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, 2019

OR

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

Commission File Number 001-36912

CIDARA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which is registered
Common Stock, $.0001 Par Value	"CDTX"	The Nasdaq Stock Market LLC

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 o 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 o 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 o

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 o

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	o	Accelerated filer	o
Non-accelerated filer	x	Small reporting company	x
Emerging growth company	x		

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. o

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o 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, 2019, was approximately $43.5 million.

The number of shares of Registrant's common stock outstanding as of February 25, 2020 was 40,513,558.

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 2020 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, 2019.

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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 and prevention of diseases that are inadequately addressed by current standard of care therapies. We are developing a pipeline of product and development candidates, with a focus on serious fungal and viral 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 first-line treatment and prevention of serious, invasive fungal infections. In addition, we are using our Cloudbreak® platform to develop Antiviral Fc-Conjugates, or AVCs, for the prevention and treatment of influenza and other viral 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
- an opportunity to commercialize products for indications in both treatment and prevention of infectious disease.

While the advantages above apply to many product candidates in the anti-infectives market, we are focused on the antifungal and antiviral segments. We believe these are commercially more attractive segments of the market, particularly when compared to the antibacterial segment. For example, rezafungin will be positioned in 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 first-line treatment and prevention of serious, invasive fungal infections which are associated with high mortality rates.

STRIVE Phase 2 clinical trial

In July 2019, we reported positive topline results from Part B of our global, randomized Phase 2 STRIVE clinical trial of rezafungin. We previously reported topline results from Part A of the STRIVE clinical trial in March 2018. References to our STRIVE clinical trial below include results from both Parts A and B collectively of the STRIVE clinical trial. STRIVE was 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 the STRIVE clinical trial, rezafungin met all of its objectives for efficacy, safety and tolerability in the treatment of patients with candidemia and/or invasive candidiasis.

Phase 3 clinical trials

Our Phase 3 clinical development plans for rezafungin are as follows:

- 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 ReSTORE clinical trial protocol is modeled after our Phase 2 STRIVE clinical trial. Rezafungin dosed 400 mg for the first week followed by 200 mg once weekly for up to four weeks in total, is being compared to caspofungin dosed daily with an optional step down to oral fluconazole, in a 1:1 randomization regime. The primary efficacy outcome for the U.S. Food and Drug Administration, or FDA, is all-cause mortality at day 30, and the primary efficacy outcome for the European Medical Agency, or EMA, is global response (clinical, radiological, and mycological response) at day 14. We expect this trial to enroll approximately 184 evaluable patients. We previously announced that we expect topline results from the ReSTORE trial in late-2020. We are closely monitoring a number of factors affecting our enrollment and clinical trial operations, including the effect of the COVID-19 coronavirus, and we are taking steps to mitigate this impact. Based on the current information available to us, we expect our topline data will be delayed into the first half of 2021. We expect that the results of the ReSTORE clinical trial, along with the results

from the STRIVE clinical trial, will be sufficient to support the submission of marketing approval applications for rezafungin in this indication.

- 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*. Rezafungin will be dosed at 400 mg for the first week followed by 200 mg once weekly doses out to 90 days, 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 and EMA is fungal-free survival at day 90. We expect this trial to enroll approximately 462 patients. We expect to commence the ReSPECT clinical trial initially in Europe and/or Canada in the first quarter of 2020. Commencement of the ReSPECT clinical trial in the United States is contingent upon obtaining agreement with the FDA. We expect that the results of the ReSPECT clinical trial, along with the results from the ReSTORE clinical trial, will be sufficient to support the submission of marketing approval applications for rezafungin in this indication.

Mundipharma Collaboration

On September 3, 2019, we announced a strategic partnership with Mundipharma Medical Company, or Mundipharma, to develop and commercialize rezafungin in an intravenous formulation for the treatment and prevention of invasive fungal infections. Under the terms of the collaboration agreement, we granted Mundipharma exclusive commercialization rights to rezafungin outside the United States and Japan. Mundipharma AG also made a concurrent $9.0 million equity investment in our company. The total potential transaction value is $568 million, including the equity investment, an up-front payment, global development funding, and certain development, regulatory, and commercial milestones. To date, we have received $9.0 million from the sale of our equity to Mundipharma, $30.0 million in up-front payments and $0.7 million in global development funding. We expect to receive an additional $41.6 million in near-term funding, the majority of which we expect to receive in 2020.

Cloudbreak® Platform

We believe our Cloudbreak platform is a fundamentally new approach to prevent and treat life-threatening infectious disease that provides potent antimicrobial activity and immune system engagement in a single long-acting molecule. The Cloudbreak platform recognizes that infectious disease often results when a microbial pathogen is able to evade or overcome the host immune system. Our Cloudbreak candidates are designed to counter infection in two ways, by directly targeting and destroying invading pathogens and by focusing the immune system at the site of infection. We believe this is a potentially transformative approach, distinct from current therapies, monoclonal antibodies and vaccines. Our lead Cloudbreak candidates are Antiviral Fc-Conjugates, or AVCs, for the prevention and treatment of influenza. The Cloudbreak platform has enabled us to expand the development of AVCs to target other life-threatening viruses including HIV and RSV.

We have generated preclinical, in vivo proof of concept data for our Cloudbreak influenza program. In July 2019, we began conducting studies in support of a future investigational new drug application on our lead development candidate, CD377 for influenza prevention and pandemic preparedness.

Our Strategy

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

- **Advance rezafungin to commercialization.** We plan to leverage the favorable regulatory environment for anti-infectives to expedite the development of rezafungin.
- **Develop product candidates from our Cloudbreak antiviral platform.** We expect to progress our lead development candidate, CD377 for influenza prevention and treatment, towards a future investigational new drug application and evaluate new antiviral development candidates in other indications, such as HIV and RSV, alone or through new partnerships we may consider. 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 rezafungin in the United States, addressing the relatively small base of well-defined customers for the treatment and prevention of invasive fungal infections in both the hospital and outpatient settings. In geographies outside the United States and Japan, our strategic partner Mundipharma has the right to commercialize rezafungin.

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_{max}, or maximum concentration reached, safety and tolerability profile, lack of drug-drug interactions, tissue penetration and high AUC, or area under the curve, which measures the overall drug exposure per dose.

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, blood and marrow transplantation (BMT), chemotherapy and other forms of immune suppression.

We estimate that the annual worldwide sales of prescription systemic antifungals in 2017 were approximately $4.2 billion. This includes therapies used as prophylaxis (preventive) in the inpatient and outpatient setting, particularly in patients with hematologic malignancies such as acute myeloid leukemia, or AML, or those undergoing BMT, 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 U.S. Centers for Disease Control and Prevention, or 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 limited number of fungal-specific drug targets for research and a previously challenging regulatory environment that necessitated large and costly clinical trials. As a result, the number of antifungals has decreased to only one new approval since 2006, 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 significant changes in a drug's effect on the body when taken together with a second drug, or drug-drug interactions, or DDIs. In the hematology setting, patients are at increased risk for serious DDIs given many newly approved therapies used to treat blood cancers have contraindications or precautions when taken with azole antifungals, the current standard of care for antifungal prophylaxis. For prevention of PCP, trimethoprim/sulfamethoxazole, or TMP/SMX, known as Bactrim, is the agent of choice for first-line prophylaxis. Challenges with TMP/SMX include bone marrow suppression, allergies, and nephrotoxicity.

Current prophylaxis requires multiple drugs for coverage of common pathogens. The complex nature of the immunocompromised patient and the complexity of the current antifungal drugs used today for prophylaxis (azoles and TMP/SMX), create significant opportunity for improvement.

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 that echinocandins have demonstrated statistical superiority to azoles for the initial treatment of candidemia and invasive candidiasis, and now recommend echinocandins as first-line treatment for this indication.

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 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 order to be effective, an echinocandin drug should be present early in therapy at an exposure that is as high as is safely possible. The key pharmacokinetic parameters affecting exposure include the drug's half-life, C_{max} and AUC. The maximum dose that can be used is based on the drug's overall safety profile. With echinocandin drugs, high drug exposures early in therapy, as measured by C_{max} or AUC, maximize the antifungal therapeutic benefit of these drugs.

When a fungus starts to develop resistance to a drug, the 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_{max} and an AUC that are far greater than the starting MIC provides the best chance of treating infections caused by strains resistant to other antifungals, including other echinocandins. 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_{97} 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_{max} 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 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 QIPD 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

Phase 2: The STRIVE Clinical Trial

In July 2019, we reported topline results from Part B of our global, randomized Phase 2 STRIVE clinical trial of rezafungin. We previously reported topline results from Part A of the STRIVE clinical trial in March 2018. References to our STRIVE clinical trial below include results from both Parts A and B collectively of the STRIVE clinical 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. The STRIVE clinical trial enrolled 183 patients in the microbiological intent-to-treat, or mITT, population. Patients were randomized to receive either 400 mg of rezafungin administered intravenously once weekly for two to four weeks, 400 mg of rezafungin for the first week followed by 200mg of rezafungin once weekly for an additional one to three weeks, or daily caspofungin administered intravenously according to the approved prescribing information, with an optional step down to oral fluconazole. In the STRIVE clinical trial, rezafungin met all of its objectives for efficacy, safety and tolerability in the treatment of patients with candidemia and/or invasive candidiasis.

The STRIVE Phase 2 results show that patients treated with rezafungin had numerically improved outcomes as compared to caspofungin across all efficacy measures at the 400 mg/200 mg dosing regimen selected for the ReSTORE Phase 3 trial. Data from the clinical trial indicated that a 400mg/200mg dosing regimen of rezafungin had lower All Cause Mortality at Day 30 (4.3%), higher Clinical Response at Day 14 (80.4%), and a higher Overall Success at Day 14 (76.1%) when compared with once daily caspofungin (13.1%, 70.5%, and 67.2%, respectively).

Rezafungin was generally well-tolerated at both dosing regimens. Treatment Emergent Adverse Events, or TEAEs, were observed in most patients, with an incidence of 87.7% in Group 1, 92.5% in Group 2, and 80.9% in Group 3. The rates of serious adverse events were 43.2%, 52.8%, and 42.6%, respectively. There were 11 adverse events leading to study drug discontinuation across all study groups: six in Group 1, one in Group 2 and four in Group 3.

There were four serious adverse events possibly related to study drug: one in Group 1, one in Group 2 and two in Group 3, and both rezafungin 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.

In addition, a post-hoc analysis evaluated the STRIVE Phase 2 clinical trial endpoints of Day 30 All-Cause Mortality and Day 14 Clinical Response, which represent the FDA and EMA primary endpoints, respectively, for the ReSTORE Phase 3 clinical trial. For the two cohorts considered, the 400 mg/200 mg rezafungin dosing regimen (Phase 3 ReSTORE clinical trial regimen) and the combined 400 mg/200 mg and 400 mg/400 mg dosing regimens, the results from the post hoc analysis of STRIVE showed that, for both primary endpoints, the limits of the 95% confidence intervals for both cohorts were within the 20% noninferiority margins that will be applied to evaluate the data generated by the ReSTORE clinical trial.

Phase 1: Hepatic Impairment Study

In January 2020, the first subject was enrolled into our Phase 1 Hepatic Impairment study. The study is an open label, single dose study design to evaluate the safety, tolerability, and pharmacokinetics of rezafungin in adult subjects with hepatic impairment relative to matched controls. The study is expected to be completed in late 2020.

Phase 1: Subcutaneous Formulation Trial

In December 2019, the National Institutes of Health initiated a Phase 1 trial to evaluate safety, tolerability, and pharmacokinetics for a subcutaneous formulation of rezafungin.

Phase 1: AME Study

In May 2019, we completed our Phase 1, single-center, open-label study to evaluate the excretion, metabolism, pharmacokinetics, and mass balance following a single intravenous dose of radiolabeled rezafungin in healthy adult male subjects. The primary route of excretion was via the feces. Rezafungin concentrations and radiolabeled rezafungin equivalents were quantifiable at all scheduled postdose collections through Day 60. Rezafungin underwent minimal metabolism in human subjects. A single dose of radiolabeled rezafungin was well tolerated.

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 representing the most common metabolic (CYP enzymes) and transporter pathways. 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: Photosafety Study

In March 2018, we completed our phase 1, multiple-dose, assessor-blinded study to determine the photosensitivity of rezafungin when administered intravenously as multiple doses to healthy adult subjects. The pharmacokinetic profile of multiple doses of rezafungin was comparable to prior studies of rezafungin. Based on the results of this study, the increased risk for photosensitivity in subjects who are administered rezafungin is mild. Overall, Rezafungin for Injection was well tolerated by healthy adult subjects.

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.

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_{max} 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.

Clinical Development Plan

Our Phase 3 clinical development plans for rezafungin are as follows:

- 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 ReSTORE clinical trial protocol is modeled after our Phase 2 STRIVE clinical Trial. Rezafungin dosed 400 mg for the first week followed by 200 mg once weekly for up to four weeks in total, is being compared to caspofungin dosed daily with an optional step down to oral fluconazole, 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 evaluable patients. We previously announced that we expect topline results from the ReSTORE trial in late-2020. We are closely monitoring a number of factors affecting our enrollment and clinical trial operations, including the effect of the COVID-19 coronavirus, and we are taking steps to mitigate this impact. Based on the current information available to us, we expect our topline data will be delayed into the first half of 2021. We expect that the results of the ReSTORE clinical trial, along with the results from the STRIVE clinical trial, will be sufficient to support the submission of marketing approval applications for rezafungin in this indication.
- 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. Rezafungin will be dosed at 400 mg for the first week followed by 200 mg once weekly doses out to 90 days, 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 and EMA is fungal-free survival at day 90. We expect this trial to enroll approximately 462 patients. We expect to commence the ReSPECT clinical trial initially in Europe and/or Canada in the first quarter of 2020. Commencement of the ReSPECT clinical trial in the United States is contingent upon obtaining agreement with the FDA. We expect that the results of the ReSPECT clinical trial, along with the results from the ReSTORE clinical trial, will be sufficient to support the submission of marketing approval applications for rezafungin in this indication.

Cloudbreak Platform

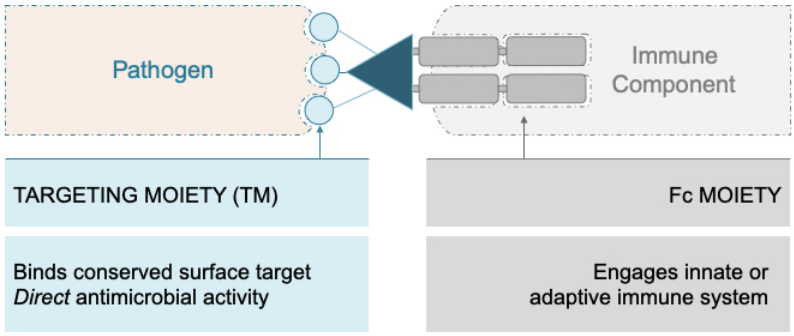
The Cloudbreak platform is a fundamentally new approach to the fight against life-threatening infectious disease that provides potent antimicrobial activity and immune system engagement in a single molecule. Our lead Cloudbreak candidates are Antiviral Fc-Conjugates, or AVCs, for the prevention and treatment of influenza. The Cloudbreak platform has enabled us to expand the development of AVCs to target HIV, RSV and other life-threatening viruses.

The Cloudbreak platform recognizes that most infectious disease results when a microbial pathogen is able to evade or overcome the host immune system. Our Cloudbreak candidates are designed to counter infection in two ways, by directly targeting and destroying invading pathogens and by focusing the immune system at the site of infection. In this way, Cloudbreak anti-infective candidates are similar to certain cancer immunotherapies that unlock the potential of the immune system to destroy cancer cells.

Cloudbreak candidates targeting viral infections are called AVCs, single molecules consisting of two distinct moieties with discrete, yet complementary mechanisms of action:

- Targeting Moiety (TM): Novel and highly potent small molecule that binds surface targets on the pathogen to directly destroy it and/or inhibit replication.
- Effector Moiety (EM): Fragment crystallizable, or Fc, region of human IgG1 antibodies, which was selected to maximize engagement of the human immune system via Fc-gamma, or Fcy, receptors and for its long half-life.

AVCs not only mediate pathogen clearance through a multimodal mechanism of action but also have potential for months of activity with a single dose.



Cloudbreak AVC (Antiviral Fc Conjugate) Program Overview

Cidara is leveraging the Cloudbreak Platform to develop multiple AVCs. Each AVC targets a life-threatening virus. Our AVC research and development programs include:

- Influenza;
- HIV;
- RSV; and
- Other viruses.

AVCs provide direct, sustained antiviral activity as well as immune system engagement, for effective prevention and treatment of disease. This is a potentially transformative approach, distinct from current approaches. They are not vaccines, small-molecule drugs, or monoclonal antibodies. AVCs are novel, Fc-conjugates designed for the following features:

- Multimodal mechanism of action: Potent, direct antiviral activity and immune system engagement
- Strong target binding: High affinity to an essential, conserved target on the virus surface
- Long duration of action: Months of protection from disease with a single dose
- Rapid onset: Rapid distribution to site of infection for treatment of disease

Cloudbreak Influenza Program and Our Lead AVC Development Candidate CD377

Influenza, or flu, is a respiratory infection caused by influenza viruses. The influenza 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 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 influenza is the seasonal vaccine, which remains the best mode to prevent influenza related illness, despite its limitations. However, the efficacy of the vaccine varies, with recent studies estimating that the influenza vaccine reduces the risk of influenza 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 such as the 2018-2019 influenza season when the CDC estimated vaccine effectiveness to be 29% in the US, 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®);
- zanamivir (Relenza®);

- peramivir (Rapivab®); and
- 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.

Potential Advantages of Cloudbreak AVCs for Influenza

- **Broad-Spectrum, Universal Coverage:** Cloudbreak AVCs have demonstrated activity against pandemic and seasonal influenza A and B viruses, including resistant strains (e.g. oseltamivir-resistant H1N1) and strains with high pandemic potential (e.g. H5N1, H7N9)
- **Superior Resistance Profile:** AVCs may be less prone to viral resistance, by virtue of the AVC multimodal mechanism of action
- **Protection for High-Risk Populations:** Unlike vaccines, the potent intrinsic activity of the AVCs should provide antiviral protection independent of immune system status. Even in immune-compromised patients, AVCs can focus the existing immune system at the site of infection
- **Seasonal and Pandemic Readiness:** AVCs are well-suited for immediate and robust response to influenza challenges by providing rapid onset of protection and coverage of strains that may have been missed by the seasonal vaccine. Moreover, AVCs are not subject to the lengthy and unpredictable process of vaccine manufacturing
- **Long Duration of Action:** A single AVC dose may protect from influenza for an entire flu season

Our Lead AVC Development Candidate for Influenza: CD377

Pre-Clinical Studies of CD377 for Influenza

We plan to develop novel AVCs that provide a direct and sustained antiviral effect and engage the immune system for additional potency. The results of multiple preclinical studies of CD377 indicate that it is effective in both the treatment and prevention of influenza infections.

In Vitro Studies Measuring CD377 Potency Against Multiple Influenza Strains

We evaluated CD377 *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 2009 H1N1 pandemic strain, H3N2 and H5N1, H1N1 oseltamivir (Tamiflu)-resistant strain, as well as Influenza B. CD377 showed potent activity against all of the strains tested, including influenza B, which is less sensitive to oseltamivir phosphate.

In Vivo Studies Measuring CD377 Potency Against Multiple Influenza Strains in Lethal Infection Models

We evaluated CD377 *in vivo* in lethal mouse models of H1N1 and H3N2 compared to oseltamivir phosphate. CD377 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. CD377 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 CD377. The CD377 dosed mice maintained stable body weights over the 14 day course of the experiment demonstrating the potency of CD377 at low doses and the potency and tolerability of CD377 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 and cynomolgus monkeys indicate the potential for a broad safety margin for CD377 with no signs of acute or chronic toxicity at over 100-fold the efficacious dose in prophylactic efficacy models.

In Vivo Study Evaluating CD377 as a Long-Acting Prophylactic Agent Against Influenza

We tested mean plasma concentrations of CD377 in mice and based on the long half life we observed, we evaluated CD377 *in vivo* in a lethal mouse model of H1N1 by administering CD377 to the mice 28 days before we administered the lethal influenza challenge. CD377 provided 100% protection from mortality across a broad range of dose levels, demonstrating its potential suitability as a long-acting prophylactic agent for seasonal prevention.

In Vivo Study Measuring CD377 Treatment Window Against Influenza

We evaluated CD377 and oseltamivir phosphate *in vivo* in a lethal mouse model of H1N1 by challenging the mice with the influenza virus and then administering antiviral treatment at different time periods after challenge. CD377 and oseltamivir phosphate both provided 100% protection against influenza 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 CD377 was more effective at reducing mortality than multiple doses of oseltamivir phosphate.

License and Collaboration Agreements

Mundipharma Collaboration Agreement

In September 2019, we entered into a Collaboration and License Agreement, or the Mundipharma Collaboration Agreement with Mundipharma for a strategic collaboration to develop and commercialize rezafungin in an intravenous formulation, or the Licensed Product, for the treatment and prevention of invasive fungal infections.

Collaboration. Under the Mundipharma Collaboration Agreement, we will be responsible for leading the conduct of an agreed global development plan, or the Global Development Plan, that includes our ongoing Phase 3 ReSTORE Treatment Trial of the Licensed Product for the treatment of candidemia and/or invasive candidiasis our planned Phase 3 ReSPECT Prophylaxis (Prevention) Trial of the Licensed Product, as well as specified GLP-compliant non-clinical studies and chemistry, manufacturing and controls, or CMC, development activities for the Licensed Product. Mundipharma will be responsible for performing all development activities, other than Global Development Plan activities, that may be necessary to obtain and maintain regulatory approvals for the Licensed Product outside of the U.S. and Japan, or the Munipharma Territory, at Mundipharma's sole cost.

Licenses. Pursuant to the Mundipharma Collaboration Agreement, we granted Mundipharma an exclusive, royalty-bearing license to develop, register and commercialize the Licensed Product in the Munipharma Territory, subject to our retained right to lead a global development program for the Licensed Product in both the Mundipharma Territory and in the United States and Japan, or the Company Territory, as described below.

The Company also granted Mundipharma an option to obtain exclusive licenses to develop, register and commercialize rezafungin in a formulation for subcutaneous administration, or Subcutaneous Product, and in formulations for other modes of administration, or Other Products, in the Mundipharma Territory, subject to similar rights retained by us to conduct mutually agreed global development activities for such products. In addition, we granted Mundipharma a co-exclusive, worldwide license to manufacture the Licensed Product and rezafungin.

Until the seventh anniversary of the first commercial sale of the Licensed Product in the Mundipharma Territory, each party has granted the other party an exclusive, time-limited right of first negotiation to obtain a license to any anti-fungal product (other than Licensed Product, Subcutaneous Product and Other Products) that such party proposes to out-license in the other party's territory. However, in the event of the acquisition of a party by a third party, this right of first negotiation will not apply to any such anti-fungal product of the acquiring third party prior to consummation of the acquisition of such party, acquired by such acquiring third party from another third party after consummation of the acquisition of such party, or developed internally by the acquiring third party, either before or after consummation of the acquisition of such party, without the use of, reliance upon or reference to any technology of the acquired party that is licensed to the other party under the Mundipharma Collaboration Agreement, any technology of the other party that is licensed to the acquired party under the Mundipharma Collaboration Agreement, or any technology jointly developed by the parties pursuant to the Mundipharma Collaboration Agreement.

Our Retained Rights. We retain the exclusive right to develop, register and commercialize the Licensed Product, Subcutaneous Product and Other Products in the Company Territory, and Mundipharma has granted us certain licenses under Mundipharma-controlled technology and jointly-developed technology to develop, register and commercialize Licensed Product, Subcutaneous Product and Other Products in the Company Territory and to manufacture such products and rezafungin worldwide.

Financial Terms. We and Mundipharma agreed to share equally (50/50) the costs of Global Development Plan activities, or Global Development Costs, subject to a cap on Mundipharma's Global Development Cost share of $31.207 million. We would receive additional financial support for Global Development Plan activities through a near-term milestone payment by Mundipharma of $11.145 million. Mundipharma is entitled to credit the full amount of this milestone payment toward

future royalties payable to us, subject to a limit on the amount by which royalty payments to us may be reduced in any quarter. If Mundipharma has not fully credited the amount of such milestone payment toward royalties payable to us before the earlier of (i) December 31, 2024 and (ii) termination of the Mundipharma Collaboration Agreement by Mundipharma, we will be obligated to refund the uncredited portion of such milestone payment to Mundipharma on the earlier of such dates.

In addition to the cost-sharing and the $11.145 million milestone payment described above, we will received under the Mundipharma Collaboration Agreement a $30 million upfront payment, and may receive up to $523.267 million in development, regulatory and commercial milestone payments (which includes milestone payments on the Licensed Product and up to $25.076 million in regulatory milestone payments related to Subcutaneous Product that we will become eligible for should Mundipharma exercise its option with respect to Subcutaneous Product), as well as double-digit royalties on tiers of annual net sales of the Licensed Product in the Mundipharma Territory in the teens.

Termination. Either party may terminate the Mundipharma Collaboration Agreement for uncured material breach by the other party. After September 3, 2020, Mundipharma may terminate the Mundipharma Collaboration Agreement at will, provided that if Mundipharma terminates the Mundipharma Collaboration Agreement in its entirety prior to the last visit of the last patient in both the ReSPECT Trial and the ReSTORE Trial, Mundipharma will continue to be liable for its share of Global Development Costs as described above. We may terminate the Agreement if Mundipharma or any of its affiliates or sublicensees, directly or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any of our patent rights licensed to Mundipharma, or upon an insolvency event of Mundipharma.

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 an NDA to the FDA as necessary to provide sufficient commercial quantities of each product.

Intellectual Property

The proprietary nature of, and protection for, rezafungin, our AVCs, 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 March 3, 2020, 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.

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 are generic versions of one or more of the current echinocandins available now, which will create added competition at the time of rezafungin regulatory approval. 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 vaccines for influenza and approved 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.

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.

Clinical Trials

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

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

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

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

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to a substantial application 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.

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. 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 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 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, as defined by such law, 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, 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. There remain 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". Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. 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 December 2018, the Centers for Medicare & Medicaid Services, or CMS, published a new 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions,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 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs 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 solicited feedback on some of these measures and has implemented others under its existing

authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning on January 1, 2020. The final rule codified a CMS policy change that was effective January 1, 2019. While some of these and other proposed measures may require additional authorization 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 25, 2020, we had 68 total employees, all of whom were full-time employees, and 22 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) ended December 31, 2020, (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 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. 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.

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 program, neither of which may be successful.

We have completed six Phase 1 clinical trials of rezafungin, as well as the STRIVE Phase 2 clinical trial of rezafungin for the treatment of candidemia and invasive candidiasis. We are currently conducting two additional Phase 1 clinical trials of rezafungin and the ReSTORE Phase 3 clinical trial of rezafungin for treatment of candidemia and invasive candidiasis. We expect to commence the ReSPECT Phase 3 clinical trial of rezafungin for prophylaxis in patients undergoing allogeneic blood and marrow transplants initially in Europe and / or Canada in the first quarter of 2020. Commencement of the ReSPECT trial in the US is contingent upon obtaining agreement with the FDA. Completion of our planned Phase 3 trials is contingent on our ability to secure adequate additional funding. We are also conducting preclinical studies of AVCs in our Cloudbreak program for viral infections. Our assumptions about why rezafungin is worthy of continued development, as well as our assumptions about the market for rezafungin or any potential products from our Cloudbreak program, are based on data primarily collected by other companies. The timing and costs of our preclinical and clinical development programs, the likelihood of marketing approval for rezafungin, and the regulatory paths for marketing approval for products from our Cloudbreak program 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:

- our ability to secure adequate additional funding;
- agreement with regulatory authorities on study design and other requirements for study initiation;
- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials;
- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;

- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and technologies;
- launching commercial sales of the product candidates if and when approved;
- 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 reach agreement with regulatory authorities on requirements for study initiation, timely enroll the ReSTORE and ReSPECT Phase 3 clinical trials, or if we are unable to secure additional funding, we will not be able to complete the Phase 3 clinical development plans for rezafungin. If we do not accomplish one or more of any of the other goals in a timely manner, or at all, we could experience significant delays or an inability to successfully complete the development of and commercialize our product candidates, which would harm our business.

If we experience delays or difficulties in enrolling patients in the ReSTORE or ReSPECT clinical trials, our timing to complete the rezafungin clinical development program, and therefore our receipt of necessary regulatory approvals, could be delayed or prevented.

We may not be able to complete the ReSTORE or ReSPECT clinical trials if we are unable to identify and enroll a sufficient number of eligible patients, 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 can be enrolled in a reasonable timeframe.

Our rezafungin Phase 3 clinical development program is a global program and, as such, our ability to timely enroll the ReSTORE and ReSPECT clinical trials may be affected by many different factors specific to those global localities, such as, delays in our receipt of approval to commence our Phase 3 clinical trials in a particular country from applicable regulatory authorities and ethics committees, timely completion of clinical trial site initiation within each country, delays in local importation and receipt of necessary clinical trial supplies, and our ongoing compliance with local regulations, which may change during the course of the clinical trial. In addition, the ReSTORE and ReSPECT clinical trials are heavily reliant on third-party contractors, including contractors that import clinical trial materials, and contract research organizations that conduct and monitor our clinical trials, and interact with regional or local regulators and ethics committees on our behalf. If we experience significant difficulties with any of our key contractors such that we determine it is in the best interests of the clinical trials to replace a key contractor, this could result in a significant delay in enrollment.

Additionally, timely enrollment in the ReSTORE and ReSPECT trials is reliant on global clinical trial sites which may be adversely affected by global health matters, such as pandemics. For example, clinical trial sites located in Asia, including China and South Korea, are an important part of our ReSTORE clinical trial and clinical trial sites located in Europe are an important part of both the ReSTORE and ReSPECT trials, and these regions are currently being afflicted by the COVID-19 coronavirus. Some factors from the COVID-19 coronavirus outbreak that we believe have adversely affected enrollment in our Phase 3 trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials,;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and
- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

These and other factors arising from the COVID-19 coronavirus could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact our Phase 3 trials. The global outbreak of the COVID-19 coronavirus continues to evolve and the conduct of our Phase 3 trials may continue to be adversely affected, despite efforts to mitigate this impact.

In addition, some of our competitors may have ongoing or new clinical trials for product candidates that would treat the same indications as rezafungin, 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 may also be affected by other factors, including:

- eligibility criteria, including regional or local practices that place additional limitations on patient eligibility;
- availability, safety and efficacy of approved medications or other investigational medications being studied clinically for the disease under investigation;
- perceived risks and benefits of rezafungin;
- 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 rezfungin addresses.

Our inability to enroll a sufficient number of patients in a reasonable timeframe may require us to abandon the entire rezafungin Phase 3 clinical development program or terminate one of our Phase 3 clinical trials. Enrollment delays in ReSTORE or ReSPECT will result in increased development costs, which could cause the value of our company to decline and could limit our ability to obtain necessary additional financing.

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 complete our rezafungin Phase 3 development program is dependent on our ability to secure adequate additional funding, and our ability to commence the ReSPECT Phase 3 clinical trial is also subject to the approval of the 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 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 our ReSTORE Phase 3 clinical trial for treatment, nor does it indicate whether our planned ReSPECT Phase 3 clinical trial for prophylaxis will be successful.

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 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 ReSPECT Phase 3 clinical trial for prophylaxis will begin on time or at all, or whether either ReSTORE or ReSPECT will be completed on schedule, or at all. We may experience numerous unforeseen events 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;
- 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 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 AVCs, 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, 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.

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

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

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

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

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.), and 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 or prevention of viral influenza infections, including neurominidase 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 reported topline data from Part B of our STRIVE Phase 2 clinical trial in July 2019. The topline data was 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 intend to enroll in the ReSPECT Phase 3 clinical trial. There can be no guarantee that a favorable futility 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.

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 AVCs for the treatment of viral infections. We have nominated the AVC CD377 as our lead Cloudbreak development candidate for influenza. It is structurally similar to previously announced development candidates. Our Cloudbreak platform may not be successful in identifying additional AVCs 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 limited 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 successfully advance this program and identify future product candidates. 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 complete the development of rezafungin and to advance our Cloudbreak program.

In connection with the preparation of our financial statements for the period ended December 31, 2019, 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 not be sufficient to fund our obligations for the next twelve months. Our ability to continue to fund the development of rezafungin through completion of our planned Phase 3 trials depends on our ability to obtain additional funding. Our ability to advance our Cloudbreak program is also dependent on our ability to obtain additional funding.

On September 3, 2019, we entered into a collaboration and development agreement for rezafungin with Mundipharma Medical Company, the Mundipharma Collaboration, pursuant to which we granted Mundipharma exclusive commercialization rights to rezafungin outside the U.S. and Japan in exchange for a $30 million upfront payment, near-term funding to support the global Phase 3 ReSTORE and ReSPECT trials, and the potential to receive development, regulatory and commercial milestone payments and double-digit royalties on product net sales. The Mundipharma Collaboration requires, among other things, that we complete the rezafungin development program. Our ability to meet our development obligations under the rezafungin collaboration depends on our ability to obtain additional funding.

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. 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.

Even if we raise additional capital, 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, manufacturing 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.

Identifying potential development candidates and conducting preclinical studies, manufacturing development 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, 2019, our operations have been financed primarily by gross proceeds of approximately $309.1 million from equity and debt financings, grant funding and the Mundipharma Collaboration Agreement. As of December 31, 2019, we had cash, cash equivalents, and restricted cash of $60.3 million.

If we are unable to raise additional capital on attractive terms or at all, we may be forced to delay, reduce or eliminate our development programs, including our Cloudbreak program, be unable to continue the development of rezafungin, complete the ReSTORE and ReSPECT Phase 3 clinical trials and meet our development obligations under the Mundipharma collaboration and/or be forced to make reductions in spending, extend payment terms with suppliers, and/or liquidate or grant rights to assets where possible. 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, debt or other financing structures, receipt of payments under the Mundipharma collaboration agreement, as well as potentially entering into other collaborations, strategic alliances or licensing arrangements with third parties 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 and, other than the Mundipharma collaboration, it is our only current committed external source of funds, subject to the fulfillment of specified conditions.

In September 2019, we issued $9.0 million of our common stock to Mundipharma in connection with entering into the Mundipharma Collaboration Agreement. In February 2020, we issued $30.0 million of our common stock and series X preferred stock upon the closing of a rights offering. To the extent that we raise additional capital through the sale of equity or convertible debt securities, like the sale of our common stock to Munipharma, the sale of our common stock and Series X Preferred stock issued in our rights offering or the sale of common stock under our controlled equity offering sales agreement, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may be secured by all or a portion of our assets.

If we raise funds by entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. On September 3, 2019, we licensed all rights to rezafungin outside of the United States and Japan to Mundipharma Medical Company in exchange for certain payments and

royalties on net sales. We may need to enter into similar agreements with other third parties for the development and commercialization of rezafungin outside of the Mundipharma territory, or for the development of our Cloudbreak program, which may require we relinquish valuable rights to these products.

If we raise funds through government grants and contracts, we may be subject to restrictions on our operations or certain unfavorable terms. United States government grants and contracts, if available, 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 are unable to raise additional funds through equity, debt or other financing structures, or through collaborations, strategic alliances or licensing arrangements with third parties, or through receiving government and/or charitable grants or contracts, we may be required to delay, reduce or terminate our rezafungin development program, including our ReSTORE and ReSPECT Phase 3 clinical trials, be unable to meet our development obligations under the Mundipharma collaboration, and be unable to continue advancing the Cloudbreak program or be forced to grant rights in the Cloudbreak program that we would otherwise prefer to retain for ourselves.

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, July 2018 and November 2019 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.

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 November 2019, we entered into an amendment to the Loan Agreement that requires we maintain the cash value of the amounts borrowed on hand in our bank account, and a failure to comply with this obligation will also constitute an event of default and allow Pacific Western to declare all obligations immediately due and payable.

In connection with the audit of our 2019 financial statements, we received an unqualified auditor opinion with a going concern explanatory paragraph. Pacific Western may determine that the underlying circumstances resulting in the receipt of a going concern explanatory note in the auditor opinion for our 2019 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.

If we default under the facility, Pacific Western may accelerate all of our repayment obligations. At such time, we may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required. If we are unable to access funds to meet those obligations or to renegotiate the Loan Agreement, Pacific Western could take control of and may sell our pledged assets. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If our assets were liquidated, Pacific Western's right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Pacific Western of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness under the Loan Agreement. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

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 losses were $41.1 million, $59.0 million and $55.7 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had an accumulated deficit of $259.8 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 offering sales agreement with Cantor Fitzgerald & Co., which has since been terminated, our May 2018 registered direct offering of common stock, the payments received in connection with the Mundipharma Collaboration, the sale of our common stock to Mundipharma AG, sales of our common stock during the fourth quarter of 2019 and first quarter of 2020 under our new controlled equity offering sales agreement with Cantor Fitzgerald & Co and sales of our common stock and series X preferred stock in connection with the closing of our rights offering in February 2020. We have devoted substantially all of our financial resources and efforts to research and development. We have completed the STRIVE Phase 2 clinical trial of rezafungin, and are currently conducting the ReSTORE Phase 3 clinical trial of rezafungin, Phase 1 and non-clinical studies of rezafungin, and preclinical studies of our AVCs, and we are planning to commence 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 AVCs 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 our value 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 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 withdrawal of the United Kingdom, or the U.K., from the EU, commonly referred to as "Brexit," may adversely impact our ability to obtain regulatory approvals of our current or future products in the U.K or the EU, result in restrictions or imposition of taxes and duties for importing our products into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our products in the U.K. or the EU.

In January 2020, the U.K. and EU entered into a withdrawal agreement pursuant to which the U.K. formally withdrew from the EU on January 31, 2020. Following such withdrawal, the U.K. entered into a transition period scheduled to end on December 31, 2020, or the Transition Period. During the transition period, the U.K. will remain subject to EU law and maintain access to the EU single market and to the global trade deals negotiated by the EU on behalf of its members. There remains substantial uncertainty surrounding the ultimate impact of Brexit and any associated transition period.

The ultimate effects of Brexit will depend on any agreements the U.K. makes to retain access to EU markets, either during the Transition Period or more permanently. These outcomes could disrupt the markets we serve and the tax jurisdictions in which we operate and create uncertainty and challenges (particularly in the near term) with respect to trading relationships between our U.K. subsidiary and other EU nations. Remaining EU member countries may also seek to make it more difficult for us to trade effectively or competitively in those regions.

Since a significant proportion of the regulatory framework in the U.K. is derived from European Union directives and regulations, Brexit could materially change the regulatory regime applicable to our operations and those of our collaborators, including with respect to potential future marketing authorizations for our current and future products. Although during the Transition Period European Union rules will continue to apply, Brexit may lead to legal uncertainty and potentially divergent laws and regulations between the U.K. and the EU as the U.K. determines which EU laws to replicate or replace. We cannot predict whether or not the U.K. will significantly alter its current laws and regulations in respect of the pharmaceutical industry and, if so, what impact any such alteration would have on us or our business.

Further, there is considerable uncertainty resulting from a lack of precedent and the complexity of the U.K. and EU's intertwined legal regimes as to how Brexit will impact the life sciences industry in Europe, including with respect to ongoing or future clinical trials. The impact will largely depend on the model and means by which the U.K.'s relationship with the EU is governed post Brexit. For example, following Brexit, the U.K. will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including our product candidates, will be required in the U.K., the potential process for which is currently unclear. Brexit may adversely affect and delay our ability to commercialize, market and sell our product candidates in the U.K. Brexit may also result in a reduction of funding to the EMA if the U.K. no longer makes financial contributions to European institutions, such as the EMA. If U.K. funding is so reduced, it could create delays in the EMA issuing regulatory approvals for our product candidates and, accordingly, have a material adverse effect on our business, financial condition, results or prospects.

Moreover, there is currently considerable uncertainty in relation to U.K. financial and banking markets in the U.K. following the Transition Period. Furthermore, the U.K. is likely to lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers and could make it more difficult for us and our collaborators to do business in the U.K. In addition, currency exchange rates for the British Pound and the Euro with respect to each other and the U.S. dollar have already been affected by Brexit. Should this foreign exchange volatility continue, it could cause volatility in our quarterly financial results. In any event, we cannot predict to what extent these changes will impact our business or results of operations, or our or our collaborators' ability to continue to conduct operations in Europe or our ability to build and maintain a commercial infrastructure in Europe.

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 are dependent on our collaboration partner to provide funding to continue the development of rezafungin, and for the commercialization of rezafungin outside of the United States and Japan. If the collaboration is not successful, we may not be able to complete the development of rezafungin or capitalize on the full market potential for rezafungin.

On September 3, 2019, we licensed the rights to rezafungin outside of the U.S. and Japan to Mundipharma Medical Company, a large international pharmaceutical company. Our ability to complete the development of rezafungin is dependent, in part, on funds provided by Mundipharma. Additionally, our ability to receive payments from this arrangement will depend on Mundipharma's ability to successfully commercialize rezafungin in its territory.

The Mundipharma Collaboration poses many risks to us, including that our collaborator, Mundipharma:

- has significant discretion in determining the efforts and resources it will apply to commercializing rezafungin in its territory, and may not commit sufficient resources to the marketing and distribution of rezafungin;
- may terminate the collaboration agreement at will;
- may be subject to changes in key personnel or strategic focus, have limited available funding or be subject to other external factors diverting resources or creates competing priorities, all of which could negatively impact the commercialization of rezafungin in its territory;
- may independently develop, or develop with third parties, products that compete directly or indirectly with rezafungin 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;
- may use our intellectual property or 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;
- may not agree with certain development decisions resulting in the delay or termination of the program, or that result in costly litigation or arbitration that diverts management attention and resources; and
- could be involved in a business combination and the continued pursuit and emphasis on rezafungin could be delayed, diminished or terminated.

If our ability to generate revenue under the Mundipharma Collaboration is adversely impacted by these or any other risks, our right to receive additional payments from the Mundipharma Collaboration, including our share of the revenues generated by net sales of rezafungin, if approved, could be insufficient to allow us to complete the rezafungin development program including the ReSTORE and ReSPECT Phase 3 clinical trials, to achieve or maintain profitability or may result in rezafungin being less valuable to us than if we had not entered into the Collaboration.

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

We may seek to collaborate with other pharmaceutical and biotechnology companies to advance the Cloudbreak program, or for the completion of development and commercialization of rezafungin in the U.S. and Japan. We may also seek funding from government grants or contracts to advance the Cloudbreak program. We cannot be certain that we would be successful in completing any such collaboration or obtaining any such government grants or contracts, or completing any of them on commercially reasonable terms.

We face significant competition in seeking appropriate pharmaceutical or biotech collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, on 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, CMC development activities or clinical trials;
- the likelihood of approval by the FDA or similar regulatory authorities outside the United States;
- the potential market for the 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.

We also face significant competition for government grants and contracts for the Cloudbreak program, and there can be no assurances that such funding would be available to us if and when needed, or at all. For instance, government funding may be available only at certain phases of research and development, such as only after Phase 1 clinical trials have been completed. In order to advance the Cloudbreak Program, we will need to obtain significant funding to complete IND-enabling studies, manufacturing development and Phase 1 clinical trials. Government grants and contracts may not be available to fund our activities at this earlier phase of the research and development process.

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. Many of these third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory 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, 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.

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.

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;
- 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 payments to physicians, as defined by such law, 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 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. There remain judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as 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.” Further, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the PPACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. 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 2018, CMS published a new 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the PPACA are invalid as well. It is unclear how this decision, future decisions, 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 2029 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.

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 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. 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 solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning on January 1, 2020. The final rule codified a CMS policy change that was effective January 1, 2019. While some of these and other proposed measures may require additional authorization 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.

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 AVCs 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 AVCs. 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 AVCs 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, 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 AVCs 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 AVC 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 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 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.

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.

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.

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.

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 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 do not maintain “key person” insurance for any of our executives or employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

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

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

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

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

In the future, we may enter into transactions to acquire other businesses, products or technologies and our ability to do so successfully is unproven. If we do identify suitable candidates, we may not be able to make such acquisitions on favorable terms, or at all. Any acquisitions we make may fail to strengthen our competitive position and these transactions may be viewed negatively by customers or investors. We may decide to incur debt in connection with an acquisition or issue our common stock or other equity securities to the stockholders of the acquired company, which would reduce the percentage ownership of our existing stockholders. We could incur losses resulting from undiscovered liabilities of the

acquired business that are not covered by the indemnification we may obtain from the seller. In addition, we may not be able to successfully integrate the acquired personnel, technologies and operations into our existing business in an effective, timely and non-disruptive manner. Acquisitions may also divert management attention from day-to-day responsibilities, increase our expenses and reduce our cash available for operations and other uses. We cannot predict the number, timing or size of future acquisitions or the effect that any such transactions might have on our operating results.

Risks Related to Ownership of our Common Stock

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

The trading price of our common stock is highly volatile and 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:

- changes in the market valuations of similar companies;
- 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 or limitations on the ability of hospitals and outpatient treatment centers to receive adequate reimbursement for the purchase and use of our products;
- 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;
- 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;
- 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, pharmaceutical companies and companies in the anti-infective sector in particular, have experienced extreme price and volume fluctuations that may or may not have been related or proportionate to the operating performance of these companies or their product potential. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

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

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

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

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company through 2020, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (a) December 31, 2020, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1.07 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 33,838,466 shares of common stock outstanding as of December 31, 2019. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate and 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 for the twelve months following the filing of this report. Significant additional capital will be needed to

continue our operations as currently planned, 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.

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

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

Our management will have broad discretion in the application of our working capital. Because of the number and variability of factors that will determine our use of our working capital, its ultimate use may vary substantially from its currently intended use. Our management might not apply our working capital in ways that ultimately increase the value of your investment. We expect to use our working capital to fund research and development activities and general operating expenses. The failure by our management to apply this working capital effectively could harm our business. Pending its use, we may invest our working capital in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply our working capital in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

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

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

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

cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

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

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

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

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of 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, 2019, we had U.S. net operating loss carryforwards of approximately $214.6 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, public health crisis, pandemic diseases 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 also vulnerable to a major earthquake, wildfire, inclement weather and other natural and man-made disasters and public health crisis and pandemic diseases, such as coronavirus, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster, public health crisis or pandemic diseases and do not have an applicable recovery plan in place. In addition, if any of our third-party contract manufacturers are affected by natural disasters, such as earthquakes, power shortages or outages, floods, wildfire, public health crises, such as pandemics and epidemics,

terrorism or other events outside of our control, our business and operating results could suffer. For example, in December 2019, a strain of coronavirus was reported to have surfaced in Wuhan, China. At this point, the extent to which the coronavirus may impact our business and operating results is uncertain. 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.

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 25, 2020, there were approximately 15 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 and prevention of diseases that are inadequately addressed by current standard of care therapies. We are developing a pipeline of product and development candidates, with a focus on serious fungal and viral 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 first-line treatment and prevention of serious, invasive fungal infections.

In addition, we are using our Cloudbreak® platform to develop Antiviral Fc-Conjugates, or AVCs, for the prevention and treatment of influenza and other viral infections.

Rezafungin

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

STRIVE Phase 2 clinical trial

In July 2019, we reported topline results from Part B of our global, randomized Phase 2 STRIVE clinical trial of rezafungin. We previously reported topline results from Part A of the STRIVE clinical trial in March 2018. References to our STRIVE clinical trial below include results from both Parts A and B collectively of the STRIVE clinical trial. STRIVE was 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 the STRIVE clinical trial, rezafungin met all of its objectives for efficacy, safety and tolerability in the treatment of patients with candidemia and/or invasive candidiasis.

Phase 3 clinical trials

Our Phase 3 clinical development plans for rezafungin are as follows:

- 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 ReSTORE clinical trial protocol is modeled after our Phase 2 STRIVE clinical trial. Rezafungin dosed 400 mg for the first week followed by 200 mg once weekly for up to four weeks in total, is being compared to caspofungin dosed daily with an optional step down to oral fluconazole, 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 evaluable patients. We previously announced that we expect topline results from the ReSTORE trial in late-2020. We are closely monitoring a number of factors affecting our enrollment and clinical trial operations, including the effect of the COVID-19 coronavirus, and we are taking steps to mitigate this impact. Based on the current information available to us, we expect our topline data will be delayed into the first half of 2021. We expect that the results of the ReSTORE clinical trial, along with the results from the STRIVE clinical trial, will be sufficient to support the submission of marketing approval applications for rezafungin in this indication.
- 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. Rezafungin will be dosed at 400 mg for the first week followed by 200 mg once weekly doses out to 90 days, 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 and EMA is fungal-free survival at day 90. We expect this trial to enroll approximately 462 patients. We expect to commence the ReSPECT clinical trial initially in Europe and/or Canada in the first quarter of 2020. Commencement of the ReSPECT clinical trial in the United States is contingent upon obtaining agreement with the FDA. We expect that the results of the ReSPECT clinical trial, along with the results from the ReSTORE clinical trial, will be sufficient to support the submission of marketing approval applications for rezafungin in this indication.

Cloudbreak Platform

We believe our Cloudbreak platform is a fundamentally new approach to prevent and treat life-threatening infectious disease that provides potent antimicrobial activity and immune system engagement in a single long-acting molecule. The Cloudbreak platform recognizes that infectious disease often results when a microbial pathogen is able to evade or overcome the host immune system. Our Cloudbreak candidates are designed to counter infection in two ways, by directly targeting and destroying invading pathogens and by focusing the immune system at the site of infection. We believe this is a potentially transformative approach, distinct from current therapies, monoclonal antibodies and vaccines. Our lead Cloudbreak candidates are Antiviral Fc-Conjugates (AVCs) for the prevention and treatment of influenza. The Cloudbreak platform has enabled us to expand the development of AVCs to target other life-threatening viruses.

We have generated preclinical, in vivo proof of concept data for our Cloudbreak influenza program. In July 2019 we began conducting studies in support of a future investigational new drug application on our lead development candidate, CD377 for influenza prevention and pandemic preparedness.

FINANCIAL OPERATIONS OVERVIEW

Revenues

To date, we have generated all of our revenues from our strategic partnership with Mundipharma. 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 CD377 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.

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):

	Year ended December 31,		
	2019	2018	2017
Rezafugin	$ 27,100	$ 30,634	$ 24,394
CD101 topical	—	—	1,385
Cloudbreak platform	3,392	3,147	2,915
Personnel costs	13,559	12,378	11,022
Other research and development expenses	2,350	2,983	3,107
Total research and development expenses	$ 46,401	$ 49,142	$ 42,823

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 efficacy, 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. 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 $0.4 million and $3.9 million were recorded during the years ended December 31, 2019 and 2018, respectively.

On August 7, 2019, we notified the purchasers in the May 2018 registered direct offering that we had elected not to consummate the second closing of the offering. Accordingly, the obligations of the parties to the registered direct offering terminated and are of no further force or effect, and the second closing will not be held. As a result of this election, the optional third closing of the offering and the related concurrent private placement of warrants will not be held.

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 revenue recognition, 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:

Revenue Recognition

We recognize revenue is accordance with Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers, which applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for contracts with customers, we perform the following five steps: (i) identify the 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 revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We utilize key assumptions to determine a stand-alone selling price for performance obligations, which may include revenue forecasts, expected development timelines, discount rates, probabilities of technical and regulatory success and costs for manufacturing clinical supplies. Because the amount of revenue recognized for each performance obligation is determined based upon its relative stand-alone selling price, an increase or decrease of 10% in the estimated fair value of each performance obligation would not have a significant impact on the amount of revenue recognized.

Subaward Agreement and Partnership Grants

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

Restricted Stock Units

In 2018 and 2019, we granted Restricted Stock Units (RSUs) and Performance-based RSUs (PRSUs). We estimate the fair value of RSUs and PRSUs based on the closing price of our 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.

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.

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.

In December 2019, we completed an option exchange program, or the Option Exchange, which allowed eligible employees to exchange certain outstanding stock options, or Eligible Options, whether vested or unvested, with an exercise price greater than the greater of (i) $2.28 and (ii) the closing price of the Company's common stock on Wednesday, December 18, 2019. These new options vest over one to three years, subject to the terms of the Option Exchange and expire seven years from the date of grant. We determined this Option Exchange was an option modification. The exchange of these stock options was treated as a modification for accounting purposes. The difference in the fair value of the canceled options immediately prior to the cancellation and the fair value of the modified options resulted in incremental value, of approximately $0.7 million, which was calculated using the Black-Scholes-Merton option pricing model. Total stock-based compensation expense to be recognized over the requisite service period is equal to the remaining unrecognized expense for the exchanged option, as of the exchange date, plus the incremental value of the modification to the award.

Restricted Stock Units

In 2017, 2018 and 2019, 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.

In September 2019, we sold 4,781,408 shares of common stock to Mundipharma at a price per share of $1.884 (a 20% premium to the volume weighted average price of our common stock for the 10 trading days prior to September 3, 2019) for net proceeds of approximately $9.0 million.

In 2019, we sold shares of common stock under a controlled equity offering sales agreement with Cantor Fitzgerald & Co. During the year months ended December 31, 2019, we sold 2,095,887 shares for net proceeds of approximately $5.3 million, after deducting placement agent fees.

RESULTS OF OPERATIONS

Comparison of the years ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018 (in thousands):

	Year ended December 31,		
	2019	2018	Change
Collaboration revenue	$ 20,915	$ —	$ 20,915
Research and development	46,401	49,142	(2,741)
General and administrative	16,238	14,143	2,095
Other income, net	632	4,269	(3,637)

Collaboration revenue

Collaboration revenue was $20.9 million for the year ended December 31, 2019. Our collaboration revenue is generated from our ongoing collaboration with Mundipharma, and generally consists of an upfront payment for the license to develop, register and commercialize the rezafungin outside of the United States and Japan and reimbursements for global development expenses.

Research and development expenses

Research and development expenses were $46.4 million for the year ended December 31, 2019 compared to $49.1 million for the year ended December 31, 2018. The decrease in research and development expenses is primarily due to lower clinical expenses associated with the rezafungin clinical trials.

General and administrative expenses

General and administrative expenses were $16.2 million for the year ended December 31, 2019 compared to $14.1 million for the year ended December 31, 2018. The increase in general and administrative expenses is primarily due higher legal and personnel costs.

Other income

Other income for the years ended December 31, 2019 and 2018 related primarily to changes in the fair value of the contingent forward purchase obligation as well as income generated from cash held in interest-bearing investments.

Comparison of the year 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,		
	2018	2017	Change
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

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.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have received $309.1 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 offering sales agreement, our May 2018 registered direct offering and our September 2019 Collaboration Agreement and Stock Purchase Agreement with Mundipharma.

As of December 31, 2019, we had $60.3 million in cash, cash equivalents and restricted cash. The following table shows a summary of our cash flows for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Year ended December 31,		
	2019	2018	2017
Net cash provided by (used in):			
Operating activities	$ (28,532)	$ (56,705)	$ (49,909)
Investing activities	(35)	14,301	4,471
Financing activities	14,273	56,153	20,884
Net increase (decrease) in cash and cash equivalents	$ (14,294)	$ 13,749	$ (24,554)

Operating activities

Net cash used in operating activities was $28.5 million for the year ended December 31, 2019 compared to $56.7 million and $49.9 million for the years ended December 31, 2018 and 2017, respectively. The decrease in net cash used in operating activities was attributable to a net loss of $41.1 million for the year ended December 31, 2019 compared to net losses of $59.0 million and $55.7 million for the years ended December 31, 2018 and 2017, respectively. The lower net loss for the year ended December 31, 2019 includes $20.9 million recognized under our Collaboration Agreement with Mundipharma. 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 and 2017 consisted of purchases and maturities of short-term investments. For the years ended December 31, 2018 and 2017 we purchased approximately $14.5 million and $19.5 million, respectively, of short-term investments and received proceeds of $29.0 million and $24.3 million, respectively, from the maturity of short-term investments. Net cash used for the purchase of property and equipment was $0.2 million and $0.3 million for the years ended December 31, 2018 and 2017, respectively.

Financing activities

Net cash provided by financing activities was $14.3 million for the year ended December 31, 2019 compared to $56.2 million and $20.9 million for the years ended December 31, 2018 and 2017, respectively. During the year ended December 31, 2019, net proceeds from the sale of common stock was $14.3 million, which included $9.0 million from the sale of common stock to Mundipharma under the Mundipharma Collaboration Agreement and $5.3 million from sales made under our controlled equity offering sales agreement. 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.

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 not be sufficient to fund our obligations for the next twelve months. Our ability to execute our operating plan 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.

Off-Balance Sheet Arrangements

We have not entered into, nor do we currently have, any off-balance sheet arrangements (as defined under SEC rules).

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.

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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and shareholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, 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.

Adoption of ASU No. 2016-02

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842), and the related amendments.

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

March 3, 2020

CIDARA THERAPEUTICS, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 50,268	$ 74,562
Restricted cash	10,000	—
Accounts receivable, prepaid expenses and other current assets	5,546	2,567
Total current assets	65,814	77,129
Property and equipment, net	429	712
Operating lease right-of-use asset	1,632	—
Other assets	1,101	1,271
Total assets	$ 68,976	$ 79,112
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,887	$ 2,846
Accrued liabilities	4,068	3,883
Accrued compensation and benefits	3,658	2,824
Deferred revenue	9,803	—
Current portion of term loan	9,965	9,928
Current portion of lease liability	818	—
Contingent forward purchase obligation	—	411
Total current liabilities	30,199	19,892
Lease liability	942	—
Other long-term liabilities	—	81
Total liabilities	31,141	19,973
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2019 and December 31, 2018:	—	—
Series X Convertible Preferred stock, $0.0001 par value; 5,000,000 shares authorized at December 31, 2019 and 2018; 565,231 shares issued and outstanding at December 31, 2019; 445,231 shares issued and outstanding at December 31, 2018	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2019 and 2018; 33,838,466 shares issued and outstanding at December 31, 2019; 27,816,014 shares issued and outstanding at December 31, 2018	3	3
Additional paid-in capital	297,659	277,871
Accumulated deficit	(259,827)	(218,735)
Total stockholders' equity	37,835	59,139
Total liabilities and stockholders' equity	$ 68,976	$ 79,112

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, 2019	2018	2017
Revenues:			
Collaboration revenue	$ 20,915	$ —	$ —
Total revenues	20,915	—	—
Operating expenses:			
Research and development	46,401	49,142	42,823
General and administrative	16,238	14,143	12,898
Total operating expenses	62,639	63,285	55,721
Loss from operations	(41,724)	(63,285)	(55,721)
Other income (expense):			
Change in fair value of contingent forward purchase obligation	411	3,851	—
Interest income (expense), net	221	629	(7)
Other expense	—	(211)	—
Total other income (expense)	632	4,269	(7)
Net loss	$ (41,092)	$ (59,016)	$ (55,728)
Recognition of beneficial conversion feature	—	(10,329)	—
Net loss attributable to common shareholders	$ (41,092)	$ (69,345)	$ (55,728)
Basic and diluted net loss per common share	$ (1.41)	$ (2.76)	$ (3.18)
Shares used to compute basic and diluted net loss per common share	29,093,174	25,142,976	17,500,853
Net loss	$ (41,092)	$ (59,016)	$ (55,728)
Unrealized gain (loss) on short-term investments	—	8	(7)
Comprehensive loss	$ (41,092)	$ (59,008)	$ (55,735)

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				
Balance, December 31, 2016	—	$ —	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)
Balance, December 31, 2017	—	—	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)
Balance, December 31, 2018	445,231	—	27,816,014	3	277,871	(218,735)	—	59,139
Issuance of stock pursuant to Stock Purchase Agreement	—	—	4,781,408	—	9,008	—	—	9,008
Public offering of common stock, net of issuance costs	—	—	2,095,887	—	5,289	—	—	5,289
Issuance of Series X Convertible Preferred Stock in exchange for common stock	120,000	—	(1,200,000)	—	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	242,501	—	411	—	—	411
Stock-based compensation	—	—	—	—	5,073	—	—	5,073
Issuance of common stock for exercise of options	—	—	2,952	—	7	—	—	7
Issuance of common stock for restricted share units vested	—	—	99,704	—	—	—	—	—
Net loss	—	—	—	—	—	(41,092)	—	(41,092)
Balance, December 31, 2019	565,231	$ —	33,838,466	$ 3	$ 297,659	$ (259,827)	$ —	$ 37,835

See accompanying notes.

CIDARA THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(In thousands)	Years ended December 31, 2019	2018	2017
Operating activities:			
Net loss	$ (41,092)	$ (59,016)	$ (55,728)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	328	523	667
Stock-based compensation	5,073	5,710	5,714
Non-cash interest expense	28	43	61
Amortization of discount or premium on short-term investments	—	31	(33)
Amortization of debt issue costs	8	13	18
Operating lease right-of-use assets and liabilities, net	47	—	—
Deferred rent	—	30	(29)
Change in fair value of contingent forward purchase obligations	(411)	(3,851)	—
Contingent forward purchase obligation offering costs	—	211	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(2,946)	(211)	(1,481)
Deferred revenue	9,803	—	—
Accounts payable and accrued liabilities	(784)	(59)	642
Accrued compensation and benefits	1,244	822	453
Other assets	170	(951)	(193)
Net cash used in operating activities	(28,532)	(56,705)	(49,909)
Investing activities:			
Purchases of short-term investments	—	(14,548)	(19,523)
Maturities of short-term investments	—	29,026	24,300
Purchases of property and equipment	(35)	(177)	(306)
Net cash (used in) provided by investing activities	(35)	14,301	4,471
Financing activities:			
Proceeds from Registered Direct Offering, net of offering costs	—	49,509	—
Proceeds from issuance of common stock pursuant to Stock Purchase Agreement	9,008	—	—
Proceeds from issuance of common stock, net of offering costs	5,289	6,440	20,735
Proceeds from exercise of stock options	7	204	228
Deferred public offering costs	(31)	—	—
Repurchase of unvested restricted stock	—	—	(79)
Net cash provided by financing activities	14,273	56,153	20,884
Net increase (decrease) in cash, cash equivalents, and restricted cash	(14,294)	13,749	(24,554)
Cash, cash equivalents, and restricted cash at beginning of year	74,562	60,813	85,367
Cash, cash equivalents, and restricted cash at end of year	$ 60,268	$ 74,562	$ 60,813
Supplemental disclosure of cash flows:			
Interest paid	$ 616	$ 582	$ 511
Non-cash investing activity:			
Property and equipment acquired but not yet paid	$ 10	$ 14	$ 30
Non-cash financing activities:			
Vesting of early exercised stock options	$ —	$ 21	$ 44
Purchase of shares pursuant to Employee Stock Purchase Plan	$ 411	$ 570	$ 543
Receivable for issuance of common stock, net of offering costs	$ —	$ —	$ 36

See accompanying notes.

1. THE COMPANY AND BASIS OF PRESENTATION

Description of Business

Cidara Therapeutics, Inc., or the Company, was originally incorporated in Delaware in December 2012 as K2 Therapeutics, Inc., and its name was changed to Cidara Therapeutics, Inc. in July 2014. The Company is a biotechnology company focused on the discovery, development and commercialization of novel anti-infectives. The Company's 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, 2019, the Company had an accumulated deficit of $259.8 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, 2019, the Company had cash, cash equivalents and restricted cash of $60.3 million. Based on the Company's current business plan, management believes that existing cash and cash equivalents will not be sufficient to fund the Company's obligations for twelve months from the issuance of these financial statements. The Company's ability to execute its operating plan 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, estimated collaboration expenses and incurred expenses related to the Mundipharma Collaboration Agreement, 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, Cash Equivalents, and Restricted Cash

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

Restricted cash represents cash that the Company is required to maintain on hand in order to maintain compliance with an operating covenant in the Third Amendment to the Company's Loan Agreement with Pacific Western Bank. See Note 5 for more information.

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. 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.

Revenue Recognition

The Company recognizes revenue is accordance with ASC Topic 606, *Revenue from Contracts with Customers*, which applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the

consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the 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 revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

In a contract with multiple performance obligations, the Company must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation, which determines how the transaction price is allocated among the performance obligations. The estimation of the stand-alone selling price(s) may include estimates regarding forecasted revenues or costs, development timelines, discount rates, and probabilities of technical and regulatory success. The Company evaluates each performance obligation to determine if it can be satisfied at a point in time or over time. Any change made to estimated progress towards completion of a performance obligation and, therefore, revenue recognized will be recorded as a change in estimate. In addition, variable consideration must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in a contract, the Company recognizes revenues from the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the allocated transaction price. The Company evaluates the measure of progress at each reporting period and, if necessary, adjusts the measure of performance and related revenue or expense recognition as a change in estimate.

At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or a collaboration partner's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, the Company re-evaluates the probability of achievement of milestones that are within its or a collaboration partner's control, such as operational developmental milestones and any related constraint, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which will affect collaboration revenues and earnings in the period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

For arrangements that include sales-based royalties, including commercial milestone payments based on the level of sales, and a license is deemed to be the predominant item to which the royalties relate, the Company will recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied, or partially satisfied. To date, the Company has not recognized any royalty revenue from collaborative arrangements.

In September 2019, the Company entered into a Collaboration and License Agreement (the Collaboration Agreement) with Mundipharma Medical Company (Mundipharma). The Company concluded that there were three significant performance obligations under the Collaboration Agreement: the license, the research and development services, and the clinical supply services, and that the obligations are distinct from each other. Revenue associated with the license was recognized upon delivery in September 2019.

The Company concluded that progress towards completion of the research and development and clinical supply performance obligations related to the Collaboration Agreement is best measured in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses. The Company periodically reviews and updates the estimated collaboration expenses, when appropriate, which may adjust revenue recognized for the period. While such changes to the Company's estimates have no impact on the Company's reported cash flows, the amount of revenue recorded in the period could be materially impacted. The transaction price to be recognized as

revenue under the Collaboration Agreement consists of the upfront payment and estimated reimbursable research and development and clinical supply costs.

Potential future payments for variable consideration, such as clinical, regulatory or commercial milestones, will be recognized when it is probable that, if recorded, a significant reversal will not take place. Potential future royalty payments will be recorded as revenue when the associated sales occur.

See Note 8 - Significant Agreements and Contracts for more information.

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 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.

Preclinical and Clinical Trial Accruals

The Company makes estimates of its accrued expenses as of each balance sheet date in the financial statements based on the facts and circumstances known at that time. 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, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other available information. If the Company underestimates or overestimates 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, estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in accruals.

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,	
	2019	**2018**
Common stock warrants	12,517,328	12,517,328
Series X Convertible Preferred stock	5,652,310	4,452,310
Common stock options, RSUs and PRSUs issued and outstanding	5,360,563	4,392,671
Total	23,530,201	21,362,309

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, restricted cash, marketable securities, contingent forward purchase obligations, and long-term debt. Fair value estimates of these instruments are made at each reporting period end 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, restricted cash, accounts receivable, prepaid expenses, accounts payable, and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The fair value of short-term investments is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The fair value of contingent forward purchase obligations is based on a probability-weighted valuation approach (See Note 3). The Company believes that the fair value of long-term debt approximates its carrying value.

Recently Issued Accounting Standards

Recently Issued Accounting Standards Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, "Simplifying the Accounting for Income Taxes," which eliminates certain exceptions within ASC 740, Income Taxes, and clarifies other aspects of the current guidance to promote consistency among reporting entities. The updated guidance is effective for interim and annual periods beginning after December 15, 2020. Early adoption is permitted. The Company does not expect the standard to have a material impact on its financial statements upon adoption.

In August 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 does not expect the standard to have a material impact on its financial statements upon adoption.

In June 2016, the FASB issued ASU No. 2016-13, "Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments." The updated guidance replaces the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The updated guidance is effective for interim and annual periods beginning after December 15, 2019. Early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

Recently Adopted Accounting Standards

In March 2019, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2019-01, "Leases (Topic 842): Codification Improvements." In July 2018, the FASB issued Accounting Standards Update No. 2018-11, "Leases (Topic 842): Targeted Improvements" and Accounting Standards Update No. 2018-10, "Codification Improvements to Topic 842, Leases." These updates provide additional clarification, an optional transition method, a practical expedient and implementation guidance on the previously issued Accounting Standards Update No. 2016-02, "Leases (Topic 842)." Collectively, these updates supersede the lease guidance in Accounting Standards Codification, or ASC, Topic 840 and require lessees to recognize for all leases, with the exception of short-term leases, a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis. Concurrently, lessees are required to recognize a right of use asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. We adopted this standard on January 1, 2019 by applying the optional transition method on the adoption date and did not adjust comparative periods. We also elected the package of practical expedients permitted, which among other things, allowed us to carry forward the lease classification for our existing leases. The adoption of this standard impacted our 2019 opening consolidated balance sheet as we recorded operating lease liabilities of $2.5 million and right of use assets of $2.3 million, which equals the lease liabilities net of accrued rent. The adoption of this standard did not have an impact on our consolidated statements of income or cash flows.

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. These updates align the guidance for share-based payments to nonemployees with the guidance 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 adopted ASU 2018-07 effective January 1, 2019. The adoption of this standard did not have a material impact on the Company's financial statements.

3. 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.

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 6, 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. Fair value adjustments resulting in a gains of $0.4 million and $3.9 million were recorded during the years ended December 31, 2019 and 2018, respectively. The contingent forward purchase obligation had no value as of December 31, 2019 and was valued at $0.4 million as of 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
December 31, 2019				
Assets:				
Cash and money market accounts	$ 50,268	$ 50,268	$ —	$ —
Restricted cash and money market accounts	10,000	10,000	—	—
	$ 60,268	$ 60,268	$ —	$ —
December 31, 2018				
Assets:				
Cash and money market accounts	$ 74,562	$ 74,562	$ —	$ —
Total assets at fair value	$ 74,562	$ 74,562	$ —	$ —
Liabilities:				
Contingent forward purchase obligations	$ 411	$ —	$ —	$ 411
Total liabilities at fair value	$ 411	$ —	$ —	$ 411

4. PROPERTY AND EQUIPMENT

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

	December 31,	
	2019	2018
Laboratory equipment	$ 2,104	$ 2,114
Leasehold improvements	425	425
Computer hardware and software	481	455
Office equipment	119	119
Furniture and fixtures	142	142
	3,271	3,255
Less accumulated depreciation and amortization	(2,842)	(2,543)
Total	$ 429	$ 712

Depreciation and amortization of property and equipment of $0.3 million, $0.5 million and $0.7 million were recorded for the years ended December 31, 2019, 2018 and 2017 respectively.

5. DEBT

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 "Milestone"), the Company had the option to borrow, at its sole discretion, until; October 3, 2018, from the Lender up to an additional $10.0 million (the "Term B Loan,"). 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 Milestone 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.

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 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 greater of (i) 4.5% or (ii) the Lender's prime interest rate plus 0.75%. At December 31, 2019, the Term Loans bear interest at 5.50%.

On July 29, 2019, the Company announced positive data from Part B of the STRIVE clinical trial, which satisfied the Milestone. Within 30 days of satisfying the Milestone, the Company was required to agree with the Lender on an amendment to the Loan Agreement to define a new financial covenant and/or Milestone for fiscal year 2019 and all subsequent fiscal years during the term of the Loan Agreement. On August 27, 2019, the Lender extended the deadline to execute this amendment to October 15, 2019, and on October 11, 2019, the Lender further extended this deadline until November 7, 2019.

On November 5, 2019, the Company and the Lender entered into a Third Amendment to the Loan Agreement, which reset the operating covenant to require the Company to maintain cash equal to or greater than the Company's outstanding indebtedness to the Lender, which is equivalent to a compensating balance and results in a restricted cash balance of $10.0 million as of December 31, 2019. The amendment also extended the interest-only period through April 3, 2020 and the maturity date through July 3, 2022.

The Company evaluated the First, Second and Third 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 Third 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, or the occurrence of a material adverse change, the Lender has 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, 2019 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, 2019, future principal payments due under the Third Amendment of the Term A Loan are as follows (in thousands):

Year ended:		
December 31, 2020	$	2,963
December 31, 2021		4,444
December 31, 2022		2,593
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 $36,000, $56,000 and $78,000 for the years ended December 31, 2019, 2018 and 2017, respectively, for the amortization of the fair value of the warrants and debt issue costs.

6. STOCKHOLDERS' EQUITY

Mundipharma Stock Purchase Agreement— On September 3, 2019, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with Mundipharma AG (the "Purchaser"), a related party, pursuant to which the Company issued to the Purchaser 4,781,408 shares of its common stock (the "Shares") in a private placement at a price per share of $1.884 (a 20% premium to the volume weighted average price of the Company's common stock for the 10 trading days prior to September 3, 2019) for an aggregate purchase price of approximately $9.0 million.

Under the Purchase Agreement, until September 3, 2020 (the "Lock-Up Period"), the Purchaser may not transfer or sell the Shares without the prior written consent of the Company. In addition, the Company agreed to (i) no later than 90 days prior to the expiration of the Lock-Up Period, file a registration statement with the U.S. Securities and Exchange Commission covering the resale by the Purchaser of the Shares, (ii) cause such registration statement to become effective as soon as practicable following the filing thereof and (iii) take all other actions as may be necessary to keep such registration statement continuously effective during the timeframes set forth in the Purchase Agreement. If the Company fails to comply with certain obligations with respect to filing and securing effectiveness of such registration statement, the Company would be obligated to pay liquidated damages to the Purchaser in the amount of 1% of the total purchase price of the Shares for each applicable 30-day period, up to an aggregate maximum of 6% of the purchase price, so long as the event giving rise to the damages remains uncured.

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.

The second closing of the registered direct offering was contingent on the Company's announcement of topline data from Part B of its STRIVE global randomized Phase 2 clinical trial of rezafungin provided that the Company would not be obligated to complete the second closing if the purchase price was less than $4.70 per share, and the third closing of the registered direct offering was to occur after the second closing, but at the Company's option. On July 29, 2019, the Company announced positive data from Part B of its STRIVE clinical trial. Because the volume weighted average price of the Company's common stock for the five trading days following the public release of topline data from Part B of the STRIVE clinical trial of rezafungin was below $6.81, the resulting purchase price for the second and third closings of the May 2018 registered direct offering would have been less than $4.70 per share. Accordingly, the Company was unable to complete the second and third closings without first obtaining the approval of its stockholders.

On August 7, 2019, the Company notified the purchasers in the May 2018 registered direct offering that it had elected not to consummate the second closing of the offering. Accordingly, the obligations of the parties to the registered direct offering terminated and are of no further force or effect, and the second closing will not be held. As a result of this election, the optional third closing of the offering and the related concurrent private placement of warrants will not be held.

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, 2019.

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.

On March 22, 2019, the Company entered into an Exchange Agreement with Biotechnology Value Fund, L.P., and certain of its affiliated entities (collectively, "BVF"), pursuant to which BVF, without monetary consideration, agreed to exchange an aggregate of 1,200,000 shares of the Company's common stock for an aggregate of 120,000 shares of the Company's Series X Convertible Preferred Stock. As of December 31, 2019, 565,231 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. Holders 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.

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, 2019. 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.

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 offering 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.

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 included 6,185,987 shares of common stock at an offering price of $4.70 per share.

On September 3, 2019, the Company entered into the Purchase Agreement with Mundipharma, pursuant to which the Company issued to Mundipharma 4,781,408 shares of its common stock (in a private placement at a price per share of $1.884 (a 20% premium to the volume weighted average price of the Company's common stock for the 10 trading days prior to September 3, 2019) for an aggregate purchase price of approximately $9.0 million.

In September 2019, the Company began to sell shares of common stock under a controlled equity offering sales agreement with Cantor Fitzgerald & Co. During the year ended December 31, 2019, the company sold 2,095,887 shares for net proceeds of approximately $5.3 million after deducting placement agent fees.

Common Stock Warrants

As of December 31, 2019 and 2018, warrants to purchase 12,517,328 shares of the Company's common stock were outstanding with a weighted average exercise price of $6.82 per share.

The warrants had no intrinsic value at December 31, 2019 and 2018. 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.

Common Stock Reserved for Future Issuance

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

	Years ended December 31,	
	2019	**2018**
Common stock warrants	12,517,328	12,517,328
Series X Convertible Preferred stock	5,652,310	4,452,310
Stock options, RSUs and PRSUs issued and outstanding	5,360,563	4,392,671
Authorized for future stock awards	559,898	669,873
Awards available under the ESPP	463,741	706,242
Total	24,553,840	22,738,424

7. 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, 2019, 242,501 shares were issued pursuant to the ESPP.

Restricted Stock Units

The following table summarizes RSU and PRSU activity during the year ended December 31, 2019:

	Number of RSUs and PRSUs
Outstanding at December 31, 2018	260,000
RSUs and PRSUs granted	259,520
RSUs and PRSUs vested	(97,204)
RSUs and PRSUs canceled	(38,431)
Outstanding at December 31, 2019	383,885

For the year ended December 31, 2019, stock-based compensation expense related to RSUs and PRSUs was approximately $0.6 million. At December 31, 2019, estimated unrecognized compensation expense related to RSUs and PRSUs granted to employees was approximately $1.3 million.

2019 Option Exchange

On November 20, 2019, the Company commenced an option exchange program pursuant to which it offered to certain employees the option to exchange some or all of their outstanding stock options, whether vested or unvested, for new stock options (the "Option Exchange"). Stock options were eligible for exchange ("Eligible Options") if they had an exercise price greater than greater of (i) $2.28 and (ii) the closing price of the Company's common stock on Wednesday, December 18, 2019 (the "Exchange Date"). An exchange ratio of 1 for 1 was applied to options held by eligible employees who were not executive officers for purposes of Section 16 of the Exchange Act as designated by the Board (a "Section 16 Officer") and an exchange ratio of 1.5 for 1 applied to options held by Section 16 officers.

The Option Exchange closed on December 18, 2019. Eligible Options to purchase an aggregate of 1,656,379 shares of the Company's common stock, representing 60.4% of the total shares underlying the Eligible Options were exchanged for new options to purchase 1,529,814 of the Company's common stock at $2.45 per share, the closing price of the Company's common stock on the Exchange Date. All surrendered options were canceled effective as of the closing of the Option Exchange. These new options were granted pursuant to the 2015 EIP and vest over one to three years, subject to the terms of the Option Exchange and expire seven years from the date of grant. The Company determined this option exchange was an option modification. The difference in the fair value of the canceled options immediately prior to the cancellation and the fair value of the modified options resulted in incremental value, of approximately $0.7 million, which was calculated using the Black-Scholes option pricing model. The incremental value of the modified award will be recognized over the requisite service period of the exchanged option.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Total Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2018	4,132,671	$ 6.58	7.41	$ 25
Options granted	2,698,964	2.50		
Options exercised	(2,952)	2.29		
Options canceled	(1,852,005)	6.58		
Outstanding at December 31, 2019	4,976,678	$ 4.37	7.27	$ 3,880
Vested and expected to vest at December 31, 2019	4,976,678	$ 4.37	7.27	$ 3,880
Exercisable at December 31, 2019	2,339,718	$ 6.16	6.67	$ 866

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,	
	2019	2018
2015 EIP		
Risk-free interest rate	1.42% - 2.57%	2.55% - 3.06%
Expected dividend yield	0%	0%
Expected volatility	80% - 82%	83%
Expected term (years)	5.27 - 6.08	5.50 - 6.08
2015 ESPP		
Risk-free interest rate	1.55% - 2.42%	2.14% - 2.81%
Expected dividend yield	0%	0%
Expected volatility	67% - 82%	77% - 92%
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,	
	2019	2018
Research and development	$ 2,502	$ 2,676
General and administrative	2,571	3,034
Total	$ 5,073	$ 5,710

The weighted-average grant date fair value of stock options granted to employees during the year ended December 31, 2019 was $1.78 per share. As of December 31, 2019, total unrecognized share-based compensation expense related to unvested stock options was approximately $4.5 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 1.84 years.

As of December 31, 2019, total unrecognized compensation expense related to the Company's ESPP was approximately $0.4 million. This unrecognized compensation cost is expected to be recognized over approximately 0.5 years.

8. SIGNIFICANT AGREEMENTS AND CONTRACTS

Mundipharma Collaboration Agreement

On September 3, 2019, the Company entered into a Collaboration and License Agreement (the "Collaboration Agreement") with Mundipharma Medical Company ("Mundipharma"), a related party, for a strategic collaboration to develop and commercialize rezafungin in an intravenous formulation (the "Licensed Product") for the treatment and prevention of invasive fungal infections.

Under the Collaboration Agreement, the Company will be responsible for leading the conduct of an agreed global development plan (the "Global Development Plan") that includes the Company's ongoing Phase 3 pivotal clinical trial of the Licensed Product for the treatment of candidemia and/or invasive candidiasis (the "ReSTORE Trial") and the Company's planned Phase 3 pivotal clinical trial of the Licensed Product for the prophylaxis of invasive fungal infections in adult allogeneic blood and marrow transplant recipients (the "ReSPECT Trial"), as well as specified GLP-compliant non-clinical studies and chemistry, manufacturing and controls ("CMC") development activities for the Licensed Product. Mundipharma will be responsible for performing all development activities, other than Global Development Plan activities, that may be necessary to obtain and maintain regulatory approvals for the Licensed Product in the Mundipharma Territory, at Mundipharma's sole cost.

Pursuant to the Collaboration Agreement, the Company granted Mundipharma an exclusive, royalty-bearing license to develop, register and commercialize the Licensed Product outside of the United States and Japan (the "Mundipharma Territory"), subject to the Company's retained right to lead a global development program for the Licensed Product in both the Mundipharma Territory and in the United States and Japan (the "Company Territory") as described below.

The Company also granted Mundipharma an option to obtain exclusive licenses to develop, register and commercialize rezafungin in a formulation for subcutaneous administration ("Subcutaneous Product") and in formulations for other modes of administration ("Other Products") in the Mundipharma Territory, subject to similar retained rights of the Company to conduct mutually agreed global development activities for such products. In addition, the Company granted Mundipharma a co-exclusive, worldwide license to manufacture the Licensed Product and rezafungin.

Until the seventh anniversary of the first commercial sale of the Licensed Product in the Mundipharma Territory, each party has granted the other party an exclusive, time-limited right of first negotiation to obtain a license to any anti-fungal product (other than Licensed Product, Subcutaneous Product and Other Products) that such party proposes to out-license in the other party's territory. However, in the event of the acquisition of a party by a third party, this right of first negotiation will not apply to any such anti-fungal product of the acquiring third party prior to consummation of the acquisition of such party, acquired by such acquiring third party from another third party after consummation of the acquisition of such party, or developed internally by the acquiring third party, either before or after consummation of the acquisition of such party, without the use of, reliance upon or reference to any technology of the acquired party that is licensed to the other party under the Collaboration Agreement, any technology of the other party that is licensed to the acquired party under the Collaboration Agreement, or any technology jointly developed by the parties pursuant to the Collaboration Agreement.

The Company retains the exclusive right to develop, register and commercialize the Licensed Product, Subcutaneous Product and Other Products in the Company Territory, and Mundipharma has granted the Company certain licenses under Mundipharma-controlled technology and jointly-developed technology to develop, register and commercialize Licensed Product, Subcutaneous Product and Other Products in the Company Territory and to manufacture such products and rezafungin worldwide.

The parties have agreed to share equally (50/50) the costs of Global Development Plan activities ("Global Development Costs"), subject to a cap on Mundipharma's Global Development Cost share of $31.2 million. The Company would receive additional financial support for Global Development Plan activities through a near-term milestone payment by Mundipharma of $11.1 million. Mundipharma is entitled to credit the full amount of this milestone payment toward future royalties payable to the Company, subject to a limit on the amount by which royalty payments to the Company may be reduced in any quarter. If Mundipharma has not fully credited the amount of such milestone payment toward royalties payable to the Company before the earlier of (i) December 31, 2024 and (ii) termination of the Collaboration Agreement by Mundipharma, the Company will be obligated to refund the uncredited portion of such milestone payment to Mundipharma on the earlier of such dates.

The total potential transaction value is $568 million, including an equity investment (see Note 6), an up-front payment, global development funding, and certain development, regulatory, and commercial milestones. The Company is also eligible for double-digit royalties in the teens on tiers of annual net sales.

Either party may terminate the Collaboration Agreement for uncured material breach by the other party. After September 3, 2020, Mundipharma may terminate the Collaboration Agreement at will, provided that if Mundipharma terminates the Collaboration Agreement in its entirety prior to the last visit of the last patient in both the ReSPECT Trial and the ReSTORE Trial, Mundipharma will continue to be liable for its share of Global Development Costs as described above. The Company may terminate the Agreement if Mundipharma or any of its affiliates or sublicensees, directly or indirectly through any third party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any of the Company's patent rights licensed to Mundipharma, or upon an insolvency event of Mundipharma.

Revenue Recognition

The Company determined the transaction price is equal to the up-front fee of $30.0 million plus the research and development funding of $31.2 million. The price paid for the common stock was determined to be at fair market value after applying a lack of marketability discount as Mundipharma received restricted shares. Therefore, no additional premium or discount was allocated to the transaction price of the Agreement for the share issuance. The total transaction price of $61.2 million was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In estimating the stand-alone selling price for each performance obligation, the Company developed assumptions that require judgment and included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success and costs for manufacturing clinical supplies. A description of the distinct performance obligations identified under the Agreement, as well as the amount of revenue allocated to each distinct significant performance obligation, is as follows:

Licenses of Intellectual Property. The license to the Company's intellectual property, bundled with the associated know-how, represents a distinct performance obligation. The license and associated know-how was transferred to Mundipharma during in September 2019, therefore the Company recognized the full revenue related to this performance obligation in the amount of $17.9 million during the quarter ended September 30, 2019 as license revenue in its condensed consolidated statements of operations and comprehensive income.

Research and Development Services. The Company and Mundipharma share equally in the costs of ongoing rezafungin clinical development in the Licensed Territory up to the specified cap. The Company records these cost-sharing payments due from Mundipharma as collaboration revenue. The Company concluded that progress towards completion of the performance obligation related to the research and development services is best measured in an amount proportional to the research and development expenses incurred and the total estimated research and development expenses. The Company recognized $2.7 million for this performance obligation for the year ended December 31, 2019.

Clinical Supply Services. The Company's initial obligation to supply rezafungin for ongoing clinical development in the Licensed Territory represents a distinct performance obligation. The Company concluded that progress towards completion of the performance obligations related to the clinical supply services is best measured in an amount proportional to the clinical supply services expenses incurred and the total estimated clinical supply services. The Company recognized $0.4 million for this performance obligation for the year ended December 31, 2019.

Milestone Payments. The Company determined that as of December 31, 2019, all the potential milestone payments are probable of significant revenue reversal as their achievement is highly dependent on factors outside the Company's control or are otherwise constrained under the variable consideration guidance. Therefore, these

payments have been fully constrained and are therefore not included in the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint. No revenue related to milestones was recognized during the year ended December 31, 2019.

Royalties. As the license is deemed to be the predominant item to which sales-based royalties relate, the Company will recognize revenue when the related sales occur. No royalty revenue was recognized during the year ended December 31, 2019.

The following table presents a summary of the activity in the Company's contract liabilities (recorded as deferred revenue on the balance sheet) during the year ended December 31, 2019 (in thousands):

Opening balance, January 1, 2019	$ —
Payments received	30,718
Revenue from performance obligations satisfied during reporting period	(20,915)
Closing balance, December 31, 2019	$ 9,803

The closing balance as of December 31, 2019 is classified as a current liability since the rights to consideration is expected to be satisfied within one year.

The following table presents our contract revenues disaggregated by timing of revenue recognition and excludes royalty revenue (in thousands):

	Year Ended December 31, 2019	
	Point in Time	Over Time
Revenue from Mundipharma Collaboration Agreement:		
License of Intellectual Property	$ 17,861	$ —
Research and Development Services	—	2,670
Clinical Supply Services	—	384
Total revenue from Mundipharma Collaboration Agreement	$ 17,861	$ 3,054

The Company has received cost reimbursement payments of $0.7 million from Mundipharma during the year ended December 31, 2019.

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, 2019, 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, 2019, 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 AVCs. The Company is no longer seeking funding under the Subaward Agreement relating to CD201.

9. INCOME TAXES

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

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

	Years Ended December 31,		
	2019	2018	2017
Federal income taxes at 21% for 2019 and 2018 and 34% for 2017	$ (8,629)	$ (12,393)	$ (18,947)
State income tax, net of federal benefit	(1,899)	—	—
Tax effect on nondeductible expenses	561	(278)	3,389
Research credits	(4,141)	(4,737)	(8,125)
Rate change	(664)	—	—
Change in valuation allowance	13,692	16,421	5,133
Reserve for uncertain tax positions	1,035	1,184	1,451
Tax Cuts and Jobs Act	—	—	17,334
Other	45	(197)	(235)
Income tax expense	$ —	$ —	$ —

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

	Years Ended December 31,	
	2019	2018
Deferred tax assets:		
Net operating losses	$ 47,468	$ 38,268
Research credits	17,113	14,007
Intangibles	270	241
Stock compensation	2,916	1,940
Lease liability	458	—
Other	895	548
Total deferred tax assets	69,120	55,004
Less valuation allowance	(68,695)	(55,004)
Deferred tax assets, net of valuation allowance	425	—
Deferred tax liabilities:		
Right-of-use assets	(425)	—
Total deferred tax liabilities	(425)	—
Net deferred tax assets	$ —	$ —

At December 31, 2019, the Company had federal and state net operating loss carryforwards of approximately $214.6 million and $214.0 million, respectively. The federal and state loss carryforwards begin to expire in 2033 and 2029, respectively, unless previously utilized. The Company also has federal research and development and orphan drug credit carryforwards totaling $20.5 million and state research and development credit carryforwards totaling $3.1 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, with the exception of $3.1 million which have no expiration date.

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 $68.7 million and $55.0 million as of December 31, 2019 and 2018, respectively, has been established to offset the net 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 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, 2019 and 2018, the unrecognized tax benefits recorded were approximately $22.6 million and $16.5 million, respectively. Approximately $18.4 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 2019, 2018 and 2017 is as follows (in thousands):

	Years Ended December 31,		
	2019	2018	2017
Balance as of the beginning of the year	$ 16,524	$ 10,756	$ 4,642
Increases related to current year tax positions	1,074	1,224	2,149
Increases related to prior year tax positions	4,960	4,544	3,965
Balance as of the end of the year	$ 22,558	$ 16,524	$ 10,756

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 2013 are subject to examination by the federal and state tax authorities due to the carryforward of unutilized net operating losses and research and development credits. The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company has not recognized interest or penalties since inception.

10. COMMITMENTS AND CONTINGENCIES

Litigation—From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company at December 31, 2019 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—The Company adopted ASU 2016-02, "Leases," on January 1, 2019, which resulted in the recognition of operating leases on the balance sheet. See Note 2 for more information on the adoption of the ASU. The Company determines if a contract contains a lease at inception and recognizes operating lease right-of-use assets and operating lease liabilities based on the present value of the future minimum lease payments at the commencement date. As the Company's leases do not provide an implicit rate, management develops incremental borrowing rates based on the information available at the commencement date in determining the present value of future payments. Lease agreements that have lease and non-lease components are accounted for as a single lease component. Lease expense is recognized on a straight-line basis over the lease term.

The Company's single lease upon adoption is for laboratory and office space in San Diego, California and was entered into in June 2014. 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

was also 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 Company did not exercise this option prior to expiration.

The lease expires in December 2021 with options for two individual two-year extensions. As of January 1, 2019, the Company was not reasonably certain that it would exercise the extension option, and therefore did not include this option in the determination of the total lease term for accounting purposes. The lease is subject to charges for common area maintenance and other costs, and base rent is subject to 3% annual increases every January. The adjusted incremental borrowing rate used in measuring the Company's lease liability was 10.8%.

The following table presents information about the amount, timing and uncertainty of cash flows arising from the Company's operating lease as of December 31, 2019 (in thousands):

2020	$	969
2021		998
Total undiscounted operating lease payments		1,967
Less: Imputed interest		(207)
Present value of lease payments	$	1,760

The balance sheet classification of the Company's operating lease is as follows (in thousands):

Balance Sheet Classification:		
Operating lease right-of-use asset	$	1,632
Current lease liability	$	818
Lease liability		942
Total operating lease liability	$	1,760

Rent expense was $1.0 million, $0.8 million and $0.7 million for the years ended December 31, 2019, 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.

11. SUBSEQUENT EVENTS

On January 22, 2020, the Company initiated a rights offering to raise $30.0 million through the distribution of subscription rights to holders of its common stock, Series X Preferred stock, and participating warrants (the "Rights Offering"). On February 12, 2020, the Company sold 6,639,307 shares of common stock and 531,288 shares of Series X Preferred stock under the Rights offering for aggregate gross proceeds of $30.0 million.

12. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2019				
Revenues	$ —	$ —	$ 19,100	$ 1,815
Operating expenses	16,404	14,268	16,072	15,895
Other income (expense)	(157)	721	11	57
Net income (loss) attributable to common shareholders	(16,561)	(13,547)	2,595	(14,023)
Basic earnings (loss) per share	$ (0.60)	$ (0.49)	$ 0.08	$ (0.42)
Diluted earnings (loss) per share	$ (0.60)	$ (0.49)	$ 0.08	$ (0.42)
Shares used to compute basic earnings (loss) per share	27,729,977	27,786,808	33,006,280	33,272,964
Shares used to compute diluted earnings (loss) per share	27,729,977	27,786,808	38,687,937	33,272,964
2018				
Operating expenses	$ 16,810	$ 15,152	$ 14,725	$ 16,598
Other income (expense)	61	(1,154)	1,106	4,256
Net loss attributable to common shareholders	(16,749)	(26,635)	(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

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, 2019, 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, 2019.

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, 2019. 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, 2019, 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 2020 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days after the fiscal year ended December 31, 2019, and is incorporated herein by reference.

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

Item 11. Executive Compensation.

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

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

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

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

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

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

Item 14. Principal Accounting Fees and Services.

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

PART IV

Item 15. Exhibits, Financial Statement Schedules.

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

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

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

Item 16. Form 10-K Summary.

None.

Exhibit Index

Exhibit Number	Description
1.1	Controlled Equity OfferingSM Sales Agreement, dated as of November 8, 2018, by and between Cidara Therapeutics, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3, filed on November 8, 2018).
3.1	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).
3.2	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).
3.3	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).
4.1	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).
4.2	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).
4.3	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)
4.4	Description of the Registrant's Securities
10.1+	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).
10.2+	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).
10.3+	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).
10.4+	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).
10.5+	Non-Employee Director Compensation Policy, as amended.
10.6+	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).
10.7	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).
10.8	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).
10.9	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).
10.10	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).
10.11	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).
10.12	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).
10.13	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).

10.14*	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).
10.15+	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).
10.16	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).
10.17	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).
10.18	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).
10.19	Collaboration and License Agreement, dated September 3, 2019, by and between the Registrant and Mundipharma Medical Company (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed November 8, 2019).
10.20	Stock Purchase Agreement, dated September 3, 2019, by and between the Registrant and Mundipharma Medical Company (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed November 8, 2019).
21.1	List of subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Reference is made to the signature page hereto.
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
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: March 3, 2020

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.

Name	Title	Date
/s/ Jeffrey Stein, Ph.D. **Jeffrey Stein, Ph.D.**	President and Chief Executive Officer *(Principal Executive Officer)*	March 3, 2020
/s/ James Levine **James Levine**	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 3, 2020
/s/ Daniel D. Burgess **Daniel D. Burgess**	Chairman of the Board of Directors	March 3, 2020
/s/ Timothy R. Franson, M.D. **Timothy R. Franson, M.D.**	Member of the Board of Directors	March 3, 2020
/s/ David Gollaher, Ph.D. **David Gollaher**	Member of the Board of Directors	March 3, 2020
/s/ Chrysa Mineo **Chrysa Mineo**	Member of the Board of Directors	March 3, 2020
/s/ Theodore R. Schroeder **Theodore R. Schroeder**	Member of the Board of Directors	March 3, 2020

DESCRIPTION OF COMMON STOCK

General

The following description summarizes the most important terms of our common stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this "Description of Common Stock," you should refer to our amended and restated certificate of incorporation (the "Restated Certificate") and amended and restated bylaws (the "Restated Bylaws"), which are included as exhibits to our Annual Report on Form 10-K, and to the applicable provisions of the Delaware General Corporation Law (the "DGCL"). Our authorized capital stock consists of 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share. Our board of directors has the authority, without stockholder approval, except as required by the listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock. In addition, our board of directors has the authority, without further action by our stockholders, to designate the rights, preferences, privileges, qualifications and restrictions of our preferred stock in one or more series.

Voting Rights

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election. For most other matters, the approval of a majority of the shares voting at an annual or special meeting of stockholders will be required. Exceptions to this include removing directors for cause and amending our Restated Certificate and Restated Bylaws, each of which will require the approval of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock.

Dividends and Distributions

Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of outstanding shares of common stock may receive dividends, if any, as may be declared from time to time by the Board of Directors out of legally available funds. We have never issued a dividend on shares of our common stock and have no intention to do so in the future.

Liquidation, Dissolution or Winding Up

In the event of our liquidation, dissolution or winding up, the assets legally available for distribution shall be distributed ratably to the holders of shares of common stock and preferred stock, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Other Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that our board of directors may designate and issue in the future.

Anti-Takeover Provisions

Delaware Anti-Takeover Law

We are subject to Section 203 of the DGCL, which generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 of the DGCL defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws Provisions

Provisions of the Restated Certificate and the Restated Bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, the Restated Certificate and the Restated Bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that the authorized number of directors may be changed only by resolution adopted by a majority of the authorized number of directors constituting the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law or subject to the rights of holders of preferred stock as designated from time to time, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exists any vacancies).

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66 2/3% of our then outstanding common stock.

The foregoing provisions may make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Choice of Forum

Our Restated Certificate and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders; (iii) any action asserting a claim against us or any of our directors or officers or other employees arising out of or pursuant to any provision of the DGCL, our Restated Certificate or Restated Bylaws; or (iv) any action asserting a claim against us or any of our directors or officers or other employees governed by the internal affairs doctrine. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction.

CIDARA THERAPEUTICS, INC.
AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Each member of the Cidara Therapeutics, Inc. Board of Directors (the ***"Board"***) who is not also serving as an employee of Cidara Therapeutics, Inc. (***"Cidara"***) or any of its subsidiaries (each such member, an ***"Eligible Director"***) will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service on and following the date that this amended policy is first adopted by the Board (the "***Effective Date***"). This policy is effective as of the Effective Date and may be amended at any time in the sole discretion of the Board (and as may be recommended by the Compensation Committee of the Board).

Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If (i) the Effective Date is a date other than the first day of a fiscal quarter or (ii) an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, the first quarterly installment of each applicable annual retainer set forth below will be pro-rated based on days served in the first fiscal quarter in which this policy is effective or in which the Eligible Director provides the service, as applicable, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
   a. All Eligible Directors: $40,000
   b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $25,000

2. Annual Committee Member Service Retainer (non-Chairman):
   a. Member of the Audit Committee: $7,500
   b. Member of the Compensation Committee: $6,000
   c. Member of the Nominating and Governance Committee: $4,000

3. Annual Committee Chairman Service Retainer:
   a. Chairman of the Audit Committee: $15,000
   b. Chairman of the Compensation Committee: $12,000
   c. Chairman of the Nominating and Governance Committee: $8,000

Equity Compensation

The equity compensation set forth below will be granted under the Cidara Therapeutics, Inc. 2015 Equity Incentive Plan, as may be amended from time to time (the ***"Plan"***). All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of Cidara (the "***Common Stock***") on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than for death, disability or cause, the post-termination exercise period will be 12 months from the date of termination).

1. Initial Grant: On the date of the Eligible Director's initial election to the Board, for each Eligible Director who is first elected to the Board following the Effective Date (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 35,000 shares of Common Stock (the "***Initial Grant***"). The shares subject to each Initial Grant will vest as follows: (i) 1/3rd of the shares will vest on the first anniversary of the date of grant and (ii) the remaining 2/3rds of the shares will vest in equal monthly installments over a two year period such that each Initial Grant is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: On the date of each Cidara annual stockholder meeting held after the Effective Date, for each Eligible Director who continues to serve as a non-employee member of the Board (or who is first elected to the Board at such annual stockholder meeting), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 17,500 shares of Common Stock (the "***Annual Grant***"). The shares subject to the Annual Grant will vest in one installment on the earlier of (i) the first anniversary of the date of grant and (ii) the day prior to the date of Cidara's first annual stockholder meeting held after the date of grant, such that each Annual Grant is fully vested on the earlier of (i) the first anniversary of the date of grant and (ii) the day prior to the date of Cidara's first annual stockholder meeting held after the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

As of the Effective Date, this Amended Non-Employee Director Compensation Policy shall replace and supersede any compensation agreements between the Company and any Eligible Director serving on the Board on the Effective Date.

1.

Exhibit 21.1

Cidara Therapeutics, Inc. Subsidiaries

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

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-3 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. 333-203434, 333-210263, 333-216722, 333-228282, and 333-231326) 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 March 3, 2020, 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, 2019.

/s/ Ernst & Young LLP

San Diego, California

March 3, 2020

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: March 3, 2020

/s/ Jeffrey Stein, Ph.D.

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

Exhibit 31.2

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

I, 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: March 3, 2020

By: /s/ James Levine

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

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Cidara Therapeutics, Inc. (the "Company") for the period ending December 31, 2019 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, Jeffrey Stein, Ph.D., President and Chief Executive 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: March 3, 2020

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

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Cidara Therapeutics, Inc. (the "Company") for the period ending December 31, 2019 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: March 3, 2020 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.