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, 2022

OR

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

Commission File Number 001-36912

CIDARA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

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

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

Title of each class	Trading symbol	Name of each exchange on which is registered
Common Stock, $0.0001 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 ☐ No ☒

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

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

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

Indicate by check mark whether the Registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Market on June 30, 2022, was approximately $33.2 million.

The number of shares of Registrant's common stock outstanding as of March 16, 2023 was 89,008,412.

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 2023 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, 2022.

CIDARA THERAPEUTICS, INC.

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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, or U.S., 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;
- the potential impact of the COVID-19 pandemic on our business; 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.

Risk Factor Summary

Below is a summary of the principal factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered.

- Our operations, business and financial results have been and could continue to be adversely impacted by the current public health pandemic related to COVID-19.
- We depend heavily on the success of rezafungin and CD388, which is currently in Phase 1 and Phase 2a clinical development, and we are very early in our efforts to develop other product candidates from our Cloudbreak program, none of which may be successful.
- If we experience delays or difficulties in enrolling patients in our clinical trials our receipt of necessary regulatory approvals could be delayed or prevented.
- If clinical trials for rezafungin, CD388, CD421 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.
- If serious adverse reactions 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.
- Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, formulary committees, third-party payors and others in the medical community necessary for commercial success.
- 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 face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We may not be successful in our efforts to identify, discover, and develop potential product candidates through our Cloudbreak platform or otherwise.
- We need substantial additional funding to complete the development of rezafungin and to advance CD388, CD421 and our Cloudbreak program.
- We are dependent on our collaboration partners to provide funding to continue the development of rezafungin and CD388; for the commercialization of rezafungin outside Japan; and for the late-stage development, manufacturing, registration and commercialization of CD388. If the collaborations are not successful, we may not be able to complete the development of rezafungin and CD388, or capitalize on the full market potential for rezafungin and CD388.
- 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.
- 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.
- 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 preclinical Cloudbreak programs.
- The price of our stock may be volatile, and you could lose all or part of your investment.

PART I

Item 1. Business.

Overview

We are a biotechnology company focused on the discovery, development and commercialization of long-acting therapeutics designed to transform the standard of care for patients facing serious diseases. We are focused on infectious diseases and oncology. Our lead product candidate is rezafungin (trade name REZZAYO™), an intravenous formulation of a novel echinocandin antifungal. Rezafungin is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections. Rezafungin will be positioned in the estimated $4.2 billion global systemic antifungal market in which there is high unmet need, high mortality rate, few new agents in development and significant market opportunity.

Our primary focus now is using our Cloudbreak® platform to develop a potential new class of drugs called drug-Fc conjugates, or DFCs, for the prevention and treatment of serious diseases. This technology couples potent inhibitors to a human antibody fragment to create long-acting DFCs designed to inhibit multiple disease targets. Our most advanced DFC program is CD388, a highly potent, long-acting antiviral designed to deliver universal prevention and treatment of seasonal and pandemic influenza, which is in Phase 1 and Phase 2a clinical trials. Additional programs are targeting the SARS-CoV-2 strains causing COVID-19 and multiple solid tumor oncology indications.

Recent Developments

Cloudbreak Oncology Program

Immune checkpoint antagonists have generated durable responses in cancers with improved side effect profiles compared to conventional chemotherapy. However, to date, improved outcomes from existing therapies have been limited to a relatively small subset of patients. To broaden the response rate to more patients, targeting additional mechanisms of tumor immune evasion will be critical. Using our DFC approach, we are seeking to generate a best-in-class CD73 inhibitor that combines the attributes of small molecule inhibitors and monoclonal antibody, or mAb, inhibitors that are currently in clinical trials.

In January 2023, we nominated CBO-212 as our first oncology DFC candidate. With our Cloudbreak oncology program we seek to develop a new generation of immunotherapies, and our lead oncology DFC candidate, CD421 (which is an enhanced version of CBO-212), is a first-in-class CD73 inhibitor that combines the strengths of small molecules and monoclonal antibodies targeting CD73. We are currently advancing CD421 that confers reduced immunogenic properties through investigational new drug application, or IND, -enabling studies.

In February 2023, we expanded our existing collaboration with WuXi XDC, a leading global contract manufacturing organization, or CMO, dedicated to end-to-end bioconjugates services, under which WuXi XDC will provide IND-enabling chemistry and manufacturing and controls, or CMC, development services for our Cloudbreak oncology program.

FDA Advisory Committee Recommendation and FDA Approval of Rezafungin for the Treatment of Candidemia and Invasive Candidiasis

On January 24, 2023, the U.S. Food and Drug Administration, or FDA, Antimicrobial Drugs Advisory Committee voted favorably 14 to 1 that we, as part of our New Drug Application, or NDA, provided sufficient evidence supporting a favorable benefit-risk assessment for a limited use indication for rezafungin for the treatment of candidemia and invasive candidiasis in adult patients with limited or no alternative treatment options.

On March 22, 2023, the FDA approved REZZAYO (rezafungin for injection) for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options. REZZAYO is the first new treatment option approved for patients with candidemia and invasive candidiasis in over a decade, and is the only available once-weekly echinocandin.

Compliance with Nasdaq Listing Requirements

On February 9, 2023, we received formal notice from The Nasdaq Stock Market, LLC, or Nasdaq, Hearings Panel, or the Panel, stating that we have regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2), subject to a discretionary Panel Monitor until November 9, 2023.

Phase 2a Interim Results

On March 1, 2023, we announced efficacy and safety data from a planned interim analysis of our ongoing Phase 2a trial evaluating the pre-exposure prophylactic activity of CD388 against the H3N2 influenza A virus strain, as of a February 13, 2023 data cut-off. The Phase 2a trial is a single-center, randomized, double-blind influenza challenge study in healthy volunteers designed to assess the prophylactic antiviral activity, safety, tolerability and pharmacokinetics of CD388 in healthy volunteers. The interim analysis is based on 56 subjects enrolled in the trial, with 28 subjects receiving a single dose of CD388 (150 mg) and 28 subjects receiving a placebo.

The interim data for the primary efficacy endpoint of Area Under the Viral Load-Time Curve (a measure of a drug's ability to attenuate viral replication), or VL-AUC, and for the secondary efficacy endpoint of influenza infection incidence for 150 mg CD388 versus placebo are shown below.

	Placebo (n=28)	CD388 150 mg (n=28)
Area Under the Viral Load-time Curve (VL-AUC)- Mean (SD)	16.1 (11.9)	10.7 (8.0)
PCR confirmed influenza infection- n (%)	14 (50%)	6 (21.4%)

As shown above, despite the small sample size in this planned interim analysis, a decrease in viral replication in the upper respiratory tract and influenza infection was observed in participants receiving a single dose of CD388 when compared to placebo. No treatment emergent adverse events leading to study discontinuation or serious adverse events were reported in the interim analysis. All participants included in the interim analysis received either CD388 or placebo and were then challenged with influenza five days later.

Cloudbreak Platform

We believe our Cloudbreak platform has the potential to offer a fundamentally new approach to prevent and treat serious diseases, by developing product candidates designed to provide potent disease targeting activity and immune system engagement in a single long-acting molecule. Because serious disease often results when a pathogen or cancer cell evades or overcomes the host immune system, our Cloudbreak DFC candidates are designed to counter diseases in two ways: prevention of disease proliferation or immune evasion by directly targeting and, where applicable, by focusing the immune system on a pathogen or infected cell. We believe this is a potentially transformative approach, distinct from current therapies, monoclonal antibodies and vaccines. In addition, DFCs are designed to have several advantages, including:

- Multivalent binding which has the potential to increase potency;
- Ability to engage different targets on the same target cell to decrease resistance or, in the case of a cancerous cell, to serve as a "drug cocktail" in a single molecule, which may improve response to treatment;
- Potential to target multiple viral pathogens or oncological targets with a single DFC; and
- Potential for universal coverage against all viral variants and all people irrespective of immune status.

In contrast to monoclonal antibodies, our DFCs are smaller, have the potential for better tissue penetration and are designed to target multiple sites. Unlike small molecules, we believe DFC optimization can be focused primarily on potency.

Our lead Cloudbreak candidates are CD388, a DFC for the prevention and treatment of influenza, or influenza DFC, and CD421, a CD73-targeting DFC for the treatment of solid tumors.

In September 2020, we nominated CD388, our influenza DFC, as a development candidate. We submitted an IND for CD388 in December 2021 and initiated a Phase 1 trial (NCT05285137) in March 2022. The Phase 1 trial is a randomized, double-blind, dose-escalation study to determine the safety, tolerability and pharmacokinetics of intramuscular and subcutaneous administration of CD388 in healthy subjects. Dosing of all six planned cohorts has been initiated as planned. In addition, a separate Phase 1 Japanese bridging study has been initiated.

In September 2022, we initiated a Phase 2a trial (NCT05523089) to evaluate the pre-exposure prophylactic activity of CD388 against influenza virus. The Phase 2a trial, which dosed its first healthy volunteer in September 2022, is a single-center, randomized, double-blind, placebo-controlled, proof-of-concept study to assess the prophylactic antiviral activity, safety, tolerability and pharmacokinetics of CD388 against influenza via a human viral challenge (influenza) model. Multiple dose levels of CD388 will be evaluated in volunteers who will receive a single administration of CD388 or placebo prior to influenza viral challenge. Interim results in February 2023 demonstrated a reduction in the viral load (area under the curve) for 150 mg of CD388 compared to placebo and a reduction in the incidence of subjects infected following influenza challenge for 150 mg of CD388 compared to placebo. Final results are expected later in 2023.

All Phase 1 and Phase 2a trials are being conducted under the Janssen Collaboration Agreement (as defined below).

In December 2022, we received the first U.S. patent for CD388. The patent includes claims directed to the composition of matter of CD388. The patent is projected to expire in 2039 plus any available patent term extension.

The Cloudbreak platform has also enabled us to expand the development of DFCs to target other life-threatening viral diseases including the SARS-CoV-2 strains causing COVID-19.

In addition, we have expanded the Cloudbreak platform beyond infectious diseases, to discover and develop highly potent DFCs that can target multiple immune checkpoint pathways with a single DFC for oncologic diseases. Cidara's lead oncology development candidate, CD421, targets CD73 in the adenosine pathway, which contributes to immune evasion in solid cancers by flooding the tumor microenvironment with adenosine, a potent immune cell suppressor. CD73 is highly expressed on a variety of tumor and stromal cells as well as immunosuppressive cell populations, such as regulatory T cells and myeloid-derived suppressor cells. CD421 is designed to address the potency, efficacy, pharmacokinetic and safety limitations of small molecule and monoclonal antibody candidates targeting CD73.

Janssen Collaboration Agreement

On March 31, 2021, we entered into the exclusive, worldwide license and collaboration agreement, or the Janssen Collaboration Agreement, with Janssen Pharmaceuticals, Inc., or Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize one or more DFCs based on our Cloudbreak platform for the prevention and treatment of influenza.

Under the terms of the Janssen Collaboration Agreement, we are collaborating in the research, preclinical and early clinical development of CD388, under a mutually-agreed research plan with the objective of advancing development through Phase 1 clinical trials and the first Phase 2a clinical trial. We are responsible for performing all IND-enabling nonclinical studies and early-stage clinical trials under the research plan. Both parties are responsible for conducting certain specified chemistry, manufacturing and controls development activities under the research plan. Janssen is solely responsible, and reimburses us for internal personnel and out-of-pocket costs incurred in performing the research plan activities in accordance with an agreed budget. After completion of the research plan and upon its election to proceed with development, Janssen will be solely responsible for late-stage development, manufacturing, licensure and commercialization. Upon the effectiveness of the Janssen Collaboration Agreement, Janssen paid us an upfront payment of $27.0 million. As of the execution of the Janssen Collaboration Agreement, we are eligible for reimbursement by Janssen of up to $58.2 million in research and development costs incurred in conducting research plan activities. As of December 31, 2022, we have received the $27.0 million up-front payment, $25.1 million in research and development reimbursements, and $3.0 million in milestone payments.

We are eligible to receive up to an additional $237.0 million in development and regulatory milestone payments from Janssen for successful completion of certain activities over the next several years, including but not limited to Janssen's decision to proceed with clinical development and initiation of a pivotal trial. In addition, we may be eligible to receive approximately $455.0 million in commercial milestones as well as royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits.

Rezafungin

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

ReSTORE Phase 3 clinical trial

In December 2021, we reported positive topline results from ReSTORE, our Phase 3 pivotal clinical trial in patients with candidemia and/or invasive candidiasis (NCT03667690). ReSTORE was a global, randomized, double-blind, controlled trial evaluating the efficacy and safety of rezafungin as a potential first-line treatment for candidemia and invasive candidiasis. ReSTORE enrolled 187 patients and evaluated one 400 milligram, or mg, loading dose of rezafungin for the first week followed by 200 mg of rezafungin dosed once-weekly for up to four weeks in total. The treatment arm was compared to approved daily dosing of caspofungin in a 1:1 randomization.

Results from the ReSTORE trial showed that rezafungin met the primary endpoint for the FDA of all-cause mortality at Day 30, and also met the primary endpoint for the European Medicines Agency, or EMA, of global cure at Day 14. Both results demonstrated statistical non-inferiority of rezafungin dosed once-weekly, versus caspofungin dosed once-daily, the current standard of care.

ReSPECT Phase 3 clinical trial

We are currently conducting the ReSPECT, single, global, randomized, double-blind, controlled Phase 3 pivotal clinical trial (NCT04368559) 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, dosed at 400 mg for the first week followed by 200 mg once weekly out to 90 days, is being compared to a regimen containing two drugs (an azole and Bactrim) dosed once daily for 90 days. The primary efficacy outcome for this trial for the FDA and EMA is fungal-free survival at Day 90. We expect this trial to enroll approximately 462 patients, and over 50% of patients have been enrolled thus far. While the ReSPECT trial remains open for enrollment, we continue to monitor the near- and long-term impact of COVID-19 on the ability of our clinical investigators to recruit patients at each of our global clinical trial sites. The study is currently enrolling in the European Union, or EU, Canada and the U.S.

Melinta License Agreement

On July 26, 2022, we entered into a License Agreement, or the Melinta License Agreement, with Melinta Therapeutics, LLC, or Melinta, under which we granted Melinta an exclusive license to develop and commercialize products that contain or incorporate rezafungin in the U.S.

Melinta will be solely responsible for the commercialization of rezafungin in the U.S., at its sole expense. We are responsible for conducting an agreed upon development plan that includes, among other activities, completion of the ongoing ReSPECT Phase 3 pivotal clinical trial for the prevention of invasive fungal infections in adult allogeneic blood and marrow transplant recipients. We will initially remain the holder of the rezafungin IND and NDA. Both applications will transfer to Melinta on a transfer date determined based on the status of the ReSPECT trial and the associated supplemental NDA for the prophylaxis indication. Following the transfer date, we will remain financially responsible for post-marketing commitments and other remaining development obligations and the costs for those will be deducted from royalties owed to us by Melinta.

The total potential transaction value of the Melinta License Agreement is $460.0 million, including a $30.0 million upfront payment and up to $430.0 million in regulatory and commercial milestones. In addition, we are eligible to receive tiered royalties on U.S. sales in the low double digits to mid-teens. As of December 31, 2022, we have received the $30.0 million up-front payment.

Mundipharma Collaboration Agreement

On September 3, 2019, we announced a strategic partnership with 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 and License Agreement, or the Mundipharma Collaboration Agreement, with Mundipharma Medical Company, or Mundipharma, we granted Mundipharma an exclusive, royalty-bearing license to develop, register and commercialize rezafungin outside the U.S. and Japan. The total potential transaction value is $568.4 million, including an equity investment, an up-front payment, global development funding, and certain development, regulatory, and commercial milestones. The Company is also eligible to receive double-digit royalties in the teens on tiers of annual net sales.

As of December 31, 2022, we have received $9.0 million from the sale of our equity to Mundipharma, a $30.0 million up-front payment, $31.2 million in global development funding, and $25.1 million in milestone payments (including an $11.1 million milestone payment creditable against future royalties payable to us).

Our Strategy

Our objective is to become the leading biotechnology company in the discovery, development and commercialization of novel, best-in-class long-acting therapeutics designed to transform the standard of care for patients facing serious diseases. Key elements of our strategy include:

- **Develop product candidates from our Cloudbreak platform.** In December 2021, we submitted an IND for CD388 for seasonal and pandemic influenza prevention and treatment, which is in Phase 1 and Phase 2a clinical trials, and are developing new product candidates targeting the prevention and treatment of other life-threatening viral diseases including the SARS-CoV-2 strains causing COVID-19. In addition, we have expanded the Cloudbreak platform beyond infectious diseases, to discover and develop highly potent DFCs that can target multiple immune checkpoint pathways with a single DFC for oncologic diseases. Our lead oncology development candidate, CD421, targets CD73 in the adenosine pathway. We have recently expanded our existing collaboration with WuXi XDC under which WuXi XDC will provide IND-enabling CMC development services for our Cloudbreak oncology program. We may fund these programs alone, with grant or government contract funding 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.

- **Advance rezafungin to approval.** We are developing rezafungin, a once-weekly echinocandin antifungal, to address serious fungal infections, including, but not limited to those considered urgent and serious threats by the U.S. Centers for Disease Control and Prevention, or CDC. We successfully completed our ReSTORE Phase 3 treatment clinical trial, which served as the basis for our NDA filing for the treatment indication, and are currently enrolling our ReSPECT Phase 3 prophylaxis clinical trial. Approval in these indications would enable our licensing partners to target two distinct and commercially-attractive market segments with significant unmet needs from the current standard of care: the treatment of candidemia and invasive candidiasis, and the prevention of invasive fungal infections in a highly vulnerable population, adults undergoing allogeneic blood and marrow transplantation.

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 once-weekly dosing, high front -loaded exposure, high tissue penetration, safety and tolerability profile, lack of drug-drug interactions and broad spectrum.

Rezafungin is being developed for both 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 or 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 U.S.

Despite advances achieved in the diagnosis and treatment of candidemia, these infections continue to cause high mortality rates. According to a study published in Clinical Infectious Disease (2009), candidemia has a crude mortality rate of 35% within 12 weeks of diagnosis. By contrast, the CDC reports that the mortality rate due to methicillin-resistant staphylococcus aureus, or MRSA, infections is 13%. Further, it is estimated that each case of candidemia results in an additional 23 days of hospitalization and over $68,000 in additional treatment costs.

Physicians' options for the treatment of systemic 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. Patients who have received a BMT, cancer chemotherapy or solid organ transplant may receive antifungal prophylaxis to prevent deadly *Candida*, *Aspergillus* and/or *Pneumocystis* infections for several weeks to over a year, depending on the period of immunosuppression or development of Graft Versus Host Disease. Current paradigms for the prevention of invasive fungal disease are complex because they require patient-specific plans and drug cocktails, dictated by the underlying disease and the local epidemiology of fungal infections which may be subject to change even when customized.

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 pneumocystis pneumonia 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 U.S. 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, roughly ten percent of patients on echinocandins receive once-daily infusions at home or need to travel to an outpatient infusion center daily, for weeks if not months. This use 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 U.S. In 2019, the CDC issued its Report on Antibiotic Resistant Threats. The list included several fungal pathogens: *Candida auris* is listed as an ‘Urgent Threat’, Drug-resistant Candida is listed as a ‘Serious Threat’ and Azole-resistant *Aspergillus fumigatus* as a ‘Watch List Threat’.

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, maximum plasma concentration, or C_{max}, and area under the plasma concentration-time curve, or 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 U.S., 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 pharmacokinetic 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, simplicity, outpatient use and pharmacokinetic.

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 may improve clearance 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 U.S. and the EU.
- **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 and/or ICU setting may reduce the risk for contracting nosocomial infections. Data from the Phase 3 ReSTORE trial suggest a numerically shorter length of stay for patients in the rezafungin arm vs patients in the caspofungin arm, in both the ICU and hospital. 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.

We have sought multiple designations from regulators, including the FDA and the EMA, to support the rapid evaluation of rezafungin in the development phase and to enhance the commercial attributes of rezafungin in the commercial phase.

In the U.S., the FDA has granted rezafungin the following designations:

- For the treatment of candidemia and invasive candidiasis, rezafungin has designations for Qualified Infectious Disease Product, or QIDP, Fast Track, and Orphan Drug. QIDP and Orphan Drug designations together provide a total of 12 years of marketing exclusivity in the U.S. from the time of FDA approval.
- For the prophylactic use in patients undergoing allogeneic blood and marrow transplant, rezafungin has designations for QIDP and Fast Track. The QIDP designation provides a total of five years of marketing exclusivity in the U.S. from the time of FDA approval.

The FDA's QIDP and Fast Track designations are designed to provide eligibility for (1) more frequent interactions with the FDA to expedite drug development and review, (2) priority review, which seeks to reduce the total time for FDA to take action on a NDA from 12 months to eight months, and (3) QIDP provides a five-year extension to any marketing exclusivity period for which the drug qualifies on approval. The FDA's Orphan Drug designation is designed to provide eligibility for (1) a seven-year period of market exclusivity in the U.S. upon FDA approval, (2) financial benefits including a waiver from payment of user fees and tax credits for the cost of the clinical research, and (3) an exemption from performing clinical trials in pediatric patients.

In the EU, the European Commission has granted rezafungin Orphan Drug Designation for the treatment of invasive candidiasis. The Orphan Drug Designation provides (1) unlimited scientific advice on the trials needed to assess benefit risk, (2) reduced fees, (3) 10 years of market exclusivity protection from similar medicines with similar indications upon approval of the marketing authorization, and (4) two additional years of market exclusivity when the results from pediatric studies compliant with an approved Pediatric Investigational Plan, or PIP, are included in the Summary of Product Characteristics, or SmPC.

We, together with our partners Mundipharma and Melinta, plan to seek orphan drug designation for rezafungin for prophylactic use in the U.S. and Europe.

Cloudbreak Platform

The Cloudbreak DFC platform has the potential to offer a fundamentally new approach to prevent and treat serious diseases. Our product candidates called DFCs are designed to provide both potent disease targeting activity and immune system engagement in a single molecule. Because serious disease often results when a pathogen or cancer cell evades or overcomes the host immune system, our Cloudbreak DFC candidates are designed to counter diseases in two ways: prevention of disease proliferation or immune evasion by directly targeting and, where applicable, by focusing the immune system on a pathogen or infected cell. We believe this is a potentially transformative approach, distinct from current therapies, monoclonal antibodies and vaccines. In addition, DFCs are designed to have several advantages, including:

- Multivalent binding which has the potential to increase potency;

- Ability to engage different targets on the same target cell to decrease resistance or, in the case of a cancerous cell, to serve as a “drug cocktail” in a single molecule, which may improve response to treatment;
- Potential to target multiple viral pathogens or oncological targets with a single DFC; and
- Potential for universal coverage against all viral variants and all people irrespective of immune status.

In contrast to monoclonal antibodies, our DFCs are smaller and have the potential for better tissue penetration and can be designed to target multiple sites. Unlike small molecules, we believe DFC optimization can be focused primarily on potency.

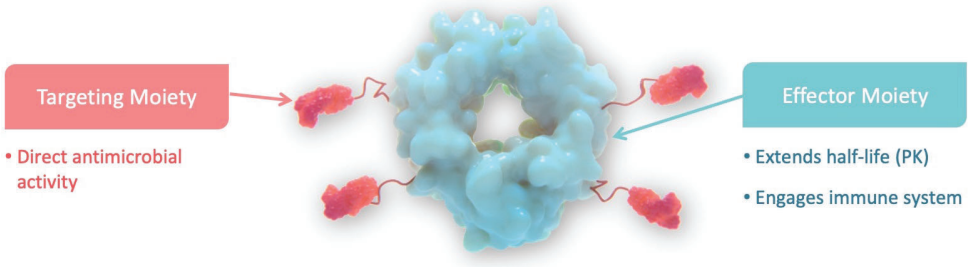
The Cloudbreak platform has enabled us to expand the development of DFCs to target other life-threatening viral diseases including the SARS-CoV-2 strains causing COVID-19.

In addition, we have expanded the Cloudbreak platform beyond infectious diseases to discover and develop highly potent DFCs that can target multiple immune checkpoint pathways with a single DFC for oncologic diseases.

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

- Targeting Moiety (TM): A highly potent small molecule and/or peptide that binds surface targets on the pathogen or host cell to directly inhibit viral proliferation.
- Effector Moiety (EM): A proprietary composition that contains the fragment crystallizable, or Fc, region of human IgG1 antibodies, which was selected to extend half-life engagement and engage the human immune system via Fc-gamma receptors.

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



Cloudbreak DFC (drug-Fc conjugate) Program Overview

Cidara is leveraging the Cloudbreak platform to address multiple diseases. Each DFC targets a life-threatening disease, focused on infectious diseases and oncology. Our DFC research and development programs include:

- Influenza;
- Cancer (solid tumors); and
- COVID-19.

DFCs 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. DFCs are not vaccines, small-molecule drugs, or monoclonal antibodies. DFCs are novel, Fc-conjugates designed for the following features:

- Multimodal mechanism of action: Potent, direct antiviral activity and tunable immune system engagement
- Strong target binding: High affinity to essential, conserved targets on the virus surface and/or surface of infected cells
- 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 DFC Development Candidate CD388

Influenza 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 influenza. 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. While today's influenza vaccines are credited with significant public health benefits and offer our current best defense, only 52% of Americans get an annual influenza vaccine. As a result, a large proportion of Americans are still at risk of getting influenza yearly. For example, during the 2018-19 influenza season, 71% did not respond to vaccination and 34,200 people died of influenza-related illness in the U.S. The estimated average annual total economic burden of influenza to the U.S. healthcare system and society is more than $11.2 billion. 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 U.S., more patients are at higher risk for serious complications resulting from influenza. 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 influenza:

- 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 DFCs for Influenza

- **Broad-Spectrum, Universal Coverage:** Cloudbreak DFCs have demonstrated activity against pandemic and seasonal influenza A and B viruses, including resistant strains (e.g. oseltamivir-resistant H1N1, zanamivir-resistant influenza B) and strains with high pandemic potential (e.g. H5N1, H7N9).
- **Superior Resistance Profile:** DFCs may be less prone to viral resistance, by virtue of the targeting mechanism and multivalent target engagement.
- **Protection for High-Risk Populations:** Unlike vaccines, the potent intrinsic antiviral activity of the DFCs has demonstrated antiviral protection independent of immune system status in animal efficacy models.
- **Seasonal and Pandemic Readiness:** DFCs are well-suited for immediate and robust response to influenza challenges by providing rapid onset of protection and coverage of strains that are frequently missed by the seasonal vaccine. Moreover, DFCs are not subject to the lengthy and unpredictable process of vaccine manufacturing.
- **Long Duration of Action:** A single DFC dose may protect from influenza for an entire influenza season.

DFC Development Candidate for Influenza: CD388

Pre-Clinical Studies of CD388 for Influenza

We have developed a novel DFC that provides a direct and sustained antiviral effect and retains potent activity in immune compromised hosts. The results of multiple preclinical studies with CD388 indicate that it is effective in both the treatment and prevention of influenza infections. CD388 has been engineered to extend half-life and has the potential to extend the duration of protection in prophylactic applications.

In Vitro Studies Measuring CD388 Potency Against Multiple Influenza Strains

We evaluated CD388 *in vitro* for its ability to inhibit viral replication in cell-based assays versus a large panel of seasonal and pandemic Influenza A strains, including 2009 H1N1 pandemic strain, H3N2 and H5N1, H7N9, oseltamivir (Tamiflu)-resistant H1N1, and influenza B strains, including zanamivir (Relenza)-resistant influenza B. CD388 showed potent activity against all the strains tested, including influenza B, which is less sensitive to oseltamivir phosphate.

In Vivo Studies Measuring CD388 Potency Against Multiple Influenza Strains in Lethal Infection Models

We evaluated CD388 *in vivo* in lethal mouse models against multiple H1N1, H3N2 and influenza B strains. CD388 provided full protection against all strains tested H1N1 with single, low doses.

In all studies, we measured the average body weights of the mice over time to support the survival data with CD388. The CD388 dosed mice maintained stable body weights over the 21-day course of the experiments demonstrating the potency of CD388 at low doses and the potency and tolerability of CD388 at high doses. In a quantitative lung burden model versus H1N1 influenza, single, low doses of CD388 demonstrated superior reduction in lung viral burden compared to oseltamivir (Tamiflu) administered daily at 10x its human equivalent dose. Unlike oseltamivir, which only minimally impacted viral burden in lung at all tested doses, viral burden in CD388 treated animals increased with dose.

In Vivo Study Evaluating CD388 as a Long-Acting Prophylactic Agent Against Influenza

We tested mean plasma concentrations of CD388 in mice and based on the long half-life we observed, we evaluated CD388 in vivo in a lethal mouse model of H1N1 by administering CD388 to the mice 7 days before lethal influenza challenge. CD388 provided 100% protection from mortality across a broad range of dose levels, demonstrating its potential suitability as a long-acting prophylactic agent for influenza prevention.

Cloudbreak Oncology Program and Our DFC Development Candidate CD421

Cloudbreak DFCs stably couple highly potent small molecules or peptides to a proprietary variant of a human antibody fragment. As a result, DFCs are long-acting, and are designed to directly inhibit specific disease targets. DFCs can be tuned to engage the immune system or to be immune silent, expanding the breadth of indications that can be targeted. Immune active DFCs can attract an immune response against cancer cells to maximize disease eradicating activity, while immune silent DFCs allow for expansion into cancer indications where immune system engagement would result in host toxicity.

With our Cloudbreak oncology program we seek to develop a new generation of immunotherapies, and our CD421 DFC is a first-in-class CD73 inhibitor that combines the strengths of small molecules and monoclonal antibodies targeting CD73. We are advancing CD421 through IND-enabling studies.

CD421 targets CD73 in the adenosine pathway, which contributes to immune evasion in solid cancers by flooding the microenvironment surrounding tumors with adenosine, a potent immune cell suppressor. CD73 is highly expressed on a variety of tumor and stromal cells as well as immunosuppressive cell populations such as regulatory T cells and myeloid-derived suppressor cells. CD421 is designed to address the potency, efficacy, pharmacokinetic and safety limitations of small molecule and monoclonal antibody candidates targeting CD73 in clinical development. CD421 has several attributes that potentially differentiate it from the most advanced small molecule and mAb inhibitors in clinical development:

- Some solid tumors evade immune mediated clearance by expressing cell-anchored and soluble forms of CD73 to elevate adenosine levels in the tumor microenvironment, or TME. CD421 fully inhibited both forms of the enzyme with high potency, whereas representative CD73 inhibitor mAbs in clinical development we evaluated (mupadolimab and oleclumab), only inhibited cell anchored CD73.
- In functional assays the ability of CD421 to restore activation of human peripheral blood mononuclear cells, or PBMCs, suppressed with adenosine monophosphate, or AMP, were measured and compared to mAb and small molecule CD73 inhibitors in clinical development. CD421 demonstrated superior activity to the mAb comparators (mupadolimab and oleclumab), and similar or improved activity compared to the small molecule inhibitor panel.
- CD73 internalization is an additional mechanism to potentially reduce adenosine levels in the TME that is only achievable via receptor cross-linking, which is not possible with small molecule inhibitors. The multivalent presentation of CD73 inhibitors on CD421 induced receptor internalization and significant reduction of CD73 receptors expressed on a human breast cancer cell line.
- These attributes, coupled with the long half-life mediated by the DFC Fc domain, led to significant tumor reduction in a mouse syngeneic tumor model after a single dose of CD421.

License and Collaboration Agreements

Mundipharma Collaboration Agreement

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

Collaboration. Under the Mundipharma Collaboration Agreement, we are responsible for leading the conduct of an agreed global development plan, or the Global Development Plan, that includes our ongoing ReSTORE Trial of the Mundipharma Licensed Product, and our ongoing ReSPECT Trial of the Mundipharma Licensed Product, as well as specified GLP-compliant non-clinical studies and CMC development activities for the Mundipharma Licensed Product. Mundipharma is responsible for performing all development activities, other than Global Development Plan activities, that may be necessary to obtain and maintain regulatory approvals for the Mundipharma Licensed Product outside of the U.S. and Japan, or the Mundipharma 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 Mundipharma Licensed Product in the Mundipharma Territory, subject to our retained right as described below.

We 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 Mundipharma Licensed Product and rezafungin.

Until the seventh anniversary of the first commercial sale of the Mundipharma 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 Mundipharma Licensed Product, Subcutaneous Product and Other Products) that such party proposes to out-license in the other party's territory.

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

Financial Terms. As of the execution of the Mundipharma Collaboration Agreement, 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 $31.2 million. The total potential transaction value is $568.4 million, including an equity investment, an up-front payment, global development funding, and certain development, regulatory, and commercial milestones. We are also eligible to receive double-digit royalties in the teens on tiers of annual net sales.

As of December 31, 2022, we have received $9.0 million from the sale of our equity to Mundipharma, a $30.0 million up-front payment, $31.2 million in global development funding, and $25.1 million in milestone payments (including an $11.1 million milestone payment creditable against future royalties payable to us).

Termination. Either party may terminate the Mundipharma Collaboration Agreement for uncured material breach by the other party. 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 ReSTORE Trial and the ReSPECT Trial, Mundipharma will continue to be liable for its share of Global Development Costs as described above. We may terminate the Mundipharma Collaboration 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.

Janssen Collaboration Agreement

On March 31, 2021, we entered into the Janssen Collaboration Agreement with Janssen to develop and commercialize one or more DFCs based on our Cloudbreak platform, for the prevention and treatment of influenza, including CD388 and CD377, or the Products. The effectiveness of the Janssen Collaboration Agreement, including the effectiveness of the terms and conditions described below, was subject to the expiration or earlier termination of all applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or HSR. HSR clearance was obtained on May 12, 2021 and the Janssen Collaboration Agreement became effective on the same date.

Collaboration. We will collaborate with Janssen in the research, preclinical development and early clinical development of CD388 or another mutually-agreed influenza DFC development candidate, or, in each case, the Development Candidate, under a mutually-agreed research and development plan, or the Research Plan, with the objective of advancing such Development Candidate through the completion of mutually-agreed Phase 1 clinical trials and the first Phase 2 clinical trial, or Phase 2 Study. Unless otherwise agreed by the parties, we will be responsible for performing, or having performed, all IND-enabling studies and clinical trials under the Research Plan, and we will be the IND holder for the Research Plan clinical trials. Both parties will be responsible for conducting certain specified chemistry, manufacturing and

controls development activities under the Research Plan. Janssen will be solely responsible, and reimburse Cidara, for internal full-time equivalent and out-of-pocket costs we incur in performing Research Plan activities in accordance with a mutually-agreed budget.

Within 90 days after delivery by Cidara to Janssen of results of the Phase 2 Study and all then-available data from other clinical trials of the Development Candidate conducted under the Research Plan, or the Election Period, Janssen will be obligated to notify Cidara of Janssen's election to proceed with further clinical development of Products, such notice, an Election to Proceed Notice. If Janssen fails to deliver an Election to Proceed Notice prior to expiration of the Election Period, the we will have the right to terminate the Janssen Collaboration Agreement upon written notice to Janssen. If Janssen provides an Election to Proceed Notice prior to expiration of the Election Period, then the parties will continue any then-ongoing Research Plan activities to completion, and Janssen will otherwise be solely responsible for the development, manufacture and commercialization of Products, at Janssen's sole expense.

Licenses. Upon the effectiveness of the Janssen Collaboration Agreement, we granted Janssen an exclusive, worldwide, royalty-bearing license to develop, register and commercialize Products, subject to our retained right to conduct Research Plan activities as described above. In addition, we granted Janssen an exclusive right of first negotiation until December 31, 2021, to negotiate and enter into a separate definitive agreement pursuant to which the parties would collaborate in the research and development of DFCs for the treatment or prevention of respiratory syncytial virus. This right of first negotiation expired on December 31, 2021.

Non-Compete Covenant. We will covenant that, except for the performance of Research Plan activities, from the effectiveness of the Janssen Collaboration Agreement until the fifth anniversary of the completion of all Research Plan activities and our delivery to Janssen of all Research Plan deliverables, Cidara and its affiliates will not directly or indirectly (including through any third-party contractor or through or in collaboration with any third-party licensee) develop, file any IND or application for marketing approval for, or commercialize any DFC that binds influenza or influenza viral proteins at therapeutic levels, except that we have the right to conduct limited internal research of such DFCs for the purposes of generating data to support patent filings and improving and further developing our DFC technology more broadly. Our non-compete covenant described above will not apply to any DFC that demonstrates high specificity for a virus other than the influenza virus and does not possess significant activity against the influenza virus.

Financial Terms. Upon the effectiveness of the Janssen Collaboration Agreement, Janssen paid Cidara an upfront payment of $27.0 million. As of the execution of the Janssen Collaboration Agreement, we are entitled to reimbursement by Janssen of up to $58.2 million in research and development costs incurred in conducting Research Plan activities. As of December 31, 2022, we have received the $27.0 million up-front payment, $25.1 million in research and development reimbursements, and $3.0 million in milestone payments. We are eligible to receive up to $237.0 million in development and regulatory milestone payments from Janssen for successful completion of certain activities over the next several years, including but not limited to Janssen's decision to proceed with clinical development and initiation of a pivotal trial. In addition, we may be eligible to receive approximately $455.0 million in commercial milestones as well as royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits.

Termination. In addition to our right to terminate the Janssen Collaboration Agreement for Janssen's failure to deliver the Election to Proceed Notice prior to expiration of the Election Period, the Janssen Collaboration Agreement includes standard termination provisions upon material breach, insolvency or safety concerns. In addition, Janssen may terminate the Janssen Collaboration Agreement for convenience as follows:

- prior to the completion of all Research Plan activities and our delivery to Janssen of all Research Plan deliverables, upon 90 days' written notice to Cidara, provided that if any clinical trial under the Research Plan is ongoing at the time of such termination, such clinical trial will be completed in accordance with the terms of the Janssen Collaboration Agreement;
- after completion of the Phase 2 Study and before expiration of the Election Period, immediately upon written notice to Cidara; or
- after delivery of the Election to Proceed Notice, upon 90 days' written notice to Cidara, which termination may be of the Janssen Collaboration Agreement in its entirety or on a country-by-country or Product-by-Product basis.

Melinta License Agreement

On July 26, 2022, we entered into the Melinta License Agreement with Melinta under which we granted Melinta an exclusive license to develop and commercialize products that contain or incorporate rezafungin, or the Melinta Licensed Product, in the U.S., or the Melinta Territory.

Licenses. Pursuant to the Melinta License Agreement, we granted Melinta an exclusive, royalty-bearing license (including the right to sublicense through multiple tiers), to develop, register and commercialize the Melinta Licensed Product for all uses in humans and non-human animals in the Melinta Territory, subject to our retained right, as described below.

Non-Compete Covenant. Until the fifth anniversary of the first commercial sale of the first Melinta Licensed Product in the Melinta Territory, neither Cidara nor Melinta, nor any of their respective majority-owned subsidiaries may, directly or indirectly, itself or in collaboration with any third party, develop, manufacture for development or commercialization, or commercialize any product in the echinocandin class of drugs in the Melinta Territory without the other party's prior written consent, subject to certain provisions in connection with a change of control of a party.

Commercialization. Melinta will be solely responsible for the commercialization of rezafungin in the Melinta Territory, at its sole expense.

Our Retained Rights. We retain the non-exclusive right to practice the intellectual property rights licensed to Melinta in the Melinta Territory solely for the purpose of performing our obligations under the Melinta License Agreement and Mundipharma Collaboration Agreement. We also retain the right to grant licenses under the intellectual property rights licensed to Melinta to third parties to which we have granted licenses or rights to market, promote and sell Melinta Licensed Product outside the Melinta Territory, to make and have made Melinta Licensed Product anywhere in the world solely to develop, register, use, sell, have sold, offer for sale, commercialize and import Melinta Licensed Product outside the Melinta Territory, subject to the terms of the Melinta License Agreement.

Continued Development and Regulatory Activities. We will be responsible, at our sole expense, for conducting an agreed upon development plan, or the Melinta Development Plan, that includes, among other activities, (a) completion of the ongoing ReSPECT Phase 3 pivotal clinical trial for the prophylaxis of invasive fungal infections in adult allogeneic blood and marrow transplant recipients, or the Prophylaxis Indication, (b) preparation and submission to the FDA of a supplemental NDA for the Melinta Licensed Product in the Prophylaxis Indication, (c) site close-out activity worldwide (outside of China) for the ReSTORE Phase 3 pivotal clinical trial for the treatment of candidemia and invasive candidiasis, or the Treatment Indication, (d) certain nonclinical studies and other nonclinical activities, (e) certain chemistry, manufacturing and controls activities for the Melinta Licensed Product, and (f) all other development activities that are required by the FDA to obtain marketing approval of the Melinta Licensed Product in the Treatment Indication and the Prophylaxis Indication in the Melinta Territory.

We will remain the holder of all FDA applications, including the rezafungin IND and NDA. The FDA applications will transfer to Melinta on a transfer date determined based on the status of the ReSPECT trial and the associated supplemental NDA for the Prophylaxis Indication, after which Melinta will be responsible for performing all activities that may be necessary to maintain NDA approvals for the Melinta Licensed Product in the Treatment Indication and the Prophylaxis Indication in the Melinta Territory, at Melinta's sole expense, subject to Melinta's right to deduct from royalties payable to the Company the internal expenses (not to exceed a specified dollar amount per calendar year) and certain out-of-pocket expenses incurred by Melinta.

Supply and Transfer of CMC activities. Until Melinta assumes responsibility for the manufacture and supply of the Melinta Licensed Product for development and commercialization in the Melinta Territory, which it may do by direct purchase from the Company's contract manufacturing organizations for the Melinta Licensed Product or by having a manufacturing technology transfer to Melinta or its designee performed at Melinta's sole expense, which, in either case, will be no later than December 31, 2026, we will be responsible for the manufacture and supply of the Melinta Licensed Product for development and commercialization by Melinta in the Melinta Territory, and during such period, shall supply Melinta Licensed Product to Melinta pursuant to the terms of a supply agreement to be negotiated by the parties.

Financial Terms. Upon execution of the Melinta License Agreement the total potential transaction value is $460.0 million, including a $30.0 million upfront payment and up to $430.0 million in regulatory and commercial milestone payments. In addition, we are eligible to receive tiered royalties on U.S. sales in the low double digits to mid-teens. As of December 31, 2022, we have received the $30.0 million up-front payment.

Termination. Either party may terminate the Melinta License Agreement for uncured material breach by the other party. After July 26, 2023, Melinta may terminate the Melinta License Agreement at will. We may terminate the Melinta License Agreement if Melinta 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 patent rights licensed to Melinta by us.

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.

For rezafungin, we have entered into commercial supply arrangements with all of the key contract manufacturers to support commercialization, including suppliers of starting materials, bulk drug substance and drug product. We are in the

process of identifying and qualifying additional manufacturers to reduce manufacturing costs and ensure continuity of supply. We have entered into commercial supply agreements with all current licensees that govern the terms under which rezafungin will be supplied for commercial use in the Melinta and Mundipharma territories.

Intellectual Property

The proprietary nature of, and protection for, rezafungin, CD388, CD421, our other DFCs, 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 U.S. 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, CD388, CD421, and other product candidates and technology in the U.S. and abroad. As of March 23, 2023, our patent portfolio included 10 families of patents and patent applications related to various aspects of rezafungin, 7 families of patents and patent applications related to various aspects of CD388, and one patent family of patent applications related to various aspects of CD421.

For our issued patents related to rezafungin, we expect the last to expire in 2038, excluding any additional term for patent term adjustments or applicable patent term extensions.

With respect to CD388, the latest of any patents that result from our currently pending applications would be expected to expire in 2042, should they be issued, excluding any additional term for patent term adjustments or applicable patent term extensions.

With respect to CD421, the latest of any patents that result from our currently pending applications would be expected to expire in 2043, should they be issued, 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.

The FDA has granted rezafungin designations as an Orphan Drug, QIDP and Fast Track for the treatment of candidemia and invasive candidiasis which together provide 12 years of marketing exclusivity in the U.S. to be granted at the time of FDA approval. The FDA has also granted rezafungin designations for QIDP and Fast Track for prophylactic use in patients undergoing allogeneic blood and marrow transplant which provides a five-year extension to any marketing exclusivity period for which the drug qualifies on approval.

The European Commission has granted rezafungin Orphan Drug Designation for the treatment of invasive candidiasis which provides 10 years of market exclusivity protection from similar medicines with similar indications upon approval of the marketing authorization, and the potential for two additional years of market exclusivity when the results from pediatric studies compliant with an approved PIP are included in the SmPC.

Further, we seek trademark protection in the U.S. 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 U.S., the EU, Australia and Canada.

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 fosmanogepix (PF-07842805), which is being developed by Pfizer, Inc. and brexafungerp, which is approved for other indications and is being developed for invasive candidiasis by Scynexis, Inc.

We expect that CD388 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 prevention and treatment of other viral infections. We are aware of a number of approved and investigational vaccines and/or therapies in these areas. We expect that CD421 will compete against approved anticancer therapeutics as well as investigational CD73-targeting small molecule drugs, including Oric-533 being developed by Oric Pharmaceutical, Inc. and quemliclustat being developed by Arcus Biosciences, Inc. as well as monoclonal antibodies, including oleclumab being developed by AstraZeneca PLC.

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 products 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 U.S., 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.

U.S. Drug Approval Process

In the U.S., 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 U.S. 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 U.S. generally involves the following:

- manufacturing of clinical supplies in compliance with good manufacturing practice, or GMP, regulations;
- 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 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 an 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, purity, and potency; 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, including 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 safety concerns or questions related to safety 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/or the effectiveness criteria to be evaluated. A protocol for each clinical trial conducted in the U.S. 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 and clinical NDA supplements are 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 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 via additional information submitted to the FDA, 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 aims 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 accepted for review. 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 Drug Designation

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 U.S. 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 U.S. 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 Product Designation

In response to the growing unmet medical need in the area of serious bacterial and fungal 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, 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 Health Care Laws

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, imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information.

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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding 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.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. In the U.S., 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.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication.

Outside the U.S., the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has, and will continue to, put pressure on the pricing and usage of therapeutics such as our product candidates.

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. There have been executive judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, President Trump signed several 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. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been enacted. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is unclear how any such challenges and the healthcare reform measures of the Biden administration 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 includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect until 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. 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 presidential executive orders and 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. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Additionally, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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.

Foreign Regulation

In order to market any product outside of the U.S., 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 March 16, 2023, we had 73 total employees, 21 of whom hold Ph.D. or M.D. degrees, 55 of whom were engaged in research and development activities and 18 of whom were engaged in business development, finance, information systems, facilities, human resources, legal or administrative support. None of our employees are subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

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 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.

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.

Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Annual Report on Form 10-K, 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. When evaluating our business, you should consider all of the factors described as well as the other information in our Annual Report on Form 10-K, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to the COVID-19 Pandemic

Our operations, business and financial results have been and could continue to be adversely impacted by the current public health pandemic related to COVID-19.

In January 2020, the World Health Organization, or WHO, announced a global health emergency because of a new strain of novel coronavirus known as COVID-19 and, in March 2020, the WHO declared the COVID-19 outbreak a pandemic, or the COVID-19 pandemic. The COVID-19 pandemic has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business interruptions and shutdowns. These precautions have disrupted our business operations and prospects. For example, we have experienced, and expect to continue to experience, trial site activation and enrollment delays for the ReSPECT clinical trial due to facility restrictions, quarantines, travel restrictions, focus on COVID-specific trials and other obstacles. The COVID-19 outbreak and mitigation measures also have had and may continue to have an adverse impact on global economic conditions which could impair our ability to raise capital when needed. While the disruption from COVID-19 has had and we expect it to continue to have an adverse effect on our business, financial condition and results of operations, we are unable to predict the extent or nature of these impacts at this time. In addition, to the extent the ongoing COVID-19 outbreak continues to adversely affect our business, financial condition, results of operations and growth prospects, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section.

Risks Related to Drug Discovery, Development and Commercialization

We depend heavily on the success of rezafungin and CD388, which is currently in Phase 1 and Phase 2a clinical development, and we are very early in our efforts to develop other product candidates from our Cloudbreak program, none of which may be successful.

We are currently conducting two Phase 3 clinical trials of rezafungin. We have completed the ReSTORE trial and conducted the primary analyses required for potential approval in U.S. and Europe but are continuing to enroll and treat patients in China to support Chinese regulatory filings. We also continue to enroll patients in the ReSPECT trial, which is designed to assess the safety and efficacy of rezafungin for the prevention of serious fungal infections in patients undergoing blood and marrow transplants. The U.S. Food and Drug Administration, or FDA, approved our New Drug Application, or NDA, for rezafungin for the treatment of candidemia and invasive candidiasis in adults with limited or no treatment options, in March 2023. Even though rezafungin has been approved for the treatment indication, we may not be successful in obtaining approval for a supplemental New Drug Application, or sNDA, for the expanded prophylaxis indication. In addition, the European Medicines Agency, or EMA, may not approve rezafungin for any indication.

The ReSPECT trial is currently enrolling globally. We received IND clearance for CD388, our DFC for prevention and treatment of influenza, from the FDA in March 2022 and subsequently initiated a Phase 1 clinical trial. In September 2022, we initiated a Phase 2a trial of CD388 to evaluate the pre-exposure prophylactic activity of CD388 against influenza virus and a separate Phase 1 Japanese bridging study has been initiated. We are also conducting in vitro and in vivo preclinical studies of other product candidates from our Cloudbreak program for viral infections and oncology indications. Our assumptions about why rezafungin and CD388 are worthy of continued development, as well as our assumptions about the markets for rezafungin, CD388 or any other 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 CD388, and the regulatory paths for marketing approval for additional 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, CD388 and any other product candidates we may develop will depend on many factors, including the following:

- the impact of the COVID-19 pandemic on our operations;
- our ability to secure adequate additional funding;
- agreement with regulatory authorities on study designs and other requirements for study initiation;
- successful completion of preclinical studies;
- successful enrollment and completion of clinical trials;
- demonstration of safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- negotiation of favorable indications and other key elements of the product labeling;
- 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 timely enroll the ReSPECT Phase 3 clinical trial, or if we are unable to secure significant additional funding, we will not be able to complete the clinical development plans for the prophylaxis indication 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 our clinical trials our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to complete the ReSPECT clinical trial or the ongoing portion of the ReSTORE trial in China if we are unable to identify and enroll a sufficient number of eligible patients, as required by the FDA or similar regulatory authorities outside the U.S., 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 clinical trials may be affected by many different factors specific to those global localities, such as, delays in our receipt of approval to commence 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 rezafungin clinical trials are heavily reliant on third-party contractors, including contractors that import clinical trial materials, and contract research organizations, or CROs, 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 ReSPECT trial is reliant on global clinical trial sites, most of which have been adversely affected by the COVID-19 global pandemic. For example, the COVID-19 global pandemic has significantly impacted our ability to activate sites and enroll patients in the ReSPECT trial in Europe and the U.S., resulting in substantial delays and increases in the cost of completing the trial. Our enrollment of patients in ReSTORE in China was also delayed in part due to the pandemic. Some factors from the COVID-19 coronavirus outbreak that 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;
- the decision of some clinical trial sites to focus on the conduct of COVID-19 clinical trials;
- limitations imposed by hospitals serving as our clinical trial sites that prohibit entry on hospital premises by persons other than those supporting the hospital's COVID-19 efforts;
- 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 quarantine or isolation 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 rezafungin addresses.

Our inability to enroll and retain a sufficient number of patients in a reasonable timeframe may require us to abandon the entire rezafungin Phase 3 clinical development program or terminate the ReSPECT trial or the ReSTORE trial in China. Enrollment delays have and will continue to 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, CD388, CD421 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 entire rezafungin clinical development program has been severely impacted by the effects of the COVID-19 global pandemic. Additionally, our ability to complete our rezafungin Phase 3 development program is dependent on our ability to secure adequate additional funding.

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.

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 either the ReSPECT trial or the Phase 1 of Phase 2a trials of CD388 will be completed on schedule. We have experienced significant delays in these trials arising from the COVID-19 global pandemic. We may experience numerous other 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.

If the FDA or similar regulatory authorities outside the U.S. do not agree with the design and implementation of our planned or ongoing clinical trials, including the safety database to support an NDA submission, or if we are unable to secure additional funding, we may not be able to complete the overall Phase 3 clinical development program for rezafungin as currently envisioned. For example, in response to feedback from the FDA, we considered supplementing the ReSTORE safety database with safety data from patients enrolled in the ReSPECT study who shared similar comorbidities and concomitant medications with patients in the ReSTORE study. This approach was ultimately unnecessary, but if we had implemented it, the timing of our NDA submission and the timing of completion of the ReSPECT study might have been impacted. 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 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 reactions 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, which could allow earlier hospital discharge, or the predicted ability of rezafungin to be effective against resistant strains of fungal pathogens, may not be realized. For our DFCs, 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, we believe that an sNDA filing for rezafungin adding the prophylaxis indication can be supported by one Phase 3 trial in prophylaxis, however, financial constraints may require us to delay our prophylaxis program.

In support of the global effort to identify effective therapeutics to treat and prevent the COVID-19 coronavirus and stem the current global pandemic, we have expended financial resources to identify DFCs which may be effective in this area. In addition, we have recently expended financial resources on identification of DFCs targeting multiple potentially synergistic oncology targets. We have limited experience in identification and nonclinical and clinical testing of oncology therapeutics. Our resource allocation decisions may not result in us identifying valuable products or 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, formulary committees, 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 hospitals and hospital pharmacies, 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 license the rights to third parties with such capabilities, 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 fosmanogepix (PF-07842805), which is being developed by Pfizer, Inc. and brexafungerp, which is approved for other indications and is being developed for invasive candidiasis by Scynexis, Inc.

We expect that CD388 will compete against approved and investigational agents for the treatment or prevention of viral influenza infections, including influenza vaccines, neuraminidase inhibitors such as Tamiflu, Relenza and Peramivir, and endonuclease inhibitors such as Xofluza. We may develop other product candidates through our Cloudbreak platform for the treatment or prevention of other serious diseases, such as RSV, HIV, the SARS-CoV-2 strains causing COVID-19 and various cancers. We are aware of a large number of approved and investigational therapies in these areas also. We expect that CD421 will compete against approved anticancer therapeutics as well as investigational CD-73 targeting small molecule drugs, including Oric-533 being developed by Oric Pharmaceutical, Inc. and quemliclustat being developed by Arcus Biosciences, Inc. as well as monoclonal antibodies, including oleclumab being developed by AstraZeneca PLC.

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, CD388, CD421, 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 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. 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.

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 U.S., 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 U.S. 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 U.S. 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. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 DFCs for the treatment and prevention of serious diseases, including influenza, the SARS-CoV-2 strains causing COVID-19, and various cancers. We have nominated the DFC CD388 as our lead development candidate for influenza, and we have nominated CD421 as our lead oncology DFC candidate. In applying our Cloudbreak platform, we may not be successful in identifying additional DFCs 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 and oncology targets. A failure to optimize our expertise using the Cloudbreak platform for the development of our Cloudbreak 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. For example, in response to the immediate global pandemic crisis, we have expended financial resources to identify therapeutics to treat or prevent the COVID-19 coronavirus, and we may be unsuccessful in identifying such a DFC. If we are unable to identify successful

product candidates from our Cloudbreak platform for preclinical and clinical development, we will have spent financial resources on programs that did not yield viable products and therefore 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 CD388, CD421 and our Cloudbreak program.

In connection with the preparation of our financial statements for the period ended December 31, 2022, 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 CD388, CD421 and other product candidates from our Cloudbreak program is also dependent on our ability to obtain additional funding.

On September 3, 2019, we entered into the Mundipharma Collaboration Agreement, pursuant to which we granted Mundipharma exclusive commercialization rights to rezafungin outside the U.S. and Japan in exchange for a $30.0 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 in the teens on tiers of annual net sales. The Mundipharma Collaboration Agreement requires, among other things, that we complete the rezafungin development program. On March 31, 2021, we entered into the Janssen Collaboration Agreement, to develop and commercialize our Cloudbreak DFCs for the prevention and treatment of seasonal and pandemic influenza. Under the collaboration, we will be responsible for the development and manufacturing of the first influenza DFC, CD388, into the clinic and through Phase 2 clinical development, and Janssen will be responsible for late-stage development, manufacturing, registration and global commercialization. We received an upfront payment of $27.0 million. Janssen will fund all future research, development, manufacturing and commercialization for CD388, of which Janssen has funded $25.1 million as of December 31, 2022. On July 26, 2022, we entered into the Melinta License Agreement, pursuant to which we granted Melinta an exclusive license to develop, register and commercialize rezafungin in the U.S. in exchange for a $30.0 million upfront payment and the potential to receive regulatory and commercial milestone payments and tiered royalties on U.S. sales in the low double digits to mid-teens. The Melinta License Agreement requires, among other things, that we complete the rezafungin development program. Our ability to meet our development obligations under the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement 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 ongoing effect of the COVID-19 global pandemic and the resulting impact on our rezafungin phase 3 clinical development program;
- the costs and timing to complete our Phase 3 ReSPECT trial, the remaining Chinese portion of the ReSTORE trial and the CD388 Phase 1 and Phase 2a trials;
- the costs, timing and outcome of any regulatory review of rezafungin, CD388, CD421 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. As of December 31, 2022, we had cash and cash equivalents of $32.7 million.

As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, it may make any additional debt or equity financing more difficult, more costly and more dilutive. In addition, we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions. For example, on March 10, 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of Silicon Valley Bank. While Cidara does not have deposits at Silicon Valley Bank, if other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition.

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 CD388, CD421 or one or more of our other Cloudbreak DFC programs, be unable to continue the development of rezafungin, complete the ReSPECT Phase 3 clinical trial and meet our development obligations under the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement, or our other current and future license or collaboration agreements, 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, the Janssen Collaboration Agreement and the Melinta License 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., or the Sales Agreement, which currently has an aggregate offering price of up to $50.0 million, and, other than the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement, it is our only current external source of potential financing.

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 Convertible Preferred Stock upon the closing of a rights offering. In October 2021, we issued $38.5 million of our common stock and Series X Convertible Preferred Stock upon the closing of concurrent but separate public offerings. In March 2023, we issued shares of our common stock and Series X Convertible Preferred Stock upon the closing of concurrent but separate public offerings, for gross proceeds of $19.5 million. As of December 31, 2022, we have issued 14,550,113 shares of common stock pursuant to the Sales Agreement with an aggregate offering price of approximately $32.1 million. 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 Mundipharma, the sale of our common stock and Series X Convertible Preferred Stock issued in our rights offering, the sale of our common stock and Series X Convertible Preferred Stock in our concurrent public offerings or the sale of common stock under the 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 U.S. and Japan to Mundipharma in exchange for certain payments and double-digit royalties in the teens on tiers of annual net sales. In March 2021, we granted exclusive worldwide rights to CD388 and other influenza DFCs to Janssen in exchange for certain payments and royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits. In July 2022, we licensed all rights to rezafungin inside of the U.S. to Melinta in exchange for certain payments and tiered royalties on U.S. sales in the low double digits to mid-teens. We may need to enter into similar agreements with other third parties for the development and commercialization of rezafungin outside of the Mundipharma

and Melinta territories, or for the development of DFCs identified from our Cloudbreak program outside the scope of the Janssen Collaboration Agreement, 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. U.S. 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 U.S. 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 ReSPECT Phase 3 clinical trial, be unable to meet our development obligations under the Mundipharma Collaboration Agreement and the Melinta License Agreement, and be unable to continue advancing the Cloudbreak program for non-influenza DFCs, or be forced to grant rights in the Cloudbreak program for non-influenza DFCs that we would otherwise prefer to retain for ourselves.

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 $29.8 million, $42.5 million and $72.1 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of $407.0 million. To date, we have financed our operations primarily through sale of our stock in public offerings and private placements, through borrowings under loan facilities, and through payments received in connection with the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement. We are currently conducting the ReSPECT and ReSTORE China Phase 3 clinical trials of rezafungin, Phase 1 and Phase 2a studies of CD388, and preclinical studies of our other DFCs, including CD421. 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 at clinical trial sites;
- continue to advance rezafungin and CD388 through clinical development;
- continue the preclinical development of our other DFCs from our Cloudbreak platform or otherwise, and advance one or more of such product candidates into clinical trials;
- seek marketing approvals for rezafungin, CD388, CD421 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.

Further, as a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, rising inflation, bank failures, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, it may make access to our liquidity within the U.S. banking system and any additional debt or equity financing more difficult, more costly and more dilutive.

The conflict between Russia and Ukraine could lead to disruption, instability and volatility in global markets and industries that could negatively impact our operations. The U.S. government and other governments in jurisdictions in which we operate have imposed severe sanctions and export controls against Russia and Russian interests and threatened additional sanctions and controls. The impact of these measures, as well as potential responses to them by Russia, is currently unknown and they could adversely affect our business, supply chain, partners or customers.

We have no history of commercializing pharmaceutical products, which may make it difficult for you to evaluate the prospect for our future viability.

We have not yet demonstrated an 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 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.

If we are unable to continue to satisfy the applicable continued listing requirements of Nasdaq, our common stock could be delisted.

Our common stock is currently listed on The Nasdaq Capital Market under the symbol “CDTX.” In order to maintain this listing, we must continue to satisfy minimum financial and other continued listing requirements and standards. We cannot assure you that we will be able to continue to comply with the applicable listing standards.

If we are not able to comply with applicable listing standards, our shares of common stock will be subject to delisting. For example, we were first notified by Nasdaq on February 28, 2022, that our common stock had failed to maintain a minimum bid price of $1.00 for 30 consecutive business days. Following extension periods to regain compliance, On February 9, 2023, the Nasdaq Hearings Panel notified us that we had regained compliance with the minimum bid price requirement subject to a discretionary Panel Monitor until November 9, 2023. The delisting of our common stock from trading on Nasdaq may have a material adverse effect on the market for, and liquidity and price of, our common stock and impair our ability to raise capital. Delisting from Nasdaq could also have other negative results, including, without limitation, the potential loss of confidence by customers and employees, the loss of institutional investor interest and fewer business development opportunities. In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further.

Risks Related to Our Dependence on Third Parties

We are dependent on our collaboration partners to provide funding to continue the development of rezafungin and CD388; for the commercialization of rezafungin outside Japan; and for the late-stage development, manufacturing, registration and commercialization of CD388. If the collaborations are not successful, we may not be able to complete the development of rezafungin and CD388, or capitalize on the full market potential for rezafungin and CD388.

On September 3, 2019, we licensed the rights to rezafungin outside of the U.S. and Japan to Mundipharma, a large international pharmaceutical company, and on July 26, 2022, we licensed the rights to rezafungin inside the U.S. to Melinta. Our ability to complete the development of rezafungin is dependent, in part, on funds provided by Mundipharma and Melinta. Additionally, our ability to receive payments from these arrangements will depend on Mundipharma's and Melinta's ability to successfully commercialize rezafungin in their respective territories.

The Mundipharma Collaboration Agreement and the Melinta License Agreement pose many risks to us, including that our collaborator, Mundipharma, and our licensee, Melinta:

- have significant discretion in determining the efforts and resources they will apply to commercializing rezafungin in their respective territories, and may not commit sufficient resources to the marketing and distribution of rezafungin;
- may terminate the Mundipharma Collaboration Agreement at will and may terminate the Melinta License Agreement at will after July 26, 2023;
- 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 their respective territories;
- 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 programs, or that result in costly litigation or arbitration that diverts management attention and resources;
- could be involved in a business combination and the continued pursuit and emphasis on rezafungin could be delayed, diminished or terminated; and
- could be financially impacted by the COVID-19 pandemic, inflation or bank failures.

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

On March 31, 2021, we licensed the exclusive worldwide rights to CD388 and other influenza DFCs to Janssen. Our ability to complete the development of CD388 is dependent, on funds provided by Janssen. Additionally, our ability to receive payments from this arrangement will depend in part on Janssen's ability to successfully commercialize CD388.

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

- has significant discretion in determining the efforts and resources it will apply to developing, manufacturing, registering and commercializing CD388;
- may terminate the collaboration agreement at will, subject to certain limitations;
- 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 development, manufacturing, registration and commercialization of CD388;
- may independently develop, or develop with third parties, products that compete directly or indirectly with CD388 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;
- could be involved in a business combination and the continued pursuit and emphasis on CD388 could be delayed, diminished or terminated; and
- could be financially impacted by the COVID-19 pandemic, inflation or bank failures.

If our ability to generate revenue under the Janssen Collaboration Agreement is adversely impacted by these or any other risks, our right to receive additional payments under the Janssen Collaboration Agreement, including milestone payments and royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits, could be insufficient to allow us to achieve or maintain profitability or may result in CD388 being less valuable to us than if we had not entered into the Janssen Collaboration Agreement.

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 for DFCs outside the scope of the Janssen Collaboration Agreement, or for the completion of development and commercialization of rezafungin in Japan. We may also seek funding from government grants or contracts to advance the Cloudbreak program for DFCs outside of the Janssen Collaboration Agreement. We cannot be certain that we will 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 U.S.;
- 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 for DFCs outside of the Janssen Collaboration Agreement, 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 CROs, 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.

In addition, the ability of these third parties to conduct certain of their operations, including monitoring of clinical sites, may be limited by the COVID-19 pandemic, and to the extent that such third parties are unable to fulfil their contractual obligations as a result of the COVID-19 pandemic or government orders in response to the pandemic, we may have limited or no recourse under the terms of our contractual agreements with such third parties. Further, if any of the third parties with whom we engage were to experience shutdowns or other substantial disruptions due to the COVID-19 pandemic, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

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 should we obtain marketing approval.

We have established agreements with third-party manufacturers for production of our products for clinical and commercial use, and our reliance on these- 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 U.S. 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 or a failure due to the COVID-19 pandemic, 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. Some of our third-party manufacturers which we use for the supply of materials for product candidates or other materials necessary to manufacture product to conduct preclinical tests and clinical trials are located in countries affected by COVID-19, and should they experience disruptions, such as temporary closures or suspension of services, we would likely experience delays in advancing these tests and trials.

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. In the U.S., rezafungin has been designated a Qualified Infectious Disease Product, or QIDP, a fast track product, and, with respect to the indication for treatment of candidemia and invasive candidiasis, rezafungin has also been designated as an orphan drug. Our product candidates may not qualify for, or maintain, designations under these or other similar incentive programs. For example, rezafungin may not receive orphan drug designation in the U.S. for the prophylaxis indication. 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 U.S. and by comparable authorities in other countries. For example, in order to commence clinical trials of our product candidates in the U.S., 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 CROs to assist us in this process. As a company we may not be able to prepare our contract manufacturers and clinical sites for inspection associated with NDA review, or appearing before an FDA advisory committee. Our NDA may receive a Complete Response Letter rather than approval. 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 U.S. 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.

The COVID-19 pandemic could also potentially affect the business of the FDA and comparable authorities in other countries, which could result in delays in meetings related to planned clinical trials and ultimately of reviews and approvals of our product candidates.

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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or 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, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates and their covered subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, which require, among other things, certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and information regarding 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.

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, disgorgement, imprisonment, 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.

If our information technology systems or sensitive data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely, may collect, store, use, transmit, receive, generate, transfer, disclose, make accessible, protect, secure, dispose of, process, and share (collectively, processing) sensitive information, including personal data, proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data (collectively, sensitive information). As a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents.

Cyberattacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent, continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyberattacks, including without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products.

We and the third parties upon which we rely are subject to a variety of threats, including, but not limited to, social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), ransomware, viruses, worms, denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit, and in public locations. Additionally, future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, CROs, contract manufacturers of clinical and commercial supplies, clinical data management organizations, medical institutions, clinical investigators, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties’ infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or

access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to manufacture or deliver our products.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We may take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process sensitive information, and as a result, we may be subject to numerous data privacy and security obligations, such as various, regulations, guidance, industry standards, external and internal privacy and security policies, contractual obligations, and other obligations related to privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, and their respective implementing regulations, impose requirements relating to the privacy, security and transmission of individually identifiable health information. Such laws may apply to us, our customers or our service providers. Most healthcare providers in the U.S., including institutions from which we may obtain customer data, are subject to data privacy and security regulations promulgated under HIPAA, as amended by HITECH. A person may be prosecuted for alleged HIPAA violations either directly or indirectly, such as under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial civil and criminal penalties and liabilities if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

Additionally, the California Consumer Privacy Act of 2018, or CCPA, applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA also provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to

recover significant statutory damages. In addition, the California Privacy Rights Act of 2020, or CPRA, expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the CPRA. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states as well as at the federal and local levels. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern privacy and security. For example, the EU's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, and Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018) impose strict requirements for processing personal data. We also conduct clinical trials in China and may be subject to new and emerging data privacy regimes in China, including China's Personal Information Protection Law, or PIPL, Cybersecurity Law, Data Security Law, Measures for Cybersecurity Review, Measures on the Security Assessment of Cross-border Data Transfer, and Measures for the Standard Contract on the Cross-border Transfer of Personal Information.

For example, under the EU GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros or 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe (including the EEA and UK), China, and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe, China and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area, or EEA, and the United Kingdom, or UK, have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. China also requires entities to rely on a transfer mechanism to lawfully transfer personal data overseas and ensure that the overseas data recipients can meet the same data protection standards as required under the PIPL. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition to data privacy and security laws, we may be contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material

adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions (including in relation to clinical trials); limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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 U.S., 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.

The pharmaceutical industry in China is highly regulated and such regulations are subject to change which may affect approval and commercialization of our drugs.

Currently, we conduct the ReSTORE trial in China and have exclusively licensed the rights to commercialize rezafungin, our investigational drug studied in the ReSTORE trial, in China to our third-party collaborator, Mundipharma. The pharmaceutical industry in China is subject to comprehensive government regulation and supervision, encompassing the approval, registration, manufacturing, packaging, licensing and marketing of new drugs. For example, in order to conduct a clinical trial in China, sponsors must not only obtain the approval of the National Medical Product Administration of China, but also a separate approval from or filing with the Ministry of Science and Technology under the Administrative Regulations on Human Genetic Resources of the People's Republic of China, or HGR Regulation, for clinical trials involving HGR Materials or Information. Any failure to comply with these requirements could cause our ReSTORE trial to be suspended by governing authorities, may result in fines and also may constitute a breach under our agreements with third parties assisting us in the conduct of the trial in China, such as our CRO. In recent years, the regulatory framework in China regarding the pharmaceutical industry has undergone significant changes, and we expect that it will continue to undergo significant changes. Certain changes or amendments to policy or law may result in increased compliance costs on our business or cause delays in the timely completion of the ReSTORE trial in China, or prevent the approval of rezafungin in China. Chinese authorities have become increasingly vigilant in enforcing laws in the pharmaceutical industry and any failure by us to maintain compliance with applicable laws and regulations or obtain and maintain required licenses and permits may result in the suspension or termination of our clinical activities in China.

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 U.S. 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. However, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and

innovator multiple source drugs, beginning January 1, 2024. Further, the Affordable Care Act imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance were also enacted under the Affordable Care Act, which may affect our business practices with healthcare practitioners. There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

In addition, 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 will remain in effect until 2031 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future.

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.

We expect that additional healthcare reform measures will be adopted within and outside the U.S. 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, CD388, CD421, our other 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 DFCs and other compounds and product candidates in the U.S. 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 DFCs. The patent applications may fail to result in issued patents in the U.S. 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 DFCs 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 U.S. 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 U.S. We may encounter significant problems in protecting, enforcing and defending our intellectual property both in the U.S. 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 DFCs 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 DFC 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 U.S.

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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. can be less extensive than those in the U.S. 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 U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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 preclinical Cloudbreak programs.

In order to continue our Cloudbreak programs for DFCs outside the scope of the Janssen Collaboration Agreement, 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 U.S. government or obtain other sources of funding to support such programs. 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 for DFCs outside the scope of the Janssen Collaboration Agreement, 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 Securities and Exchange Commission, or 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 shutdown occurs, 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.

U.S. 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 U.S. 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 ability to manage our business operations, to execute our strategic plan and to recruit talented employees may be adversely impacted by COVID-19.

Since early March 2020, we have taken precautionary measures intended to help minimize the risk of COVID-19 to our employees and their families. In accordance with state and federal guidelines, we reduced those precautionary measures in 2022 and have permitted employees to return to the office, work remotely, or adopt hybrid schedules based on job responsibilities. Further measures may be taken as the COVID-19 outbreak continues. These measures could negatively affect our business. For instance, remote work may disrupt our operations, limit our ability to interact with and effectively manage our third-party manufacturers CROs or current and planned clinical trial sites. The measures taken now or in the future to contain the COVID-19 pandemic could negatively affect our ability to recruit and engage new employees and contractors necessary to the successful operation of our business.

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;
- the impact of the COVID-19 pandemic on our business and industry as well as the global economy;
- 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 including the military conflict in Ukraine and Russia and bank failures; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Capital 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, such as the COVID-19 pandemic and actions taken to slow its spread, 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 incur significant costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Securities Exchange Act of 1934, which require, among other things, that we file with 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 Capital 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. 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.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired and our public reporting may be unreliable.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Based on our evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2022, we determined that we had a material weakness as of September 30, 2022 because our review control over the evaluation of applicable accounting standards and assessment of completeness and accuracy of valuation assumptions, related to non-routine transactions that include collaboration revenue, was not appropriately designed or operating effectively. While this improper design and operation did not result in a material error in the annual or interim financial statements, there is a reasonable possibility that a material misstatement in the annual or interim financial statements would not have been detected. A material weakness, as defined in Rule 12b-2 under the Exchange Act, is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis.

This material weakness has been remediated as of December 31, 2022. We have amended our process to add additional layers of review by members of our management team regarding the evaluation of applicable accounting standards and completeness and accuracy of valuation assumptions related to non-routine transactions that include collaboration revenue. The effectiveness of our process changes and overall remediation efforts is being assessed by management on an ongoing basis. The remediation actions are also being monitored by the Audit Committee of our Board of Directors. However, we cannot assure you that these efforts will remediate this material weakness in a timely manner, or at all, or that we will be able to maintain effective controls and procedures even if we remediate this material weakness. If we are unable to successfully remediate this material weakness, design or operate effective controls and procedures, or identify any future material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and we may experience a loss of public confidence, which could have an adverse effect on our business, financial condition and the market price of our common stock.

We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are a "non-accelerated filer," our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur additional expenses of remediation. In addition, if we are unable to remediate this material weakness, or if we are otherwise unable to conclude that our internal control over financial reporting is effective, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our securities could decline, and we could be subject to sanctions or investigations by The Nasdaq Capital Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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 72,470,440 shares of common stock outstanding as of December 31, 2022. 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 has broad discretion in the application of our working capital. Because of the number and variability of factors that 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 the following types of actions or proceedings under Delaware statutory or common law: 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. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. 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 further significant additional costs associated with resolving such action in other jurisdictions, all of which could adversely affect our business and financial condition.

While the Delaware courts have determined that exclusive choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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 current law, unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, 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 or taxes may be limited. As a result of capital raising and other transactions that have occurred since our inception in 2012, we have identified several ownership changes that will impact our ability to utilize our net operating losses and credit carryforwards. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2022, we had U.S. federal net operating loss carryforwards of approximately $185.3 million, after adjustments for Section 382 limitations to date, portions of which will begin to expire in 2035, and which could be limited if we experience an "ownership change." In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited. As a result, if we earn

net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a “permanent establishment” under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Effective January 1, 2022, the Tax Act eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation.

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, as a result of the COVID-19 pandemic, we have experienced significant disruptions in the conduct of our clinical trials and our general business operations as the result of various federal, state and local stay-at-home, shelter-in-place and quarantine measures. 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 2023, 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.

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

Item 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 Capital Market under the symbol "CDTX."

Holders of Record

As of March 16, 2023, there were 12 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. 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 on Form 10-K.

Recent Sales of Unregistered Securities

None.

Purchase of Equity Securities by the Issuer and Affiliated Purchasers

None.

Item 6. [Reserved]

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 on Form 10-K.

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 on Form 10-K. See "Special Note Regarding Forward-Looking Statements."

Overview

We are a biotechnology company focused on the discovery, development and commercialization of long-acting therapeutics designed to transform the standard of care for patients facing serious diseases. We are focused on infectious diseases and oncology. Our lead product candidate is rezafungin (trade name REZZAYO™), an intravenous formulation of a novel echinocandin antifungal. Rezafungin is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections.

Our primary focus now is using our Cloudbreak® platform to develop a potential new class of drugs called drug-Fc conjugates, or DFCs, for the prevention and treatment of serious diseases. This technology couples potent inhibitors to a human antibody fragment to create long-acting DFCs designed to inhibit multiple disease targets. Our most advanced DFC program is CD388, a highly potent, long-acting antiviral designed to deliver universal prevention and treatment of

seasonal and pandemic influenza, which is in Phase 1 and Phase 2a clinical trials. Additional programs are targeting the SARS-CoV-2 strains causing COVID-19 and multiple solid tumor oncology indications.

Our business is subject to various trends, events or uncertainties that are reasonably likely to cause our reported financial information not to be necessarily indicative of future operating results or of future financial condition. As discussed below, the COVID-19 pandemic has delayed our conduct of clinical trials and other key activities and there is uncertainty regarding the emergence of potential new COVID-19 strains. We may also be impacted by broader macroeconomic conditions, including high inflation, bank failures, labor shortages, supply chain disruptions, recession risks and potential disruptions from the ongoing Russia-Ukraine conflict and related sanctions. For example, on March 10, 2023, the Federal Deposit Insurance Corporation, took control and was appointed receiver of Silicon Valley Bank. While Cidara does not have deposits at Silicon Valley Bank, if other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. The stock market, and in particular the market for pharmaceutical and biotechnology company stocks, has recently experienced significant decreases in value. This volatility and valuation decline have affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance. These and other uncertainties are discussed in greater detail below.

Recent Developments

Cloudbreak Oncology Program

Immune checkpoint antagonists have generated durable responses in cancers with improved side effect profiles compared to conventional chemotherapy. However, to date, improved outcomes from existing therapies have been limited to a relatively small subset of patients. To broaden the response rate to more patients, targeting additional mechanisms of tumor immune evasion will be critical. Using our DFC approach, we are seeking to generate a best-in-class CD73 inhibitor that combines the attributes of small molecule inhibitors and monoclonal antibody, or mAb, inhibitors that are currently in clinical trials.

In January 2023, we nominated CBO-212 as our first oncology DFC candidate. With our Cloudbreak oncology program we seek to develop a new generation of immunotherapies, and our lead oncology DFC candidate, CD421 (which is an enhanced version of CBO-212), is a first-in-class CD73 inhibitor that combines the strengths of small molecules and monoclonal antibodies targeting CD73. We are currently advancing CD421 that confers reduced immunogenic properties through investigational new drug application, or IND, -enabling studies.

In February 2023, we expanded our existing collaboration with WuXi XDC, a leading global contract manufacturing organization, or CMO, dedicated to end-to-end bioconjugates services, under which WuXi XDC will provide IND-enabling chemistry and manufacturing and controls, or CMC, development services for our Cloudbreak oncology program.

FDA Advisory Committee Recommendation and FDA Approval of Rezafungin for the Treatment of Candidemia and Invasive Candidiasis

On January 24, 2023, the U.S. Food and Drug Administration, or FDA, Antimicrobial Drugs Advisory Committee voted favorably 14 to 1 that we, as part of our New Drug Application, or NDA, provided sufficient evidence supporting a favorable benefit-risk assessment for a limited use indication for rezafungin for the treatment of candidemia and invasive candidiasis in adult patients with limited or no alternative treatment options.

On March 22, 2023, the FDA approved REZZAYO (rezafungin for injection) for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options. REZZAYO is the first new treatment option approved for patients with candidemia and invasive candidiasis in over a decade, and is the only available once-weekly echinocandin.

Compliance with Nasdaq Listing Requirements

On February 9, 2023, we received formal notice from The Nasdaq Stock Market, LLC, or Nasdaq, Hearings Panel, or the Panel, stating that we have regained compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2), subject to a discretionary Panel Monitor until November 9, 2023.

Phase 2a Interim Results

On March 1, 2023, we announced efficacy and safety data from a planned interim analysis of our ongoing Phase 2a trial evaluating the pre-exposure prophylactic activity of CD388 against the H3N2 influenza A virus strain, as of a February 13, 2023 data cut-off. The Phase 2a trial is a single-center, randomized, double-blind influenza challenge study in healthy volunteers designed to assess the prophylactic antiviral activity, safety, tolerability and pharmacokinetics of CD388 in

healthy volunteers. The interim analysis is based on 56 subjects enrolled in the trial, with 28 subjects receiving a single dose of CD388 (150 mg) and 28 subjects receiving a placebo.

The interim data for the primary efficacy endpoint of Area Under the Viral Load-Time Curve (a measure of a drug's ability to attenuate viral replication), or VL-AUC, and for the secondary efficacy endpoint of influenza infection incidence for 150 mg CD388 versus placebo are shown below.

	Placebo (n=28)	CD388 150 mg (n=28)
Area Under the Viral Load-time Curve (VL-AUC)- Mean (SD)	16.1 (11.9)	10.7 (8.0)
PCR confirmed influenza infection- n (%)	14 (50%)	6 (21.4%)

As shown above, despite the small sample size in this planned interim analysis, a decrease in viral replication in the upper respiratory tract and influenza infection was observed in participants receiving a single dose of CD388 when compared to placebo. No treatment emergent adverse events leading to study discontinuation or serious adverse events were reported in the interim analysis. All participants included in the interim analysis received either CD388 or placebo and were then challenged with influenza five days later.

Cloudbreak Platform

We believe our Cloudbreak platform has the potential to offer a fundamentally new approach to prevent and treat serious diseases, by developing product candidates designed to provide potent disease targeting activity and immune system engagement in a single long-acting molecule. Because serious disease often results when a pathogen or cancer cell evades or overcomes the host immune system, our Cloudbreak DFC candidates are designed to counter diseases in two ways: prevention of disease proliferation or immune evasion by directly targeting and, where applicable, by focusing the immune system on a pathogen or infected cell. We believe this is a potentially transformative approach, distinct from current therapies, monoclonal antibodies and vaccines. In addition, DFCs are designed to have several advantages, including:

- Multivalent binding which has the potential to increase potency;
- Ability to engage different targets on the same target cell to decrease resistance or, in the case of a cancerous cell, to serve as a "drug cocktail" in a single molecule, which may improve response to treatment;
- Potential to target multiple viral pathogens or oncological targets with a single DFC; and
- Potential for universal coverage against all viral variants and all people irrespective of immune status.

In contrast to monoclonal antibodies, our DFCs are smaller, have the potential for better tissue penetration and are designed to target multiple sites. Unlike small molecules, we believe DFC optimization can be focused primarily on potency.

Our lead Cloudbreak candidates are CD388, a DFC for the prevention and treatment of influenza, or influenza DFC, and CD421, a CD73-targeting DFC for the treatment of solid tumors.

In September 2020, we nominated CD388, our influenza DFC, as a development candidate. We submitted an IND for CD388 in December 2021 and initiated a Phase 1 trial (NCT05285137) in March 2022. The Phase 1 trial is a randomized, double-blind, dose-escalation study to determine the safety, tolerability and pharmacokinetics of intramuscular and subcutaneous administration of CD388 in healthy subjects. Dosing of all six planned cohorts has been initiated as planned. In addition, a separate Phase 1 Japanese bridging study has been initiated.

In September 2022, we initiated a Phase 2a trial (NCT05523089) to evaluate the pre-exposure prophylactic activity of CD388 against influenza virus. The Phase 2a trial, which dosed its first healthy volunteer in September 2022, is a single-center, randomized, double-blind, placebo-controlled, proof-of-concept study to assess the prophylactic antiviral activity, safety, tolerability and pharmacokinetics of CD388 against influenza via a human viral challenge (influenza) model. Multiple dose levels of CD388 will be evaluated in volunteers who will receive a single administration of CD388 or placebo prior to influenza viral challenge. Interim results in February 2023 demonstrated a reduction in the viral load (area under the curve) for 150 mg of CD388 compared to placebo and a reduction in the incidence of subjects infected following influenza challenge for 150 mg of CD388 compared to placebo. Final results are expected later in 2023.

All Phase 1 and Phase 2a trials are being conducted under the Janssen Collaboration Agreement (as defined below).

In December 2022, we received the first U.S. patent for CD388. The patent includes claims directed to the composition of matter of CD388. The patent is projected to expire in 2039 plus any available patent term extension.

The Cloudbreak platform has also enabled us to expand the development of DFCs to target other life-threatening viral diseases including the SARS-CoV-2 strains causing COVID-19.

In addition, we have expanded the Cloudbreak platform beyond infectious diseases, to discover and develop highly potent DFCs that can target multiple immune checkpoint pathways with a single DFC for oncologic diseases. Cidara's lead oncology development candidate, CD421, targets CD73 in the adenosine pathway, which contributes to immune evasion in solid cancers by flooding the tumor microenvironment with adenosine, a potent immune cell suppressor. CD73 is highly expressed on a variety of tumor and stromal cells as well as immunosuppressive cell populations, such as regulatory T cells and myeloid-derived suppressor cells. CD421 is designed to address the potency, efficacy, pharmacokinetic and safety limitations of small molecule and monoclonal antibody candidates targeting CD73.

Janssen Collaboration Agreement

On March 31, 2021, we entered into the exclusive, worldwide license and collaboration agreement, or the Janssen Collaboration Agreement, with Janssen Pharmaceuticals, Inc., or Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to develop and commercialize one or more DFCs based on our Cloudbreak platform for the prevention and treatment of influenza.

Under the terms of the Janssen Collaboration Agreement, we are collaborating in the research, preclinical and early clinical development of CD388, under a mutually-agreed research plan with the objective of advancing development through Phase 1 clinical trials and the first Phase 2a clinical trial. We are responsible for performing all IND-enabling nonclinical studies and early-stage clinical trials under the research plan. Both parties are responsible for conducting certain specified chemistry, manufacturing and controls development activities under the research plan. Janssen is solely responsible, and reimburses us for internal personnel and out-of-pocket costs incurred in performing the research plan activities in accordance with an agreed budget. After completion of the research plan and upon its election to proceed with development, Janssen will be solely responsible for late-stage development, manufacturing, licensure and commercialization. Upon the effectiveness of the Janssen Collaboration Agreement, Janssen paid us an upfront payment of $27.0 million. As of the execution of the Janssen Collaboration Agreement, we are eligible for reimbursement by Janssen of up to $58.2 million in research and development costs incurred in conducting research plan activities. As of December 31, 2022, we have received the $27.0 million up-front payment, $25.1 million in research and development reimbursements, and $3.0 million in milestone payments.

We are eligible to receive up to an additional $237.0 million in development and regulatory milestone payments from Janssen for successful completion of certain activities over the next several years, including but not limited to Janssen's decision to proceed with clinical development and initiation of a pivotal trial. In addition, we may be eligible to receive approximately $455.0 million in commercial milestones as well as royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits.

Rezafungin

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

ReSTORE Phase 3 clinical trial

In December 2021, we reported positive topline results from ReSTORE, our Phase 3 pivotal clinical trial in patients with candidemia and/or invasive candidiasis (NCT03667690). ReSTORE was a global, randomized, double-blind, controlled trial evaluating the efficacy and safety of rezafungin as a potential first-line treatment for candidemia and invasive candidiasis. ReSTORE enrolled 187 patients and evaluated one 400 milligram, or mg, loading dose of rezafungin for the first week followed by 200 mg of rezafungin dosed once-weekly for up to four weeks in total. The treatment arm was compared to approved daily dosing of caspofungin in a 1:1 randomization.

Results from the ReSTORE trial showed that rezafungin met the primary endpoint for the FDA of all-cause mortality at Day 30, and also met the primary endpoint for the European Medicines Agency, or EMA, of global cure at Day 14. Both results demonstrated statistical non-inferiority of rezafungin dosed once-weekly, versus caspofungin dosed once-daily, the current standard of care.

ReSPECT Phase 3 clinical trial

We are currently conducting the ReSPECT, single, global, randomized, double-blind, controlled Phase 3 pivotal clinical trial (NCT04368559) 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, dosed at 400 mg for the first week followed by 200 mg once weekly out to 90 days, is being compared to a regimen containing two drugs (an azole and Bactrim) dosed once daily for 90 days. The primary efficacy outcome for this trial for the FDA and EMA is fungal-free survival at Day 90. We expect this trial to enroll approximately 462 patients, and over 50% of patients have been enrolled thus far. While the ReSPECT trial remains open for enrollment, we continue to monitor the near- and long-

term impact of COVID-19 on the ability of our clinical investigators to recruit patients at each of our global clinical trial sites. The study is currently enrolling in the European Union, or EU, Canada and the U.S.

Melinta License Agreement

On July 26, 2022, we entered into a License Agreement, or the Melinta License Agreement, with Melinta Therapeutics, LLC, or Melinta, under which we granted Melinta an exclusive license to develop and commercialize products that contain or incorporate rezafungin in the U.S.

Melinta will be solely responsible for the commercialization of rezafungin in the U.S., at its sole expense. We are responsible for conducting an agreed upon development plan that includes, among other activities, completion of the ongoing ReSPECT Phase 3 pivotal clinical trial for the prevention of invasive fungal infections in adult allogeneic blood and marrow transplant recipients. We will initially remain the holder of the rezafungin IND and NDA. Both applications will transfer to Melinta on a transfer date determined based on the status of the ReSPECT trial and the associated supplemental NDA for the prophylaxis indication. Following the transfer date, we will remain financially responsible for post-marketing commitments and other remaining development obligations and the costs for those will be deducted from royalties owed to us by Melinta.

The total potential transaction value of the Melinta License Agreement is $460.0 million, including a $30.0 million upfront payment and up to $430.0 million in regulatory and commercial milestones. In addition, we are eligible to receive tiered royalties on U.S. sales in the low double digits to mid-teens. As of December 31, 2022, we have received the $30.0 million up-front payment.

Mundipharma Collaboration Agreement

On September 3, 2019, we announced a strategic partnership with 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 and License Agreement, or the Mundipharma Collaboration Agreement, with Mundipharma Medical Company, or Mundipharma, we granted Mundipharma an exclusive, royalty-bearing license to develop, register and commercialize rezafungin outside the U.S. and Japan. The total potential transaction value is $568.4 million, including an equity investment, an up-front payment, global development funding, and certain development, regulatory, and commercial milestones. The Company is also eligible to receive double-digit royalties in the teens on tiers of annual net sales.

As of December 31, 2022, we have received $9.0 million from the sale of our equity to Mundipharma, a $30.0 million up-front payment, $31.2 million in global development funding, and $25.1 million in milestone payments (including an $11.1 million milestone payment creditable against future royalties payable to us).

COVID-19 Update

We continue to monitor the potential impact of the COVID-19 global pandemic on our business.

We are reliant on our information technology systems, infrastructure and data to conduct our business. Adopting a work-from-home policy during this pandemic has increased the complexity of our computer systems, making them inherently more vulnerable to service interruption or destruction, malicious intrusion and random attack.

While we have not experienced significant disruptions to our manufacturing supply chain or distribution to date, we are unable to fully assess the potential impact that an extended duration of this pandemic may have on our manufacturing or distribution processes in the future.

As we continue to actively advance our rezafungin Phase 3 clinical development program, we remain in close contact with our principal investigators and clinical sites and continue to monitor the impact of COVID-19 on our trials, expected timelines and costs on an ongoing basis. While the ReSPECT Phase 3 clinical trial for prophylaxis remains open for enrollment, we continue to monitor the near- and long-term impact of COVID-19 on the ability of our clinical investigators to recruit patients at each of our global clinical trial sites.

The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, impact on our clinical trials, employees and vendors, all of which are uncertain and cannot be predicted. Given these uncertainties and new information that may continue to emerge about COVID-19 strains, the full extent of the impact of the COVID-19 pandemic cannot be accurately predicted at this time, and we remain unable to reasonably estimate the related impact to our business, operating results and financial condition, if any. We will continue to evaluate and actively monitor the impact of the COVID-19 pandemic on our business.

Liquidity Overview

Since our inception, we have devoted substantially all of our financial resources and efforts to research and development and have incurred significant operating losses. As of December 31, 2022, we had an accumulated deficit of $407.0 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. In connection with the preparation of our financial statements for the year ended December 31, 2022, 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 twelve months from the issuance of these financial statements. Our ability to execute our current business plan depends on our ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. We may not be able to raise additional funding on terms acceptable to us, or at all, and any failure to raise funds as and when needed will compromise our ability to execute on our business plan.

FINANCIAL OPERATIONS OVERVIEW

Revenues

To date, we have generated all of our revenues from our strategic partnerships with Mundipharma and Janssen, and our license agreement with Melinta. 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 our Cloudbreak platform, as well as clinical development of rezafungin acetate. 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 other 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 may receive potential research and development funding through a partnership from the National Institute of Allergy and Infectious Diseases. 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:

- the impact of the COVID-19 pandemic and other similar health crises;
- 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,		
	2022	2021	2020
Rezafungin	$ 36,322	$ 43,175	$ 43,011
Cloudbreak platform	20,271	10,497	7,574
Personnel costs	16,705	17,135	15,151
Other research and development expenses	2,222	2,280	2,281
Total research and development expenses	$ 75,520	$ 73,087	$ 68,017

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

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

General and administrative expenses

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

Other income (expense), net

Other income and expense consist primarily of interest income and expense, and various income or expense items of a non-recurring nature. We earn interest income from interest-bearing accounts and money market funds for cash and cash equivalents. Interest expense represents interest payable related to term loans and the amortization of debt issuance costs.

Beneficial conversion feature

In February 2020, we completed a rights offering, pursuant to which we sold 6,639,307 shares of common stock and 531,288 shares of Series X Convertible Preferred Stock for gross proceeds of $30.0 million. Because the effective conversion price of the Series X Convertible Preferred Stock on the commitment date was below the fair value of the common stock at the date of issuance, a beneficial conversion feature with a calculated fair value of $2.8 million existed at the issuance date. As the Series X Convertible Preferred Stock was fully convertible at issuance, the full $2.8 million was recorded at issuance as a one-time deemed dividend on February 12, 2020. This one-time, non-cash deemed dividend impacted accumulated deficit and additional paid in capital at December 31, 2020 and net loss attributable to common stockholders and net loss attributable to common stockholders per share for the year ended December 31, 2020.

CRITICAL ACCOUNTING 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 U.S. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, and disclosure of contingent assets and liabilities as of the date of the financial statements, and the revenues and expenses incurred during the reporting periods. We believe that the estimates, judgments and assumptions are reasonable based upon information available to us at the time that these estimates, judgments and assumptions are made. To the extent there are material differences between these estimates, judgments or assumptions and actual results, our financial statements will be affected. Historically, revisions to our estimates have not resulted in a material change to our financial statements. While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, the significant accounting estimates that we believe are important to aid in fully understanding and evaluating our reported financial results include the following:

Revenue Recognition

We recognize revenue in accordance with ASC Topic 606, Revenue from Contracts with Customers, or Topic 606, which applies to all contracts with customers, except for elements of certain 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. 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 service we transfer to a customer. 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 and identify 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.

In a contract with multiple performance obligations, we 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 obligation. 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. We evaluate 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 our intellectual property is determined to be distinct from the other performance obligations identified in a contract, we recognize 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, we utilize 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. We evaluate the measure of progress at each reporting period and, if necessary, adjust 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, we evaluate 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 our 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, we re-evaluate the probability of achievement of milestones that are within our or a collaboration partner's control, such as operational development milestones and any related constraint, and, if necessary, adjust our 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 our 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, we 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, we have not recognized any royalty revenue from collaborative arrangements.

In September 2019, we entered into the Mundipharma Collaboration Agreement with Mundipharma. We concluded that there were three performance obligations under the Mundipharma 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.

In March 2021, we entered into the Janssen Collaboration Agreement with Janssen. We concluded that there were three performance obligations under the Janssen 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 May 2021.

In July 2022, we entered into the Melinta License Agreement with Melinta. We concluded that there were three performance obligations under the Melinta License 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 August 2022.

We concluded that progress towards completion of the research and development and clinical supply performance obligations related to the Mundipharma Collaboration Agreement, as well as progress towards completion of the research and development performance obligation related to the Melinta License Agreement, are best measured in an amount proportional to the collaboration expenses incurred and the total estimated collaboration expenses. We periodically review and update the estimated collaboration expenses, when appropriate, which may adjust revenue recognized for the period. While such changes to our estimates have no impact on our reported cash flows, the amount of revenue recorded in the period could be materially impacted. Revenue for the Janssen Collaboration Agreement is recognized based on actual amounts billed as the underlying services are provided and billed at market rates. The transaction prices to be recognized as revenue under both the Mundipharma Collaboration Agreement and the Janssen Collaboration Agreement consist of upfront payments, estimated reimbursable research and development and clinical supply costs, and milestones achieved to date. The transaction price to be recognized as revenue under the Melinta License Agreement consists of an upfront payment.

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 to the financial statements for additional information.

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. We accrue 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. We periodically confirm the accuracy of these estimates with our service providers and make adjustments if necessary.

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

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.

RESULTS OF OPERATIONS

Comparison of the years ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021 (in thousands):

	Year ended December 31,		
	2022	2021	Change
Collaboration revenue	$ 64,288	$ 49,572	$ 14,716
Research and development	75,520	73,087	2,433
General and administrative	18,486	18,740	(254)
Other income (expense), net	191	(212)	403
Income tax expense	(272)	—	(272)

Collaboration revenue

Collaboration revenue was $64.3 million and $49.6 million for the years ended December 31, 2022 and 2021, respectively. Revenue for the year ended December 31, 2022 included $25.9 million of revenue recognized upon transfer of an intellectual property license to Melinta in August 2022. The remaining revenue for the year ended December 31, 2022 relates to the achievement of milestones and ongoing research and development and clinical supply services provided to Mundipharma, Janssen and Melinta of $14.3 million, $23.3 million and $0.8 million, respectively.

Revenue for the year ended December 31, 2021 included $27.0 million of revenue recognized upon transfer of an intellectual property license to Janssen in May 2021. The remaining revenue for the year ended December 31, 2021 relates to the achievement of milestones and ongoing research and development and clinical supply services provided to Mundipharma and Janssen of $13.2 million and $9.4 million, respectively.

Research and development expenses

Research and development expenses were $75.5 million for the year ended December 31, 2022 compared to $73.1 million for the year ended December 31, 2021. The increase in research and development expenses is primarily due to increased expense associated with our Cloudbreak antiviral platform, offset by lower clinical expenses associated with the rezafungin clinical trials and lower personnel costs.

General and administrative expenses

General and administrative expenses were $18.5 million for the year ended December 31, 2022 compared to $18.7 million for the year ended December 31, 2021. The decrease in general and administrative expenses is primarily due to lower consulting and personnel costs.

Other income (expense), net

Other income for the year ended December 31, 2022 related primarily to interest income generated from cash held in interest-bearing investments, offset by interest expense in connection with our loan from Pacific Western Bank. Other expense for the year ended December 31, 2021 related primarily to interest expense in connection with our loan from Pacific Western Bank, offset by interest income generated from cash held in interest-bearing investments.

Income tax expense

Income tax expense for the year ended December 31, 2022 is primarily the result of capitalized Internal Revenue Code, or IRC, Section 174 research and development expenditures, effective January 1, 2022, creating taxable income which can be offset with net operating losses and credits that are limited in use by IRC Sections 382 and 383.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of liquidity are our cash and cash equivalents, as well as the cash flows generated from our partnerships with Mundipharma and Janssen, our license to Melinta, and equity and debt financings. We have devoted our resources to funding research and development programs, including research, preclinical and clinical development activities.

Our ability to fund future operating needs will depend on a combination of equity, debt or other financing structures, receipt of payments under the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License 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. Our ability to raise additional capital may also be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the U.S. and worldwide from geopolitical and macroeconomic events, including the COVID-19 pandemic, the ongoing Russia-Ukraine conflict and related sanctions, and bank failures.

We are eligible to receive up to $484.3 million in development, regulatory and commercial milestone payments from Mundipharma for successful completion of certain activities over the next several years, as well as double-digit royalties in the teens on tiers of annual net sales.

We are eligible to receive up to $237.0 million in development and regulatory milestone payments from Janssen for successful completion of certain activities over the next several years, including but not limited to Janssen's decision to proceed with clinical development and initiation of a pivotal trial. In addition, we may be eligible to receive approximately $455.0 million in commercial milestones as well as royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits.

We are eligible to receive up to $430.0 million in regulatory and commercial milestone payments from Melinta for successful completion of certain activities over the next several years, as well as tiered royalties on U.S. sales in the low double digits to mid-teens.

On November 8, 2018, we entered into the controlled equity offering sales agreement with Cantor Fitzgerald & Co., or the Sales Agreement, pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million. As of December 31, 2022, the aggregate offering price remaining under the Sales Agreement was $46.1 million.

In March 2023, we issued shares of our common stock and Series X Convertible Preferred Stock upon the closing of concurrent but separate public offerings, for gross proceeds of $19.5 million.

Our lease with Nancy Ridge Technology Center, L.P. expires on December 31, 2023 with options for two individual two-year extensions, which have not been exercised, and remain in effect and available to the Company. As of December 31, 2022, the Company was not reasonably certain that it would exercise the extension options, and therefore did not include these options in the determination of the total lease term for accounting purposes. Total undiscounted operating lease payments are $1.4 million as of December 31, 2022.

As discussed further below, we believe that our existing cash and cash equivalents will not be sufficient to fund our obligations for the next twelve months. There are many factors that could impact our operating cash flow, most notably achievement of milestones under our Mundipharma Collaboration Agreement, Janssen Collaboration Agreement and Melinta License Agreement.

We are mindful that conditions in the current macroeconomic environment could affect our ability to achieve our goals. We operate and conduct clinical trials in countries that face economic volatility and weakness. Sustained weakness or further deterioration of the local economies and currencies and adverse effects of the impact of the ongoing COVID-19 pandemic may pose operational challenges in those countries. We will continue to monitor these conditions and will attempt to adjust our business plans, as appropriate, to mitigate macroeconomic risks.

We enter into contracts in the normal course of business with vendors for research and development activities, manufacturing, and professional services that generally provide for termination either on notice or after a notice period. Our material cash requirements include costs to complete agreed-upon activities under our Mundipharma Collaboration Agreement, Janssen Collaboration Agreement and Melinta License Agreement, as well as personnel and general and administrative support costs.

As of December 31, 2022, we had $32.7 million in cash and cash equivalents. The following table shows a summary of our cash flows for the years ended December 31, 2022, 2021 and 2020 (in thousands):

	Year ended December 31,		
	2022	2021	2020
Net cash provided by (used in):			
Operating activities	$ (28,473)	$ (25,232)	$ (54,411)
Investing activities	(118)	(41)	(186)
Financing activities	(951)	44,597	37,278
Net increase (decrease) in cash and cash equivalents	$ (29,542)	$ 19,324	$ (17,319)

Operating activities

Net cash used in operating activities was $28.5 million for the year ended December 31, 2022, compared to $25.2 million and $54.4 million for the years ended December 31, 2021 and 2020, respectively. Cash used in operating activities for the year ended December 31, 2022 was primarily attributable to a net loss of $29.8 million, and included $2.8 million for a milestone achieved in December 2021 under the Mundipharma Collaboration Agreement, which was received in January 2022, $3.0 million for a milestone achieved in March 2022 under the Janssen Collaboration Agreement, which was received in May 2022, $11.1 million for a milestone achieved in August 2022 under the Mundipharma Collaboration Agreement, which was received in September 2022, and the $30.0 million upfront payment received in August 2022 pursuant to the Melinta License Agreement.

Cash used in operating activities for the year ended December 31, 2021 was primarily attributable to a net loss of $42.5 million and included $11.1 million for a milestone achieved in November 2020 under the Mundipharma Collaboration Agreement, which was received in January 2021, and the $27.0 million upfront payment received in May 2021 pursuant to the Janssen Collaboration Agreement.

Cash used in operating activities for the year ended December 31, 2020 was primarily attributable to a net loss of $72.1 million.

For all periods presented, the primary use of cash was to fund 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 investing activities during the years ended December 31, 2022, 2021 and 2020 consists of purchases of property and equipment.

Financing activities

Net cash used in financing activities during the year ended December 31, 2022 consisted primarily of net proceeds of $2.4 million, after deducting placement agent fees, from the sale of 3,402,926 shares of common stock under our Sales Agreement, offset by principal payments of $2.6 million made in connection with our loan from Pacific Western Bank and $0.7 million related to issuance costs for our 2021 underwritten public offering.

Net cash provided by financing activities during the year ended December 31, 2021 consisted primarily of (i) net proceeds of $36.5 million from the sale of 17,064,511 shares of common stock and 774,194 shares of Series X Convertible Preferred Stock pursuant to concurrent underwritten public offerings and (ii) $12.5 million, after deducting placement agent fees, from the sale of 5,608,510 shares of common stock under our Sales Agreement, offset by principal payments of $4.4 million made in connection with our loan from Pacific Western Bank.

Net cash provided by financing activities during the year ended December 31, 2020 consisted primarily of (i) net proceeds of $29.2 million from the sale of 6,639,307 shares of common stock and 531,288 shares of Series X Convertible Preferred Stock pursuant to the exercise of subscription rights issued in our rights offering and (ii) $11.0 million, after deducting placement agent fees, from the sale of 3,430,790 shares of common stock under our Sales Agreement, offset by principal payments of $3.0 million made in connection with our loan from Pacific Western Bank.

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.

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, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and shareholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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 suffered recurring losses from operations and negative cash flows from operating activities since its inception and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Estimated total costs expected to be incurred under the Mundipharma and Melinta Collaboration and License Agreements

Description of matter

As more fully described in Note 8 to the consolidated financial statements, the Company entered into collaboration and license agreements with Mundipharma Medical Company ("Mundipharma") and Melinta Therapeutics, LLC ("Melinta") for strategic collaborations to develop and commercialize rezafungin. For the collaboration and license agreements, the Company determined the license and intellectual property, research and development services, and clinical supply services represent the distinct performance obligations. Revenue related to research and development services and clinical supply services are recognized over the estimated period of time to conduct the research and development services and clinical supply services based on actual costs incurred compared to the estimated total costs expected to be incurred. Collaboration revenue was significant to our audit because the revenue recognition assessment process involved inherent uncertainty, used subjective assumptions, and the amounts involved are material to the financial statements taken as a whole. The subjective assumption relates to the estimated total costs expected to be incurred under the agreement.

How we addressed the matter in our audit

To test revenue recognized we performed audit procedures that included, among others, testing the assumption and underlying data used by the Company in its computation of the total estimated research and development services and clinical supply services budget expenses and testing the accuracy of the computations. We inspected evidence supporting the amount of actual costs incurred and assessed whether they were appropriate costs according to the terms of the contract by category. We performed corroborative inquiries of individuals outside of the finance department and inspected updated budget and change in estimated costs as approved by management. We assessed the reasonableness of the estimated costs to be incurred as of the reporting date based on current factors.

Initial accounting for the Melinta License Agreement

Description of matter

As more fully described in Note 8 to the consolidated financial statements, the Company entered into a collaboration and license agreement with Melinta Therapeutics, Inc., under which the Company granted Melinta an exclusive license to develop and commercialize products that contain or incorporate rezafungin in U.S. The Company determined the transaction price was equal to the up-front fee and the transaction price was allocated to the performance obligations based on the relative stand-alone selling price estimated for each performance obligation. Auditing the Company's revenue recognition for the Melinta license agreement was complex and required the Company to apply significant judgements, including the determination of performance obligations and transaction price, and the estimation of the standalone selling price of each identified performance obligation. The estimates of the standalone selling price for the performance obligations relating to the license reflect management's assumptions, which included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success and costs for manufacturing clinical supplies.

How we addressed the matter in our audit

Our audit procedures included, among others, obtaining and reading the license and collaboration agreement and evaluating the completeness of the performance obligations identified by management. We evaluated management's estimates of the standalone selling price of certain performance obligations. For example, we evaluated the projected discounted cash flow assumptions used by the Company in developing the estimates of standalone selling price by comparing the significant assumptions described above to current industry trends using available information from other similar companies within the same industry and other relevant factors. We involved our valuation professionals to assist in the assessment of the estimation methodology and the significant assumptions used in determining the estimated standalone selling price of the performance obligations. We performed a sensitivity analysis to evaluate the impact that changes in the significant assumptions would have on the estimated standalone selling price of performance obligations and the resulting impact on the allocation of transaction price to each performance obligation, as well as revenue recognized during the period.

/s/ Ernst & Young LLP

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

San Diego, California

March 23, 2023

CIDARA THERAPEUTICS, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,731	$ 59,680
Restricted cash	—	2,593
Accounts receivable	5,833	5,356
Prepaid expenses and other current assets	6,530	4,069
Total current assets	45,094	71,698
Property and equipment, net	222	256
Operating lease right-of-use asset	1,205	2,287
Other assets	1,072	1,084
Total assets	$ 47,593	$ 75,325
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,447	$ 1,301
Accrued liabilities	7,672	10,198
Accrued compensation and benefits	4,922	4,859
Current deferred revenue	14,614	13,920
Current portion of term loan	—	2,591
Current portion of lease liability	1,317	1,148
Total current liabilities	29,972	34,017
Lease liability	—	1,322
Long-term deferred revenue	20,525	18,413
Total liabilities	50,497	53,752
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2022 and December 31, 2021:		
Series X Convertible Preferred stock, $0.0001 par value; 4,947,759 shares authorized at December 31, 2022 and 2021; 1,870,713 shares issued and 1,818,472 shares outstanding at December 31, 2022 and 2021	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2022 and 2021; 72,470,440 shares issued and outstanding at December 31, 2022; 67,863,674 shares issued and outstanding at December 31, 2021	7	7
Additional paid-in capital	404,055	398,733
Accumulated deficit	(406,966)	(377,167)
Total stockholders' equity (deficit)	(2,904)	21,573
Total liabilities and stockholders' equity	$ 47,593	$ 75,325

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, 2022	2021	2020
Revenues:			
Collaboration revenue	$ 64,288	$ 49,572	$ 12,067
Total revenues	64,288	49,572	12,067
Operating expenses:			
Research and development	75,520	73,087	68,017
General and administrative	18,486	18,740	15,899
Total operating expenses	94,006	91,827	83,916
Loss from operations	(29,718)	(42,255)	(71,849)
Other income (expense):			
Interest income (expense), net	191	(212)	(262)
Total other income (expense), net	191	(212)	(262)
Loss before income taxes	(29,527)	(42,467)	(72,111)
Income tax expense	(272)	—	—
Net loss and comprehensive loss	(29,799)	(42,467)	(72,111)
Recognition of beneficial conversion feature	—	—	(2,762)
Net loss attributable to common shareholders	$ (29,799)	$ (42,467)	$ (74,873)
Basic and diluted net loss per common share	$ (0.43)	$ (0.81)	$ (1.80)
Shares used to compute basic and diluted net loss per common share	69,857,698	52,453,452	41,557,350

See accompanying notes.

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

(In thousands, except share data)	Series X Convertible Preferred Stock Shares	Series X Convertible Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2019	565,231	$ —	33,838,466	$ 3	$ 297,659	$ (259,827)	$ 37,835
Rights offering, net of offering costs	531,288	—	6,639,307	1	29,185	—	29,186
Recognition of beneficial conversion feature	—	—	—	—	2,762	(2,762)	—
Public offering of common stock, net of issuance costs	—	—	3,515,871	—	11,208	—	11,208
Issuance of common stock upon conversion of Series X Convertible Preferred Stock	(52,241)	—	522,410	—	—	—	—
Issuance of common stock for exercise of stock options	—	—	5,411	—	14	—	14
Issuance of common stock for restricted share units vested	—	—	74,804	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	280,139	—	493	—	493
Stock-based compensation	—	—	—	—	4,090	—	4,090
Net loss	—	—	—	—	—	(72,111)	(72,111)
Balance, December 31, 2020	1,044,278	—	44,876,408	4	345,411	(334,700)	10,715
Underwritten public offering, net of issuance costs	774,194	—	17,064,511	2	36,550	—	36,552
Public offering of common stock, net of issuance costs	—	—	5,523,429	1	12,315	—	12,316
Issuance of common stock for exercise of stock options	—	—	2,930	—	6	—	6
Issuance of common stock for restricted share units vested	—	—	106,725	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	289,671	—	437	—	437
Stock-based compensation	—	—	—	—	4,014	—	4,014
Net loss	—	—	—	—	—	(42,467)	(42,467)
Balance, December 31, 2021	1,818,472	—	67,863,674	7	398,733	(377,167)	21,573
Public offering of common stock, net of issuance costs	—	—	3,414,926	—	2,370	—	2,370
Issuance of common stock for restricted share units vested	—	—	828,244	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	363,596	—	140	—	140
Stock-based compensation	—	—	—	—	3,532	—	3,532
Issuance costs for underwritten public offering	—	—	—	—	(720)	—	(720)
Net loss	—	—	—	—	—	(29,799)	(29,799)
Balance, December 31, 2022	1,818,472	$ —	72,470,440	$ 7	$ 404,055	$ (406,966)	$ (2,904)

See accompanying notes.

Consolidated Statements of Cash Flows

(In thousands)	Years ended December 31, 2022	2021	2020
Operating activities:			
Net loss	$ (29,799)	$ (42,467)	$ (72,111)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation	3,532	4,014	4,090
Amortization of operating lease right-of-use assets	1,082	(1,419)	764
Depreciation and amortization	143	189	286
Non-cash interest expense	1	12	16
Amortization of debt issuance costs	—	3	5
Changes in operating assets and liabilities:			
Accounts receivable	(477)	5,819	(11,165)
Prepaid expenses, other current assets, and other assets	(2,440)	(229)	1,682
Accounts payable and accrued liabilities	(2,371)	(1,093)	6,591
Accrued compensation and benefits	203	1,085	1,045
Deferred revenue	2,806	7,323	15,207
Operating lease liabilities	(1,153)	1,531	(821)
Net cash used in operating activities	(28,473)	(25,232)	(54,411)
Investing activities:			
Purchases of property and equipment	(118)	(41)	(186)
Net cash used in investing activities	(118)	(41)	(186)
Financing activities:			
Proceeds from public offering of common stock, net of issuance costs	2,362	12,483	11,041
Issuance costs for underwritten public offering	(720)	—	—
Principal repayments of Term Loan	(2,593)	(4,444)	(2,963)
Proceeds from underwritten public offering, net of issuance costs	—	36,552	—
Proceeds from issuance of Common and Series X Preferred pursuant to rights offering, net of issuance costs.	—	—	29,186
Proceeds from exercise of stock options	—	6	14
Net cash provided by (used in) financing activities	(951)	44,597	37,278
Net increase (decrease) in cash, cash equivalents, and restricted cash	(29,542)	19,324	(17,319)
Cash, cash equivalents, and restricted cash at beginning of year	62,273	42,949	60,268
Cash, cash equivalents, and restricted cash at end of year	$ 32,731	$ 62,273	$ 42,949
Supplemental disclosure of cash flows:			
Interest paid	$ 40	$ 228	$ 445
Non-cash investing activity:			
Right-of-use asset obtained in exchange for lease liability	$ —	$ 2,341	$ —
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 69	$ 78	$ 12
Non-cash financing activities:			
Purchase of shares pursuant to Employee Stock Purchase Plan	$ 140	$ 437	$ 493
Proceeds from public offering of common stock, net of issuance costs, included in prepaid expenses and other current assets	$ 8	$ —	$ 167

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 long-acting therapeutics designed to transform the standard of care for patients facing serious diseases. The Company is focused on oncology and infectious diseases. The Company's lead product candidate is rezafungin acetate, an intravenous formulation of a novel echinocandin antifungal. Rezafungin is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections. The Company's primary scientific focus now is using its Cloudbreak® platform to develop a potential new class of drugs called drug-Fc conjugates, or DFCs, for the prevention and treatment of serious diseases. This technology couples potent inhibitors to a human antibody fragment to create long-acting DFCs designed to inhibit multiple disease targets. The Company's most advanced DFC program is CD388, a highly potent, long-acting antiviral designed to deliver universal prevention and treatment of seasonal and pandemic influenza, which is in Phase 1 and Phase 2a clinical trials. Additional programs are targeting the SARS-CoV-2 strains causing COVID-19 and multiple solid tumor oncology indications.

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, 2022, the Company had an accumulated deficit of $407.0 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, 2022, the Company had cash and cash equivalents of $32.7 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.

In addition to the foregoing, the Company is monitoring closely the impact of the COVID-19 pandemic on its business and has taken steps designed to protect the health and safety of its employees while continuing its operations. Given the level of uncertainty regarding the duration and impact of the COVID-19 pandemic on capital markets and the United States, or U.S., economy, the Company is currently unable to assess the impact of the COVID-19 pandemic on its future access to capital. The Company is continuing to monitor the spread of COVID-19 and its potential impact on the Company's operations. The full extent to which the COVID-19 pandemic will impact the Company's business, results of operations, financial condition, clinical trials, and preclinical research will depend on future developments that are highly uncertain, including actions taken to contain or treat COVID-19 and their effectiveness, as well as the economic impact on national and international markets.

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 related to the Company's collaboration and license agreements, certain accruals, including those related to nonclinical and clinical activities, and the stand-alone selling price of performance obligations associated with the Company's collaboration and license agreements. 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 represented cash that the Company was 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, which was paid in full on July 5, 2022.

See Note 5 for additional information.

Accounts Receivable

Accounts receivable is stated at the original invoice amount and consists of certain research and development and clinical supply costs subject to reimbursement under the Mundipharma Collaboration Agreement and Janssen Collaboration Agreement. The Company records accounts receivables net of any allowances for doubtful accounts for potential credit losses. An allowance for doubtful accounts is determined based on the financial condition and creditworthiness of customers and the Company considers economic factors and events or trends expected to affect future collections experience. Any allowance would reduce the net receivables to the amount that is expected to be collected. The payment history of the Company's customers will be considered in future assessments of collectability as these patterns are established over a longer period of time. The Company did not record any credit losses as of December 31, 2022 or 2021.

Property and Equipment

The Company records property and equipment at cost, which consists of laboratory 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 and comprehensive loss.

Income Taxes

The Company follows the Financial Accounting Standards Board, or FASB, *Accounting Standards Codification*, or ASC, 740, *Income Taxes*, or ASC 740, in reporting deferred income taxes. 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*, or Topic 606, which applies to all contracts with customers, except for elements of certain 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, or the Mundipharma Collaboration Agreement, with Mundipharma Medical Company, or Mundipharma. The Company concluded that there were three performance obligations under the Mundipharma 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.

In March 2021, the Company entered into an exclusive worldwide license and collaboration agreement, or the Janssen Collaboration Agreement, with Janssen Pharmaceuticals, Inc., or Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. The Company concluded that there were three performance obligations under the Janssen 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 May 2021.

In July 2022, the Company entered into a License Agreement, or the Melinta License Agreement, with Melinta Therapeutics, LLC, or Melinta. The Company concluded that there were three performance obligations under the Melinta License 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 August 2022.

The Company concluded that progress towards completion of the research and development and clinical supply performance obligations related to the Mundipharma Collaboration Agreement and the Melinta License 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. Revenue from research and development services for the Janssen Collaboration Agreement is recognized based on actual amounts billed as the underlying services are provided and billed at market rates. The transaction prices to be recognized as revenue under both the Mundipharma Collaboration Agreement and the Janssen Collaboration Agreement consist of upfront payments, estimated reimbursable research and development and clinical supply costs, and milestones achieved to date. The transaction price to be recognized as revenue under the Melinta License Agreement consists of an upfront payment.

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 for additional information.

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.

Stock-Based Compensation

The Company accounts for stock-based compensation expense related to stock options, restricted stock units, or RSUs, performance-based RSUs, or PRSUs, and Employee Stock Purchase Plan, or ESPP, rights by estimating the fair value on the date of grant. The Company estimates the fair value of stock options granted to employees and non-employees using the Black-Scholes option pricing model. The fair value of RSUs and PRSUs granted to employees is estimated based on the closing price of the Company's common stock on the date of grant.

The assumptions included in the Black-Scholes option pricing model include (a) the risk-free interest rate, (b) the expected volatility of the Company's stock, (c) the expected term of the award, and (d) the expected dividend yield. For periods ending on or before December 31, 2020, the Company based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded, due to the lack of an adequate history of a public market for the trading of the Company's common stock and a lack of adequate company-specific historical and implied volatility data. For these analyses, the Company selected companies with comparable characteristics, 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. The Company computed the expected volatility data using the daily close prices for the selected companies' shares during the equivalent period of the calculated expected term of the Company's stock-based awards. In January 2021 the Company began to compute the expected volatility data using the daily close prices for the Company's common stock during the equivalent period of the calculated expected term of the Company's stock-based awards. The Company estimated the expected life of 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. The expected dividend yield of zero reflects that the Company has not paid cash dividends since inception and do not intend to pay cash dividends in the foreseeable future.

For awards subject to time-based vesting conditions, including those with a graded vesting schedule, stock-based compensation expense is recognized using the straight-line method. For performance-based awards to employees, (i) the fair value of the award is determined on the grant date, (ii) the Company assesses the probability of the individual performance milestones under the award being achieved and (iii) the fair value of the shares subject to the milestone is expensed over the implicit service period commencing once management believes the performance criteria is probable of being met.

The Company recognizes forfeitures related to stock-based compensation as they occur and any compensation cost previously recognized for awards for which the requisite service has not been completed is reversed in the period that the award is forfeited.

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 stock equivalents outstanding for the period determined using the if-converted method. Dilutive common stock equivalents are comprised of warrants, Series X Convertible Preferred Stock, RSUs, PRSUs and options outstanding under the Company's stock option plans. For all periods presented, basic and diluted net loss per share are identical because the otherwise dilutive potential common shares become anti-dilutive and are therefore excluded.

Net loss allocable to common shares for the year ended December 31, 2020 includes non-cash deemed dividends of $2.8 million resulting from the recognition of a beneficial conversion feature. See Note 6 for additional information.

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

	December 31,		
	2022	2021	2020
Common stock warrants	12,517,328	12,517,328	12,517,328
Series X Convertible Preferred stock	18,184,720	18,184,720	10,442,780
Common stock options, RSUs and PRSUs issued and outstanding	9,323,495	9,470,178	6,787,033
Total	40,025,543	40,172,226	29,747,141

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, accounts receivable, accounts payable, accrued liabilities, accrued compensation and benefits, and lease liability. The carrying amount of these financial instruments are generally considered to be representative of their respective fair values because of their short-term nature.

Recently Issued Accounting Standards

Recently Adopted Accounting Standards

In August 2020, the FASB issued ASU 2020-06, "Accounting for Convertible Instruments and Contracts in an Entity's Own Equity," simplifies the accounting for certain convertible instruments by removing the separation models for convertible debt with a cash conversion feature or convertible instruments with a beneficial conversion feature. As a result, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. Additionally, this ASU amends the diluted EPS calculation for convertible instruments by requiring the use of the if-converted method. The treasury stock method is no longer available. Entities may adopt this ASU using either a full or modified retrospective approach, and it is effective for interim and annual reporting periods beginning after December 15, 2021. Early adoption is permitted for interim and annual reporting periods beginning after December 15, 2020. The Company adopted ASU 2020-06 effective January 1, 2022. The adoption of this standard did not have a material impact on the Company's consolidated 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.

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 accounts within Level 1 as the prices are available from quoted prices in active markets.

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, 2022				
Assets:				
Cash and money market accounts	$ 32,731	$ 32,731	$ —	$ —
Total assets at fair value	$ 32,731	$ 32,731	$ —	$ —
December 31, 2021				
Assets:				
Cash and money market accounts	$ 59,680	$ 59,680	$ —	$ —
Restricted cash and money market accounts	2,593	2,593	—	—
Total assets at fair value	$ 62,273	$ 62,273	$ —	$ —

4. PROPERTY AND EQUIPMENT

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

	December 31,	
	2022	2021
Laboratory equipment	$ 2,415	$ 2,369
Leasehold improvements	425	425
Computer hardware and software	305	425
Office equipment	93	119
Furniture and fixtures	142	142
	3,380	3,480
Less accumulated depreciation and amortization	(3,158)	(3,224)
Total	$ 222	$ 256

Depreciation and amortization of property and equipment of $0.1 million, $0.2 million and $0.3 million were recorded for the years ended December 31, 2022, 2021 and 2020, respectively.

5. DEBT

Term Loan

On October 3, 2016, the Company entered into a loan and security agreement, or the Loan Agreement, with Pacific Western Bank, as the collateral agent and a lender, or the Lender, pursuant to which the Lender agreed to lend to the Company up to $20.0 million in a series of term loans, or the Term Loan. Contemporaneously, the Company borrowed $10.0 million from the Lender, or 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, or 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, or 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 were secured by a first priority security interest in substantially all of the Company's current and future assets, other than its intellectual property, which was subject to a double negative pledge.

The Company could prepay the borrowed amounts, provided that the Company was obligated to pay a prepayment fee equal to (i) 2.0% of the applicable principal amount of the Term Loan if the prepayment occurred 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 occurred 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 were outstanding under the Loan Agreement, the Company was 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 was 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 borrowed additional amounts under the Loan Agreement, it would have, in connection with any such borrowing, issued 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 would have been 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, or Maturity Date, and the interest rate. The interest-only period was followed by equal monthly payments of principal and interest. The Term Loans bore interest at a variable annual rate equal to the greater of (i) 4.50% or (ii) the Lender's prime interest rate plus 0.75%.

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 resulted in a restricted cash balance of $2.6 million as of December 31, 2021. The amendment also extended the interest-only period through April 3, 2020 and the maturity date through July 3, 2022. The Term A Loan was paid in full on July 5, 2022.

On March 16, 2021, and April 4, 2022, the Company and the Lender entered into a Fourth Amendment and a Fifth Amendment, respectively, to the Loan Agreement, which modified certain debt covenants under the original agreement but had no impact on current or future cash flows.

The Company evaluated the First, Second, Third, Fourth and Fifth Amendments and determined that the amendments did not represent a substantial change from the original Loan Agreement. Accordingly, the Company accounted for the amendments as debt modifications. Costs previously deferred under the original terms of the Loan Agreement were 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 had 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 Company had not been notified of an event of default by the Lenders prior to the maturity date.

The fair value of the warrants to purchase common stock issued in connection with Term A Loan 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 issuance costs incurred in connection with the entry into the Loan Agreement were presented as a direct deduction from the carrying amount of the term loan on the consolidated balance sheet and were being amortized utilizing the effective interest method over the term of the loan. The Company recorded interest expense of $2,000, $12,000 and $21,000 for the years ended December 31, 2022, 2021 and 2020, respectively, for the amortization of the fair value of the warrants and debt issuance costs.

6. STOCKHOLDERS' EQUITY

Controlled Equity Sales Agreement

In September 2019, the Company began to sell shares of common stock under a controlled equity sales agreement, or the Sales Agreement, entered into on November 8, 2018 with Cantor Fitzgerald & Co, or Cantor. During the years ended December 31, 2022 and 2021, the Company sold 3,414,926 and 5,523,429 shares of common stock for net proceeds of approximately $2.4 million and $12.3 million, respectively, after deducting placement agent fees. As of December 31, 2022, the aggregate offering price remaining under the Sales Agreement is $46.1 million.

2020 Rights Offering

On January 22, 2020, the Company initiated a rights offering to raise gross proceeds of $30.0 million through the distribution of subscription rights to holders of its common stock, Series X Convertible Preferred Stock, and warrants to purchase common stock issued on May 21, 2018, or the Rights Offering. On February 12, 2020, the Company sold 6,639,307 shares of common stock and 531,288 shares of Series X Convertible Preferred Stock for $2.51 and $25.10 per share, respectively, for aggregate gross proceeds of $30.0 million. Total offering costs of $0.8 million were offset against the proceeds from the sale of common stock for total net proceeds of $29.2 million. The Rights Offering was fully backstopped by Biotechnology Value Fund, L.P. and Stonepine Capital, LP.

With respect to the Series X Convertible Preferred Stock, because the effective conversion price on the commitment date was below the fair value of the common stock at the date of issuance, a beneficial conversion feature with a calculated fair value of $2.8 million existed at the issuance date. As the Series X Convertible Preferred Stock is fully convertible at issuance, the full $2.8 million was recorded at issuance as a deemed dividend on February 12, 2020. This non-cash deemed dividend impacted accumulated deficit and additional paid in capital at December 31, 2020 and net loss attributable to common stockholders and net loss attributable to common stockholders per share for the year ended December 31, 2020.

With respect to the common stock, because the purchase price was below fair value on the issuance date, a bonus element exists at the issuance date. Basic and diluted net loss per common share and shares used to compute basic and diluted net loss per common share have been retroactively adjusted for all periods presented to reflect this bonus element.

2021 Public Offering

On October 13, 2021, the Company completed concurrent but separate public offerings of 17,064,511 shares of its common stock, including the exercise in full by the underwriters of their option to purchase an additional 2,225,805 shares of common stock, at a price to the public of $1.55 per share, and 774,194 shares of its Series X Convertible Preferred Stock at a price to the public of $15.50 per share, for aggregate gross proceeds of $38.5 million. The Company received total net proceeds of $35.8 million, after deducting underwriting discounts, commissions, and other expenses payable by the Company.

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, 2022.

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 August 12, 2020, at the request of certain holders, 52,241 shares of the Company's Series X Convertible Preferred Stock were converted to an aggregate of 522,410 shares of the Company's common stock. As of December 31, 2022 and 2021 shares of preferred stock designated as Series X Convertible Preferred Stock totaled 4,947,759.

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 liability instruments defined thereunder as convertible instruments. 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. As such, the Series X Convertible Preferred Stock is recorded as permanent equity.

Common Stock

The Company had 200,000,000 shares of common stock authorized as of December 31, 2022. 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.

Common Stock Warrants

As of December 31, 2022 and 2021, 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, 2022 and 2021. 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):

	December 31,	
	2022	2021
Common stock warrants	12,517,328	12,517,328
Series X Convertible Preferred stock	18,184,720	18,184,720
Stock options, RSUs and PRSUs issued and outstanding	9,323,495	9,470,178
Authorized for future stock awards	4,469,969	2,436,984
Awards available under the ESPP	806,968	680,228
Total	45,302,480	43,289,438

7. EQUITY INCENTIVE PLANS

2020 Inducement Incentive Plan and 2015 Equity Incentive Plan

In December 2020, the Company's board of directors approved and adopted the 2020 Inducement Incentive Plan, or 2020 IIP. Under the 2020 IIP, the Company may grant stock options, stock appreciation rights, restricted stock, RSUs, and other awards to individuals who were not previously employees or directors of the Company, or who are returning to employment following a bona fide period of non-employment with the Company, as an inducement material to such persons entering into employment with the Company.

In March 2015, the Company's board of directors and stockholders approved and adopted the 2015 Equity Incentive Plan, or 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 is 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 2020 IIP and 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 2020 IIP and 2015 EIP must be at a price no less than 100% of the fair value of the shares on the date of grant, 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 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, or the 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 years ended December 31, 2022, 2021 and 2020, 363,596, 289,671 and 280,139 shares, respectively, were issued pursuant to the ESPP.

As of December 31, 2022, total unrecognized compensation expense related to the ESPP was approximately $0.2 million. This unrecognized compensation cost is expected to be recognized over approximately 0.5 years.

Restricted Stock Units

The following table summarizes RSU and PRSU activity during the year ended December 31, 2022:

	Number of RSUs and PRSUs		Weighted Average Grant Date Fair Value
Outstanding at December 31, 2021	1,174,087	$	2.53
RSUs and PRSUs granted	1,471,454		0.83
RSUs and PRSUs vested	(1,036,190)		1.59
RSUs and PRSUs canceled	(385,480)		1.94
Outstanding at December 31, 2022	1,223,871	$	1.47

The weighted-average grant date fair value of RSUs and PRSUs granted by the Company during the years ended December 31, 2021 and 2020 was $2.27 and $2.29, respectively, per share. The total fair value of RSUs and PRSUs vested during the years ended December 31, 2022, 2021 and 2020 was approximately $1.6 million, $0.4 million and $0.3 million respectively.

At December 31, 2022, estimated unrecognized compensation expense related to RSUs and PRSUs granted was approximately $1.4 million.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Total Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	8,296,091	$ 3.21	6.31	$ —
Options granted	2,014,700	0.80		
Options exercised	—	—		
Options canceled	(2,211,167)	2.59		
Outstanding at December 31, 2022	8,099,624	$ 2.78	6.65	$ 48
Vested and expected to vest at December 31, 2022	8,099,624	$ 2.78	6.65	$ 48
Exercisable at December 31, 2022	5,593,809	$ 3.35	5.69	$ —

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 weighted-average grant date fair value of stock options granted by the Company during the years ended December 31, 2022, 2021 and 2020 was $0.51, $1.42 and $1.48, respectively, per share.

As of December 31, 2022, total unrecognized share-based compensation expense related to unvested stock options was approximately $2.2 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 1.9 years.

The following table summarizes the Black-Scholes option pricing model assumptions used to estimate the fair value of stock options granted to employees under the 2015 EIP and 2020 IIP and the shares purchasable under the 2015 ESPP during the periods presented:

	For the years ended December 31,	
	2022	2021
2015 EIP and 2020 IIP		
Risk-free interest rate	1.39% - 4.02%	0.61% - 1.35%
Expected dividend yield	0%	0%
Expected volatility	70% - 75%	67% - 70%
Expected term (years)	5.50 - 6.08	5.27 - 6.08
2015 ESPP		
Risk-free interest rate	1.57% - 2.65%	0.02% - 0.63%
Expected dividend yield	0%	0%
Expected volatility	75% - 98%	58% - 79%
Expected term (years)	0.50 - 2.00	0.50 - 2.00

Stock-based compensation expense recognized for 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,		
	2022	2021	2020
Research and development	$ 1,760	$ 1,908	$ 2,089
General and administrative	1,945	2,106	2,001
Total	$ 3,705	$ 4,014	$ 4,090

8. SIGNIFICANT AGREEMENTS AND CONTRACTS

Mundipharma Collaboration Agreement

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

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

Licenses. Pursuant to the Mundipharma Collaboration Agreement, the Company granted Mundipharma an exclusive, royalty-bearing license to develop, register and commercialize the Mundipharma Licensed Product in the Mundipharma Territory, subject to the Company's retained right 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 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 Mundipharma Licensed Product and rezafungin.

Until the seventh anniversary of the first commercial sale of the Mundipharma 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 Mundipharma Licensed Product, Subcutaneous Product and Other Products) that such party proposes to out-license in the other party's territory.

The Company's Retained Rights. As of December 31, 2022, the Company retained the exclusive right to develop, register and commercialize the Mundipharma Licensed Product, Subcutaneous Product and Other Products in Japan, or the Company Territory, and Mundipharma has granted the Company certain licenses under Mundipharma-controlled technology and jointly-developed technology to develop, register and commercialize Mundipharma Licensed Product, Subcutaneous Product and Other Products in the Company Territory and to manufacture such products and rezafungin worldwide.

Financial Terms. As of the execution of the Mundipharma Collaboration Agreement, the parties have 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 $31.2 million. The total potential transaction value is $568.4 million, including an equity investment, an up-front payment, global development funding, and certain development, regulatory, and commercial milestones. The Company is also eligible to receive double-digit royalties in the teens on tiers of annual net sales.

Termination. Either party may terminate the Mundipharma Collaboration Agreement for uncured material breach by the other party. 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 ReSTORE Trial and the ReSPECT Trial, Mundipharma will continue to be liable for its share of Global Development Costs as described above. The Company may terminate the Mundipharma Collaboration 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

As of December 31, 2022, 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, plus milestones achieved of $13.9 million. The common stock issued pursuant to the Mundipharma Stock Purchase Agreement was determined to be issued 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 Mundipharma Collaboration Agreement for the share issuance. The

transaction price 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 utilized discounted cash flows and developed assumptions that required 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 Mundipharma Collaboration Agreement, as well as the amount of revenue allocated to each distinct 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 September 2019, therefore the Company recognized the full revenue related to this performance obligation in the amount of $17.9 million in September 2019 as collaboration revenue in its consolidated statements of operations and comprehensive loss.

Research and Development Services. The Company and Mundipharma share equally in the costs of ongoing rezafungin clinical development in the Mundipharma Territory up to the specified cap, which represents a distinct performance obligation. 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.

Clinical Supply Services. The Company's initial obligation to supply rezafungin for ongoing clinical development in the Mundipharma 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.

Milestone Payments. In November 2020, the Company achieved a $11.1 million milestone under the Mundipharma Collaboration Agreement, which is recorded as long-term deferred revenue as of December 31, 2022 because the rights to consideration is not expected to be satisfied within one year. The Company received payment for this milestone in January 2021. 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 Mundipharma 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. In December 2021 and August 2022, the Company achieved milestones of $2.8 million and $11.1 million, respectively, under the Mundipharma Collaboration Agreement that the Company deems to be tied to all the performance obligations identified in the original agreement. Revenue associated with these milestones has been allocated proportionately to the original transaction price which was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In conjunction with the performance obligations already delivered, revenue is recognized based on the progress of these performance obligations, the unrecognized portion is recorded as deferred revenue at the reporting period end and will be recognized as revenue over the remaining progress of these performance obligations. The Company received payment for these milestones in January 2022 and September 2022, respectively. The Company determined that as of December 31, 2022, all remaining 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.

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 years ended December 31, 2022, 2021 and 2020.

Janssen Collaboration Agreement

On March 31, 2021, the Company and Janssen entered into the Janssen Collaboration Agreement to develop and commercialize one or more DFCs based on the Company's Cloudbreak platform, for the prevention and treatment of influenza, including CD388 and CD377, or the Products. The effectiveness of the Janssen Collaboration Agreement, including the effectiveness of the terms and conditions described below, was subject to the expiration or earlier termination of all applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or HSR. HSR clearance was obtained on May 12, 2021 and the Janssen Collaboration Agreement became effective on the same date.

Collaboration. The Company and Janssen will collaborate in the research, preclinical development and early clinical development of CD388 or another mutually-agreed influenza DFC development candidate, or, in each case, the Development Candidate, under a mutually-agreed research and development plan, or the Research Plan, with the objective of advancing such Development Candidate through the completion of mutually-agreed Phase 1 clinical trials and the first Phase 2 clinical trial, or Phase 2 Study. Unless otherwise agreed by the parties, the Company will be responsible for performing, or having performed, all investigational new drug application, or IND, -enabling studies and clinical trials under the Research Plan, and the Company will be the IND holder for the Research Plan clinical trials. Both parties will be responsible for conducting certain specified chemistry, manufacturing and controls development activities under the Research Plan. Janssen will be solely responsible, and reimburse the Company, for internal full-time equivalent and out-of-pocket costs incurred by the Company in performing Research Plan activities in accordance with a mutually-agreed budget.

Within 90 days after delivery by the Company to Janssen of results of the Phase 2 Study and all then-available data from other clinical trials of the Development Candidate conducted under the Research Plan, or the Election Period, Janssen will be obligated to notify the Company of Janssen's election to proceed with further clinical development of Products, such notice, an Election to Proceed Notice. If Janssen fails to deliver an Election to Proceed Notice prior to expiration of the Election Period, the Company will have the right to terminate the Janssen Collaboration Agreement upon written notice to Janssen. If Janssen provides an Election to Proceed Notice prior to expiration of the Election Period, then the parties will continue any then-ongoing Research Plan activities to completion, and Janssen will otherwise be solely responsible for the development, manufacture and commercialization of Products, at Janssen's sole expense.

Licenses. Upon the effectiveness of the Janssen Collaboration Agreement, the Company granted Janssen an exclusive, worldwide, royalty-bearing license to develop, register and commercialize Products, subject to the Company's retained right to conduct Research Plan activities as described above. In addition, the Company granted Janssen an exclusive right of first negotiation until December 31, 2021, to negotiate and enter into a separate definitive agreement pursuant to which the parties would collaborate in the research and development of DFCs for the treatment or prevention of respiratory syncytial virus. This right of first negotiation expired on December 31, 2021.

Non-Compete Covenant. The Company will covenant that, except for the performance of Research Plan activities, from the effectiveness of the Janssen Collaboration Agreement until the fifth anniversary of the completion of all Research Plan activities and the Company's delivery to Janssen of all Research Plan deliverables, the Company and its affiliates will not directly or indirectly (including through any third-party contractor or through or in collaboration with any third-party licensee) develop, file any IND or application for marketing approval for, or commercialize any DFC that binds influenza or influenza viral proteins at therapeutic levels, except that the Company has the right to conduct limited internal research of such DFCs for the purposes of generating data to support patent filings and improving and further developing the Company's DFC technology more broadly. The Company's non-compete covenant described above will not apply to any DFC that demonstrates high specificity for a virus other than the influenza virus and does not possess significant activity against the influenza virus.

Financial Terms. Upon the effectiveness of the Janssen Collaboration Agreement, Janssen paid the Company an upfront payment of $27.0 million. As of the execution of the Janssen Collaboration Agreement, the Company was eligible for reimbursement by Janssen of up to $58.2 million in research and development costs incurred in conducting Research Plan activities. The Company will also be eligible to receive up to $695.0 million in development, regulatory and commercial milestone payments, as well as royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits.

Termination. In addition to the Company's right to terminate the Janssen Collaboration Agreement for Janssen's failure to deliver the Election to Proceed Notice prior to expiration of the Election Period, the Janssen Collaboration Agreement includes standard termination provisions upon material breach, insolvency or safety concerns. In addition, Janssen may terminate the Janssen Collaboration Agreement for convenience as follows:

- prior to the completion of all Research Plan activities and the Company's delivery to Janssen of all Research Plan deliverables, upon 90 days' written notice to the Company, provided that if any clinical trial under the Research Plan is ongoing at the time of such termination, such clinical trial will be completed in accordance with the terms of the Janssen Collaboration Agreement;
- after completion of the Phase 2 Study and before expiration of the Election Period, immediately upon written notice to the Company; or
- after delivery of the Election to Proceed Notice, upon 90 days' written notice to the Company, which termination may be of the Janssen Collaboration Agreement in its entirety or on a country-by-country or Product-by-Product basis.

Revenue Recognition

As of December 31, 2022, the Company determined the transaction price is equal to the up-front fee of $27.0 million, the research and development funding of $60.7 million, plus milestones achieved of $3.0 million. The transaction price 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 utilized discounted cash flows and developed assumptions that required judgment and included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success, costs to continue the research and development efforts and costs for manufacturing clinical supplies. A description of the distinct performance obligations identified under the Janssen Collaboration Agreement, as well as the amount of revenue allocated to each distinct 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 Janssen in May 2021, therefore the Company recognized the revenue related to this performance obligation in the amount of $27.0 million in May 2021 as collaboration revenue in its consolidated statements of operations and comprehensive loss.

Research and Development Services. The research and development services to be performed represents a distinct performance obligation. The Company recognizes revenue based on actual amounts incurred as the underlying services are provided and billed at fair value.

Clinical Supply Services. The Company's initial obligation to supply drug supply for ongoing development represents a distinct performance obligation. The Company recognizes revenue based on actual amounts incurred as the underlying services are provided and billed at fair value.

Milestone Payments. In March 2022, the Company achieved a $3.0 million milestone under the Janssen Collaboration Agreement that the Company deems to be tied to all the performance obligations identified in the original agreement. Revenue associated with the milestone has been allocated proportionately to the original transaction price which was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In conjunction with the performance obligations already delivered, revenue is recognized based on the progress of these performance obligations, the unrecognized portion is recorded as deferred revenue at the reporting period end and will be recognized as revenue over the remaining progress of these performance obligations. The Company received payment for this milestone in May 2022. The Company determined that as of December 31, 2022 all remaining 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 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.

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 years ended December 31, 2022 and 2021.

Melinta License Agreement

On July 26, 2022, the Company entered into the Melinta License Agreement with Melinta under which the Company granted Melinta an exclusive license to develop and commercialize products that contain or incorporate rezafungin, or the Melinta Licensed Product, in the U.S., or the Melinta Territory.

Licenses. Pursuant to the Melinta License Agreement, the Company granted Melinta an exclusive, royalty-bearing license (including the right to sublicense through multiple tiers), to develop, register and commercialize the Melinta Licensed Product for all uses in humans and non-human animals in the Melinta Territory, subject to the Company's retained right, as described below.

Non-Compete Covenant. Until the fifth anniversary of the first commercial sale of the first Melinta Licensed Product in the Melinta Territory, neither the Company nor Melinta, nor any of their respective majority-owned subsidiaries may, directly or indirectly, itself or in collaboration with any third party, develop, manufacture for development or commercialization, or commercialize any product in the echinocandin class of drugs in the Melinta Territory without the other party's prior written consent, subject to certain provisions in connection with a change of control of a party.

Commercialization. Melinta will be solely responsible for the commercialization of rezafungin in the Melinta Territory, at its sole expense.

The Company's Retained Rights. The Company retains the non-exclusive right to practice the intellectual property rights licensed to Melinta in the Melinta Territory solely for the purpose of performing its obligations under the Melinta License

Agreement and Mundipharma Collaboration Agreement. The Company also retains the right to grant licenses under the intellectual property rights licensed to Melinta to third parties to which the Company has granted licenses or rights to market, promote and sell Melinta Licensed Product outside the Melinta Territory, to make and have made Melinta Licensed Product anywhere in the world solely to develop, register, use, sell, have sold, offer for sale, commercialize and import Melinta Licensed Product outside the Melinta Territory, subject to the terms of the Melinta License Agreement.

Continued Development and Regulatory Activities. The Company will be responsible, at its sole expense, for conducting an agreed upon development plan, or the Melinta Development Plan, that includes, among other activities, (a) completion of the ongoing ReSPECT Phase 3 pivotal clinical trial for the prophylaxis of invasive fungal infections in adult allogeneic blood and marrow transplant recipients, or the Prophylaxis Indication, (b) preparation and submission to the U.S. Food and Drug Administration, or FDA, of a supplemental New Drug Application, or NDA, for the Melinta Licensed Product in the Prophylaxis Indication, (c) site close-out activity worldwide (outside of China) for the Company's ReSTORE Phase 3 pivotal clinical trial for the treatment of candidemia and invasive candidiasis, or the Treatment Indication, (d) certain nonclinical studies and other nonclinical activities, (e) certain chemistry, manufacturing and controls activities for the Melinta Licensed Product, and (f) all other development activities that are required by the FDA to obtain marketing approval of the Melinta Licensed Product in the Treatment Indication and the Prophylaxis Indication in the Melinta Territory.

The Company will remain the holder of all FDA applications, including the rezafungin IND and NDA. The FDA applications will transfer to Melinta on a transfer date determined based on the status of the ReSPECT trial and the associated supplemental NDA for the Prophylaxis Indication, after which Melinta will be responsible for performing all activities that may be necessary to maintain NDA approvals for the Melinta Licensed Product in the Treatment Indication and the Prophylaxis Indication in the Melinta Territory, at Melinta's sole expense, subject to Melinta's right to deduct from royalties payable to the Company the internal expenses (not to exceed a specified dollar amount per calendar year) and certain out-of-pocket expenses incurred by Melinta.

Supply and Transfer of CMC activities. Until Melinta assumes responsibility for the manufacture and supply of the Melinta Licensed Product for development and commercialization in the Melinta Territory, which it may do by direct purchase from the Company's contract manufacturing organizations for the Melinta Licensed Product or by having a manufacturing technology transfer to Melinta or its designee performed at Melinta's sole expense, which, in either case, will be no later than December 31, 2026, the Company will be responsible for the manufacture and supply of the Melinta Licensed Product for development and commercialization by Melinta in the Melinta Territory, and during such period, shall supply Melinta Licensed Product to Melinta pursuant to the terms of a supply agreement to be negotiated by the parties.

Financial Terms. Upon execution of the Melinta License Agreement the total potential transaction value is $460.0 million, including a $30.0 million upfront payment and up to $430.0 million in regulatory and commercial milestone payments. In addition, the Company is eligible to receive tiered royalties on U.S. sales in the low double digits to mid-teens.

Termination. Either party may terminate the Melinta License Agreement for uncured material breach by the other party. After July 26, 2023, Melinta may terminate the Melinta License Agreement at will. The Company may terminate the Melinta License Agreement if Melinta 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 patent rights licensed to Melinta by the Company.

Revenue Recognition

As of December 31, 2022, the Company determined the transaction price is equal to the up-front fee of $30.0 million. The transaction price 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 utilized discounted cash flows and developed assumptions that required judgment and included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success, costs to continue the research and development efforts and costs for manufacturing clinical supplies. A description of the distinct performance obligations identified under the Melinta License Agreement, as well as the amount of revenue allocated to each distinct 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 Melinta in August 2022, therefore the Company recognized the full revenue related to this performance obligation in the amount of $25.9 million in August 2022 as collaboration revenue in its consolidated statements of operations and comprehensive loss.

Research and Development Services. The Company is required to provide research and development services, at its sole expense, as described under the Melinta Development Plan, which represents a distinct performance obligation. 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.

Clinical Supply Services. The Company's obligation to supply rezafungin for ongoing clinical development in the Melinta 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. Revenue related to the clinical supply services performance obligation recognized during the year ended December 31, 2022 was immaterial.

Milestone Payments. The Company determined that as of December 31, 2022, all remaining 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, 2022.

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, 2022.

Costs to Obtain a Contract with a Customer

The Company incurred costs to a third party to obtain the Melinta License Agreement and capitalized $2.0 million upon execution of the Melinta License Agreement in accordance with ASC 340. The Company incurred these costs in connection with all the performance obligations identified in the Melinta License Agreement and allocated the capitalized contract costs to performance obligations on a relative basis (i.e., in proportion to the transaction price allocated to each performance obligation) to determine the period of amortization. Amortization during the year ended December 31, 2022 was $1.8 million and is included within general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss. As of December 31, 2022, the remaining balance of the asset recognized from costs to obtain the Melinta License Agreement was $0.2 million.

Contract Liabilities

The following table presents a summary of the activity in the Company's contract liabilities (recorded as deferred revenue on the balance sheet) pertaining to the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement during the year ended December 31, 2022 (in thousands):

Opening balance, December 31, 2021	$	32,333
Payments received in advance		10,355
Payments receivable		14
Revenue from performance obligations satisfied during reporting period		(7,563)
Closing balance, December 31, 2022	$	35,139

Current portion of deferred revenue	$	14,614
Long-term portion of deferred revenue		20,525
Total deferred revenue, December 31, 2022	$	35,139

As of December 31, 2022, the aggregate transaction price allocated to performance obligations that are unsatisfied is $15.9 million, $31.0 million and $3.3 million under the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement, respectively. These amounts are expected to be recognized over 2 years, 1 year, and 2 years which represent the remaining research periods under the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement, respectively.

As of December 31, 2022, the Company recorded $0.2 million and $5.6 million in accounts receivable associated with the Mundipharma Collaboration Agreement and Janssen Collaboration Agreement, respectively. As of December 31, 2021, the Company recorded $2.8 million and $2.4 million in accounts receivable associated with the Mundipharma Collaboration Agreement and Janssen Collaboration Agreement, respectively.

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

	Year Ended December 31, 2022		
	Mundipharma	Janssen	Melinta
Revenue from Collaboration and License Agreements:			
Point in Time:			
License of Intellectual Property	$ 3,252	$ 816	$ 25,885
Clinical Drug Supply	484	—	—
Over Time:			
Research and Development Services	9,595	18,814	811
Clinical Supply Services	925	3,706	—
Total Revenue from Collaboration and License Agreements	$ 14,256	$ 23,336	$ 26,696

	Year Ended December 31, 2021		
	Mundipharma	Janssen	Melinta
Revenue from Collaboration and License Agreements:			
Point in Time:			
License of Intellectual Property	$ 813	$ 27,000	$ —
Clinical Drug Supply	—	—	—
Over Time:			
Research and Development Services	12,069	5,271	—
Clinical Supply Services	315	4,104	—
Total Revenue from Collaboration and License Agreements	$ 13,197	$ 36,375	$ —

	Year Ended December 31, 2020		
	Mundipharma	Janssen	Melinta
Revenue from Collaboration and License Agreements:			
Point in Time:			
License of Intellectual Property	$ —	$ —	$ —
Clinical Drug Supply	—	—	—
Over Time:			
Research and Development Services	10,513	—	—
Clinical Supply Services	1,554	—	—
Total Revenue from Collaboration and License Agreements	$ 12,067	$ —	$ —

9. INCOME TAXES

The tax provision for income taxes consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Current tax provision:		
Federal	$ 248	$ —
State	24	—
Total current tax provision	272	—
Deferred tax provision:		
Federal	—	—
State	—	—
Total deferred tax provision	—	—
Total tax provision	$ 272	$ —

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, 2022	2021	2020
Federal income taxes at 21% for 2022, 2021 and 2020	$ (6,200)	$ (8,918)	$ (15,142)
State income tax, net of federal benefit	(214)	(1,426)	(469)
Nondeductible expenses	415	339	486
Tax credits	(2,217)	(2,487)	(2,956)
Rate change	384	(30)	344
Change in valuation allowance	(20,528)	11,789	15,912
Reserve for uncertain tax positions	(10,416)	622	739
162m deferred tax asset limitation	82	76	857
382 NOL and tax credit limitation	37,825	—	—
Expired stock awards	1,052	103	290
Other	89	(68)	(61)
Income tax expense	$ 272	$ —	$ —

Current year tax expense is primarily the result of capitalized Internal Revenue Code, or IRC, Section 174 research and development expenditures, effective January 1, 2022, creating taxable income which can be offset with net operating losses and credits that are limited in use by IRC Sections 382 and 383.

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

	December 31, 2022	December 31, 2021
Deferred tax assets:		
Net operating losses	$ 42,043	$ 68,146
Tax credits	11,099	21,195
Intangibles	160	197
Capitalized R&D	14,706	—
Stock compensation	1,385	2,478
Lease liability	299	595
Deferred revenue	5,620	3,346
Other	1,019	1,151
Total deferred tax assets	76,331	97,108
Less valuation allowance	(75,869)	(96,397)
Deferred tax assets, net of valuation allowance	462	711
Deferred tax liabilities:		
Prepaid expenses	(189)	(160)
Right-of-use assets	(273)	(551)
Total deferred tax liabilities	(462)	(711)
Net deferred tax assets	$ —	$ —

At December 31, 2022, the Company had federal and state tax net operating loss carryforwards of approximately $185.3 million and $130.5 million, respectively. The federal and state net operating loss carryforwards begin to expire in 2035 and 2029, respectively, unless previously utilized. The Company also has federal research and development credit and orphan drug credit carryforwards totaling $11.2 million and state research and development credit carryforwards totaling $5.0 million. The federal research and development credit and orphan drug credit carryforwards begin to expire in 2035, unless previously utilized. The state research and development credit carryforwards begin to expire in 2029, with the exception of $4.9 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. The valuation allowance decreased by $20.5 million in 2022 and increased by $11.8 million in 2021.

Future utilization of the Company's net operating loss and tax credit carryforwards to offset future taxable income may be subject to an annual limitation, pursuant to 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 completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards through 2022 and has adjusted the attributes for their estimated limitation.

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, 2022, 2021 and 2020, the unrecognized tax benefits recorded were approximately $11.6 million, $24.0 million and $23.3 million, respectively. Approximately $9.8 million of the unrecognized tax benefits would reduce the Company's annual effective tax rates, if recognized, subject to the valuation allowance. The Company adjusted the uncertain tax position in the current year on certain attributes related to the IRC Section 382/383 analysis performed in the current year. 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 2022, 2021 and 2020 is as follows (in thousands):

	Years Ended December 31,		
	2022	2021	2020
Balance as of the beginning of the year	$ 23,990	$ 23,335	$ 22,558
Increases related to current year tax positions	586	655	777
Decreases related to prior year tax positions	(12,958)	—	—
Balance as of the end of the year	$ 11,618	$ 23,990	$ 23,335

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 U.S. 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, 2022 which will have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position or results of operations. Litigation, however, is subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm the Company's business.

Lease Obligations

In accordance with ASU 2016-02, "Leases", 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 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 July 14, 2021, the Company entered into a sixth amendment to its lease with Nancy Ridge Technology Center, L.P. which extended the term of the lease by an additional 24 months and increases the base rent to $103,733 per month effective January 1, 2022, subject to 3% increases every January. The lease expires on December 31, 2023 with options for two individual two-year extensions, as described in the original lease agreement, which have not been exercised, and remain in effect and available to the Company. As of December 31, 2022, the Company was not reasonably certain that it would exercise the extension options, and therefore did not include these options in the determination of the total lease term for accounting purposes. The 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, 2022 (in thousands):

2023	$ 1,395
Total undiscounted operating lease payments	1,395
Less: Imputed interest	(78)
Present value of lease payments	$ 1,317

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

Balance Sheet Classification:		
Operating lease right-of-use asset	$	1,205
Current portion of lease liability	$	1,317

As of December 31, 2022, the weighted average remaining lease term was 1 year.

Cash paid for amounts included in the present value of operating lease liabilities was $1.4 million for the year ended December 31, 2022.

Operating lease costs were $1.3 million, $1.2 million and $1.0 million for the years ended December 31, 2022, 2021 and 2020, respectively. These costs are primarily related to the Company's long-term operating lease, but also include immaterial amounts for variable leases and short-term leases with terms greater than 30 days.

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 notice or after a notice period.

11. SUBSEQUENT EVENTS

"At-the-market" Offering

In September 2019, the Company began to sell shares of common stock under the Sales Agreement with Cantor. During the period from January 1, 2023, through March 20, 2023, the Company sold 6,158,799 shares of common stock for net proceeds of approximately $8.6 million after deducting placement agent fees.

Underwritten Public Offerings

On March 7, 2023, the Company completed concurrent but separate underwritten public offerings with Cantor, the underwriter, to issue and sell 11,086,000 shares of its common stock, including the exercise in full by Cantor of their option to purchase an additional 1,446,000 shares of common stock, and 286,000 shares of the Company's Series X Convertible Preferred Stock. Cantor agreed to purchase the shares of common stock at a price of $1.267 per share and the shares of Series X Convertible Preferred Stock at a price of $12.67 per share. The total gross proceeds from the offerings, including the full exercise by Cantor of its option to purchase additional shares of common stock, were approximately $19.5 million, before deducting underwriting discounts and commissions and estimated offering expenses. The Company received total net proceeds of approximately $17.3 million, after deducting underwriting discounts, commissions, and other expenses payable by the Company.

Melinta Milestone Achieved

In March 2023, the Company achieved a regulatory milestone and is eligible to receive $20.0 million under the Melinta License Agreement in connection with the FDA's approval of REZZAYO™ (rezafungin for injection) for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options.

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 principal 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 is 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, 2022, 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, 2022.

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, 2022. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations, or COSO, of the Treadway Commission in its 2013 Internal Control — Integrated Framework. Based on this assessment, our management has concluded that, as of December 31, 2022, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to the Company's status as a non-accelerated filer.

Remediation of Previously Reported Material Weakness

We previously reported that our review control over the evaluation of applicable accounting standards and assessment of completeness and accuracy of valuation assumptions, related to non-routine transactions that include collaboration revenue, was not appropriately designed or operating effectively. While this improper design and operation did not result in a material error in the annual or interim financial statements, there was a reasonable possibility that a material misstatement in the annual or interim financial statements would not have been detected.

This material weakness has been remediated as of December 31, 2022. As part of the remediation process, we added additional layers of review by members of our management team regarding the evaluation of applicable accounting standards and completeness and accuracy of valuation assumptions related to non-routine transactions that include collaboration revenue.

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.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

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,” “Delinquent Section 16(A) Reports” and “Executive Officers” in our Proxy Statement for our 2023 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days after the fiscal year ended December 31, 2022, 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 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 on Form 10-K, and the inclusion of our website address in this Annual Report on Form 10-K 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 Accountant 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. Exhibit and Financial Statement Schedules.

1. ***Financial Statements***—We have filed the following documents in Item 8 of this Annual Report on Form 10-K:

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 on Form 10-K, 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 on Form 10-K.

Exhibit Index

Exhibit Number	Description
1.1	Controlled Equity OfferingSM Sales Agreement, dated as of November 8, 2018, by and between the Registrant 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 (incorporated by reference to Exhibit 4.4 to the Registrant's Quarterly Report on Form 10-Q, filed on August 13, 2020).
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 August 12, 2021).
10.7+	Cidara Therapeutics, Inc. 2020 Inducement Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8, filed on August 31, 2021).
10.8+	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Cidara Therapeutics, Inc. 2020 Inducement Incentive Plan (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on December 7, 2020).
10.9+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Cidara Therapeutics, Inc. 2020 Inducement Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed on December 7, 2020).
10.10	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).
10.11	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).
10.12	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).
10.13	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).
10.14	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).
10.15	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).
10.16+	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).
10.17	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	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 on November 8, 2019).
10.19	Stock Purchase Agreement, dated September 3, 2019, by and between the Registrant and Mundipharma Medical Company (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on November 8, 2019).
10.20	Exclusive License and Collaboration Agreement by and between the Registrant and Janssen Pharmaceuticals, Inc., dated March 31, 2021 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on May 13, 2021).
10.21	Fifth Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated January 13, 2020 (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K, filed on March 7, 2022).
10.22*	Sixth Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated July 14, 2021 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on August 12, 2021).
10.23	Letter Agreement by and between the Registrant and Mundipharma Medical Company, dated April 20, 2022 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on August 9, 2022).
10.24	License Agreement by and between the Registrant and Melinta Therapeutics, LLC, dated July 26, 2022 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on November 3, 2022).
10.25+	Employment offer letter between the Registrant and Taylor Sandison, dated March 22, 2017 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on November 3, 2022).
10.26+	Employment offer letter between the Registrant and Shane M. Ward, dated August 17, 2021 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on November 3, 2022).
10.27+	Employment offer letter between the Registrant and Preetam Shah, dated August 19, 2021 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on November 3, 2022).

21.1	List of subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K, filed on February 25, 2021).
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	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

+	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.

Item 16. Form 10-K Summary.

None

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 23, 2023

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 Preetam Shah, Ph.D., MBA, 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, Chief Executive Officer and Member of the Board of Directors *(Principal Executive Officer)*	March 23, 2023
/s/ Preetam Shah, Ph.D., MBA **Preetam Shah, Ph.D., MBA**	Chief Financial Officer and Chief Business Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 23, 2023
/s/ Daniel D. Burgess **Daniel D. Burgess**	Chairman of the Board of Directors	March 23, 2023
/s/ Bonnie Bassler, Ph.D. **Bonnie Bassler, Ph.D.**	Member of the Board of Directors	March 23, 2023
/s/ Carin Canale-Theakston **Carin Canale-Theakston**	Member of the Board of Directors	March 23, 2023
/s/ Timothy R. Franson, M.D. **Timothy R. Franson, M.D.**	Member of the Board of Directors	March 23, 2023
/s/ David Gollaher, Ph.D. **David Gollaher, Ph.D.**	Member of the Board of Directors	March 23, 2023
/s/ Chrysa Mineo **Chrysa Mineo**	Member of the Board of Directors	March 23, 2023
/s/ Theodore R. Schroeder **Theodore R. Schroeder**	Member of the Board of Directors	March 23, 2023