a>   |
| 10.16   | <a href="#"><u>Securities Purchase Agreement by and among the Registrant and each of the persons and entities, severally and not jointly, listed as a Purchaser on the Schedule of Purchasers attached as Schedule I thereto, dated October 19, 2017 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on October 19, 2017).</u></a> |
| 10.17   | <a href="#"><u>First Amendment to Loan and Security Agreement, by and between the Registrant and Pacific Western Bank, dated June 13, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed August 9, 2018).</u></a>   |
| 10.18   | <a href="#"><u>Subscription Agreement by and among the Registrant and the purchasers identified on the signature pages thereto, dated May 21, 2018 (incorporated by reference to the Registrant's Current Report on Form 8-K, filed on May 21, 2018).</u></a>   |
| 10.19   | <a href="#"><u>Placement Agency Agreement by and among the Registrant, Citigroup Global Markets, Inc. and Cantor Fitzgerald &amp; Co., date May 21, 2018 (incorporated by reference to the Registrant's Current Report on Form 8-K, filed on May 21, 2018).</u></a>   |
| 10.20   | <a href="#"><u>Fourth Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated June 29, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 3, 2018).</u></a>  |
| 10.21   | <a href="#"><u>Second Amendment to Loan and Security Agreement, by and between the Registrant and Pacific Western Bank, dated July 27, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 31, 2018).</u></a>   |
| 21.1*   | <a href="#"><u>List of subsidiaries of the Registrant.</u></a>  |
| 23.1*   | <a href="#"><u>Consent of Independent Registered Public Accounting Firm.</u></a>  |
| 24.1    | <a href="#"><u>Power of Attorney. Reference is made to the signature page hereto.</u></a>   |
| 31.1*   | <a href="#"><u>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.</u></a>  |
| 31.2*   | <a href="#"><u>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.</u></a>  |
| 32.1*   | <a href="#"><u>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.</u></a>   |
| 32.2*   | <a href="#"><u>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.</u></a>   |
| 101.INS | XBRL Instance Document  |
| 101.SCH | XBRL Taxonomy Extension Schema Document   |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document   |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document  |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document.  |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document.   |

+ Indicates management contract or compensatory plan.

\* Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission

## 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: February 28, 2019

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 James Levine, 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.

| <u>Name</u>  | <u>Title</u>   | <u>Date</u>       |
|--|--|-------------------|
| <u>/s/ Jeffrey Stein, Ph.D.</u><br><b>Jeffrey Stein, Ph.D.</b>         | President and Chief Executive Officer<br><i>(Principal Executive Officer)</i>                    | February 28, 2019 |
| <u>/s/ James Levine</u><br><b>James Levine</b>                         | Chief Financial Officer<br><i>(Principal Financial Officer and Principal Accounting Officer)</i> | February 28, 2019 |
| <u>/s/ Scott M. Rocklage, Ph.D.</u><br><b>Scott M. Rocklage, Ph.D.</b> | Chairman of the Board of Directors   | February 28, 2019 |
| <u>/s/ Daniel D. Burgess</u><br><b>Daniel D. Burgess</b>               | Member of the Board of Directors   | February 28, 2019 |
| <u>/s/ Timothy R. Franson, M.D.</u><br><b>Timothy R. Franson, M.D.</b> | Member of the Board of Directors   | February 28, 2019 |
| <u>/s/ David Gollaher, Ph.D.</u><br><b>David Gollaher</b>              | Member of the Board of Directors   | February 28, 2019 |
| <u>/s/ Chrysa Mineo</u><br><b>Chrysa Mineo</b>                         | Member of the Board of Directors   | February 28, 2019 |
| <u>/s/ Theodore R. Schroeder</u><br><b>Theodore R. Schroeder</b>       | Member of the Board of Directors   | February 28, 2019 |



**Cidara Therapeutics, Inc. Subsidiaries**

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

| <u>Name</u>                           | <u>Country or State of Incorporation</u> |
|---------------------------------------|--|
| Cidara Therapeutics UK Limited        | United Kingdom                           |
| Cidara Therapeutics (Ireland) Limited | Ireland                                  |

**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 Nos. 333-211472, 333-221535, 333-225061, 333-225445, 333-225787, and 333-228268) of Cidara Therapeutics, Inc., and
- (2) Registration Statements (Form S-8 Nos. 333-216722, 333-203434, 333-210263, and 333-228282) pertaining to the 2013 Stock Option and Grant Plan, the 2015 Equity Incentive Plan, and the 2015 Employee Stock Purchase Plan of Cidara Therapeutics, Inc.;

of our report dated February 28, 2019, with respect to the consolidated financial statements of Cidara Therapeutics, Inc. included in this Annual Report (Form 10-K) of Cidara Therapeutics, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

San Diego, California

February 28, 2019



**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, James Levine, 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 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: February 28, 2019

By: \_\_\_\_\_ /s/ James Levine

**James Levine**  
**Chief Financial Officer**  
**(Principal Financial Officer and Principal Accounting Officer)**

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**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, 2018 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, James Levine, Chief Financial Officer of the Company, 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: February 28, 2019

By:

\_\_\_\_\_  
/s/ James Levine

**James Levine**  
**Chief Financial Officer**

**(Principal Financial Officer and Principal Accounting Officer)**

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cidara Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.