UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

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	X	Smaller reporting company	X
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 Capital Market on June 30, 2023, was approximately $100.2 million.

The number of shares of Registrant's common stock outstanding as of April 12, 2024 was 91,235,020.

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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 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;
- developments and projections relating to our competitors or our industry; and
- the potential impact of broader macroeconomic conditions, including global pandemics, high inflation, bank failures, labor shortages, supply chain disruptions, recession risks and potential disruptions from the ongoing Russia-Ukraine conflict and related sanctions and the Israel-Hamas war.

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.

- We need substantial additional funding to complete the development of rezafungin and to advance CD388, CBO421 and our other Cloudbreak programs.
- 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, CBO421 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.
- Any of our product candidates that receive marketing approval 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.
- 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 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.
- 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.
- 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.

EXPLANATORY NOTE

Restatement of Consolidated Financial Statements

As described in our Current Report on Form 8-K filed on April 16, 2024, with the United States, or U.S., Securities and Exchange Commission, or the SEC, our Audit Committee of the Board of Directors, or the Audit Committee, determined on April 11 and April 15, 2024, based on management's recommendation, that our previously issued audited consolidated financial statements for the fiscal years ended December 31, 2021 and 2022 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and each of our previously issued unaudited condensed consolidated financial statements included in our Quarterly Reports on Form 10-Q for each of the quarterly periods in 2022 and 2023, or collectively the Prior Financial Statements, filed with the SEC, should no longer be relied upon and should be restated due to the matters described below.

In connection with preparing our audited consolidated financial statements for the year ended December 31, 2023, and through our financial control processes of evaluating indirect taxation consequences upon the first commercial sale of REZZAYO® (rezafungin for injection) in 2023, we determined that we had a legal obligation for indirect taxation in various tax jurisdictions outside of the U.S. based on our supply chain activities in 2023 and prior years. As a result, the Audit Committee concluded that in prior years we did not appropriately account for indirect taxes which led to understatements of accrued liabilities and operating expenses during the impacted periods.

As a result, we are restating the Prior Financial Statements in this Annual Report on Form 10-K for the fiscal year ended December 31, 2023. In addition, the following items of this Annual Report on Form 10-K include restated financial data: (i) Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and (ii) Part II, Item 8. Consolidated Financial Statements and Supplementary Data. Note 1 and Note 12 to our consolidated financial statements set forth, in a comparative presentation, the previously reported, restatement adjustments and restated amounts for those line items in the relevant periods affected by the restatement. This Annual Report on Form 10-K also includes disclosures regarding the impact of the restatement on the effectiveness of our internal control over financial reporting and disclosure controls and procedures in Part II, Item 9A. Controls and Procedures.

We have not amended our previously filed Annual Report on Form 10-K and Quarterly Reports on Form 10-Q for the periods noted above. Instead, such financial statements are superseded by the audited consolidated financial statements for the years ended December 31, 2022 and 2023 and the quarterly unaudited condensed consolidated financial statements for the 2022 and 2023 quarters contained in this Annual Report on Form 10-K, which give effect to the restatements noted above.

PART I

Item 1. Business.

OVERVIEW

We are a biotechnology company focused on developing targeted therapies designed to save lives and improve the standard of care for patients facing serious diseases.

Our first commercially approved product in the United States, or U.S., is REZZAYO® (rezafungin for injection) which is indicated for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options. On July 31, 2023, Melinta Therapeutics, LLC, or Melinta, our commercial partner in the U.S., initiated the commercial launch of REZZAYO in the U.S. On October 2, 2023, Melinta announced receipt from the Centers for Medicare & Medicaid Services, or CMS, of both a product-specific J-Code and a new technology add-on payment, or NTAP, for REZZAYO. Outside the U.S. and Japan, our development and commercial partner for REZZAYO is Mundipharma Medical Company, or Mundipharma. In December 2023, the European Medicines Agency, or EMA, granted approval for REZZAYO in the European Union, or EU, for the treatment of invasive candidiasis in adults. In January 2024, the United Kingdom, or UK, Medicines and Healthcare products Regulatory Agency, or MHRA, granted approval for REZZAYO for the treatment of invasive candidiasis in adults.

Although we have shifted our primary research focus to our proprietary Cloudbreak® platform, we continue to execute on the ongoing ReSPECT Phase 3 pivotal clinical trial for the prevention of invasive fungal infections in adult allogeneic blood and marrow transplant recipients. A significant portion of our future royalties and milestones to be received under both Melinta and Mundipharma licensing agreements are tied to the successful completion of the ReSPECT Phase 3 trial.

Our proprietary Cloudbreak platform enables development of novel drug-Fc conjugates, or DFCs, that inhibit specific disease targets while simultaneously engaging the immune system. Our most advanced DFC program is CD388, a highly potent 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 multiple oncology and autoimmune indications.

Cloudbreak Platform

We believe our Cloudbreak platform has the potential to offer a fundamentally new approach to treat and prevent serious diseases such as solid tumor cancers and viral infections, 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 and 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, including antibody drug conjugates, or ADCs, monoclonal or multispecific 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 to serve as a "drug cocktail" in a single molecule, which may improve response to treatment and prevention; and
- Potential advantages over vaccines irrespective of the immune status of patients.

DFCs are fundamentally different from ADCs: DFCs are biologically stable drug-Fc conjugates designed to engage extracellular targets, while ADCs are designed to enter target cells to deliver and release cytotoxic small molecule drugs. In contrast to ADCs and monoclonal antibodies, DFCs are smaller, providing 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 candidate for the prevention of influenza is CD388, a DFC in Phase 1 and Phase 2a clinical trials. Our lead oncology DFC is CBO421, a development candidate targeting CD73 for the treatment of solid tumors, which is in investigational new drug application, or IND, -enabling studies.

Cloudbreak Influenza Program

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. Enrollment of all six planned cohorts has been completed. In addition, a separate Phase 1 Japanese bridging study (NCT05619536) has been initiated and enrollment has been completed.

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. Enrollment has now been completed.

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.

In June 2023, the U.S. Food and Drug Administration, or FDA, granted Fast Track designation to CD388 for the prevention of influenza A and B infection in adults who are at high risk of influenza complications due to underlying immunodeficiency and may not mount an adequate response to influenza vaccine or are at high risk of severe influenza despite influenza vaccination, including those for whom vaccines are contraindicated. Fast Track designation aims to facilitate the development and expedite the review of drugs to treat serious conditions with unmet medical needs. The purpose is to get important new drugs to patients earlier. Companies that are granted this designation are given the opportunity for more frequent interactions with the FDA, and, if relevant criteria are met, eligibility for Priority Review.

Final CD388 Phase 2a Results

In our recent R&D Day, on September 21, 2023, we announced efficacy and safety data from our Phase 1 and Phase 2a trials evaluating the pre-exposure prophylactic activity of CD388 against an H3N2 influenza A virus strain.

CD388 was well-tolerated up to 900 milligrams, or mg:

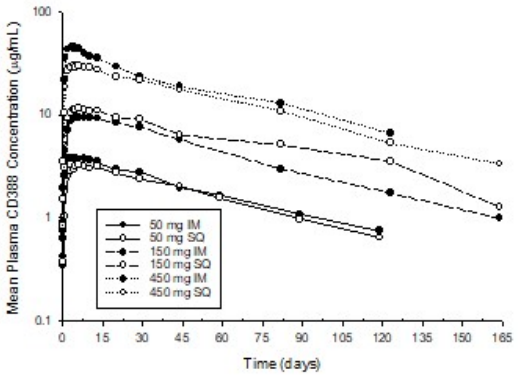
Number of participants that received one dose of CD388 in Phase 1 and Phase 2a trials

	First in Human Study (Phase 1)	Japanese Bridging Study (Phase 1)	Human Challenge Study (Phase 2a)	Total
50 mg	18	7	2	**27**
150 mg	18	7	28	**53**
450 mg	18	7	—	**25**
900 mg	9	—	—	**9**
All Doses[1]	**63**	**21**	**30**	**114**

[1] Safety Summary:

- No treatment-emergent serious adverse events, or SAEs, and no discontinuation of study drug or withdrawals due to safety findings.
- No consistent adverse event, or AE, patterns.
- No hypersensitivity reactions.
- Most treatment-emergent adverse events, or TEAEs, were Grade 1 (90%), few Grade 2, all resolved.
- Incidence of TEAE not dose-dependent.
- Few injection site events (pain, intramuscular, or IM, route mainly), Grade 1, all resolved spontaneously.
- No clinically relevant electrocardiogram, or ECG, vital signs or physical exam abnormalities.

CD388 pharmacokinetics, or PK, profile is that of a long-acting compound, potentially enabling seasonal pre-exposure prophylaxis, or PrEP:



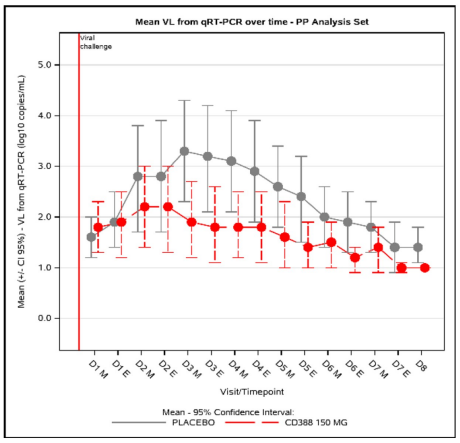
CD388 demonstrates prophylactic reduction of viral replication in the upper respiratory tract, or URT, and the incidence of PCR-confirmed influenza infection:

The Phase 2a prophylactic efficacy results are 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.

	Placebo (n=28)	CD388 150 mg (n=28)	P-value[2]
Quantitative reverse transcriptase polymerase chain reaction, or qRT-PCR, confirmed influenza infection ("attack rate" see Placebo data)	14 (50%)	6 (21%)	0.0248
qRT-PCR confirmed symptomatic influenza infection	9 (32%)	4 (14%)	0.1023
qRT-PCR confirmed moderately to severe symptomatic influenza infection	7 (25%)	3 (11%)	0.1477

[2] Statistical significance was pre-determined using a Wilcoxon rank-sum test with a one-sided type-1 error rate of 0.025.

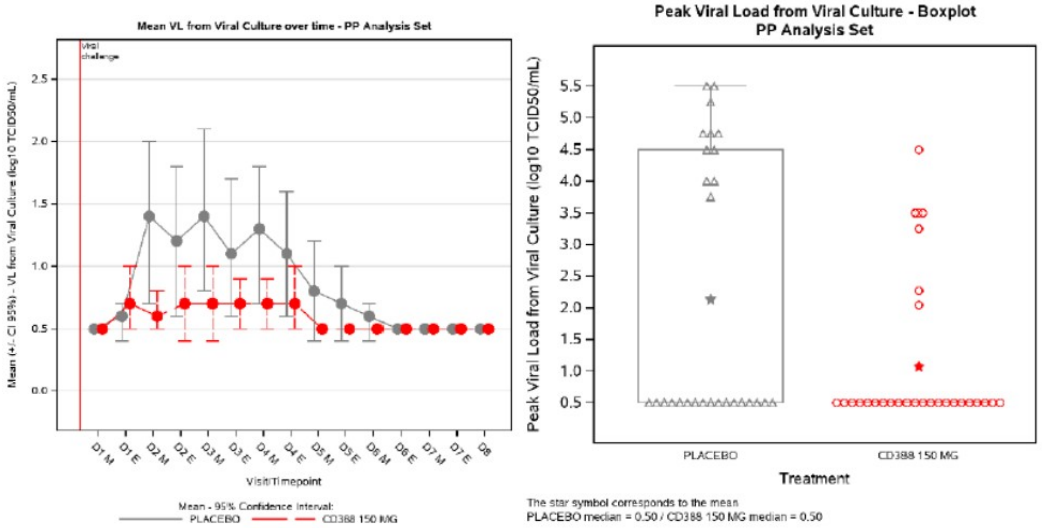
Primary endpoint: AUC viral load-time_ qRT-PCR



Statistical significance was pre-determined using a Wilcoxon rank-sum test with a one-sided type-1 error rate of 0.025

As shown above, despite the small sample size in this analysis, a decrease in viral replication in the URT 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 SAEs were reported in the analysis. All participants included in the analysis received either CD388 or placebo and were then challenged with influenza five days later.

Viral culture data confirmed efficacy seen in early analyses:



Janssen Collaboration Agreement

On March 31, 2021, we 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, 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, or CMC, 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. As part of a recent prioritization of its R&D business, in July 2023 Janssen disclosed its intention to discontinue internal development of multiple product candidates in its infectious disease pipeline, including CD388. However, in September 2023 Janssen delivered its Election to Proceed Notice for CD388 whereby Janssen will assume the future development, manufacturing and commercialization activities of CD388 but intends to transfer its rights and obligations under the Janssen Collaboration Agreement to another transferee. We continue to work in collaboration with Janssen to complete the Phase 1 and Phase 2a clinical trials and will be reimbursed for all ongoing development activities by Janssen as per the Janssen Collaboration Agreement.

Following Janssen's Election to Proceed Notice, Janssen, or any third-party transferee, is obligated at its sole expense to diligently continue development and commercialization either itself or through the transferee to whom it sublicenses or assigns the rights. If Janssen sublicenses or assigns the rights to a transferee, then all terms under the current Janssen Collaboration Agreement will survive without modification.

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 were 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, 2023, we have received the $27.0 million up-front payment, $44.5 million in research and development reimbursements, and $10.0 million in milestone payments.

We are eligible to receive up to an additional $230.0 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 whether to proceed with clinical development and initiation of Phase 2b and Phase 3 trials. 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.

Cloudbreak Oncology Programs

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

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.

Cloudbreak Oncology seeks to develop a new generation of immunotherapies targeting the tumor microenvironment. Our lead oncology DFC candidate, CBO421, is a potential best-in-class CD73 inhibitor that combines the strengths of small molecules and monoclonal antibodies targeting CD73. CBO421 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. The CD73 pathway is clinically validated in early/mid-stage clinical studies to reduce tumor growth in combination with PD-1/ PD-L1 inhibitors in disease areas that do not historically respond to checkpoint inhibition alone, such as advanced colorectal cancer, or CRC, and non-small cell lung cancer, or NSCLC. As a monotherapy and in combination with PD-1 inhibitors, CBO421 has demonstrated formation of immunologic memory in multiple murine tumor models, along with potential best-in-class activity in T-cell reactivation assays and tumor penetration compared with the most advanced CD73 antibody therapeutics in clinical development. We are currently advancing CBO421 through IND-enabling studies and expect to file an IND in mid-2024.

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

CBO421 demonstrates outstanding preclinical performance:

Potential Best-in-Class Activity

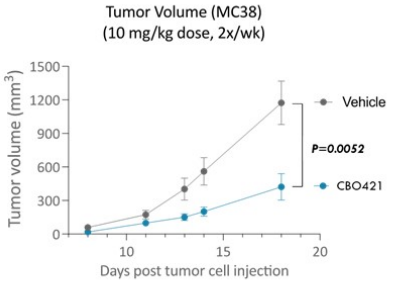
PBMC rescue assay (ATP) vs clinical stage adenosine pathway inhibitors

Test article	Target/Class	EC_{50} [nM]	
		$CD4^+CD25^+$	$CD8^+CD25^+$
CBO421	CD73/DFC	13	51
AB680*	CD73/small molecule	39	73
Oleclumab	CD73/mAb	>1,000	>1,000
IPH5201	CD39/mAb	>1,000	>1,000
AB928	A2AR/small molecule	>1,000	>1,000
CPI-444	A2AR/small molecule	>1,000	>1,000

AB680 – Arcus Biosciences CD73 inhibitor
Oleclumab – Astra Zeneca biosimilar CD73 inhibitor
IPH5201 – Innate Pharma biosimilar CD39 inhibitor
AB928 – Arcus Biosciences A2AR inhibitor
CPI-444 – Corvus A2AR inhibitor

Potent Tumor Activity

MC38 – murine colorectal carcinoma



CBO421 enhances anti-tumor activity of PD-1 inhibitors:

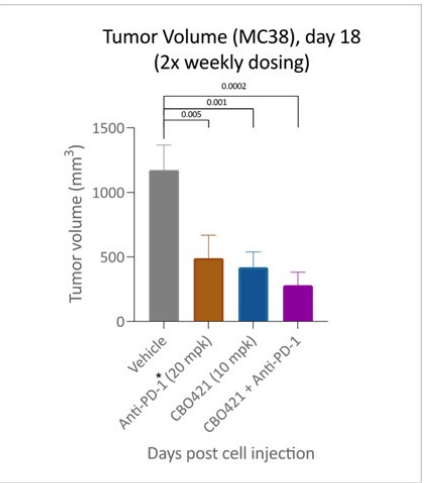
CBO421 and Anti-PD-1 combination improves response rates versus monotherapies.

MC38 – murine colorectal carcinoma

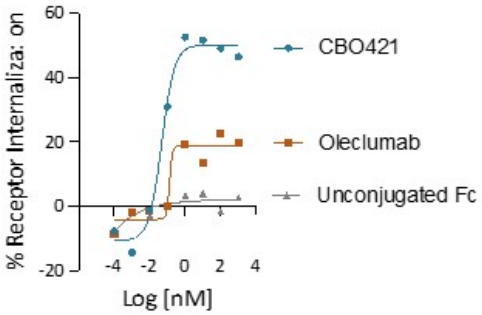
Study Arm	% Responders*
Vehicle	0
CBO421	27
Anti-PD-1	47
CBO421 + Anti-PD-1	60

*Defined as mice that demonstrate cessation of tumor growth or reduction in tumor volume across two or more timepoints

*RMP1-14



CBO421 exhibits a second mechanism of action that differentiates it from small molecule CD73 inhibitors:



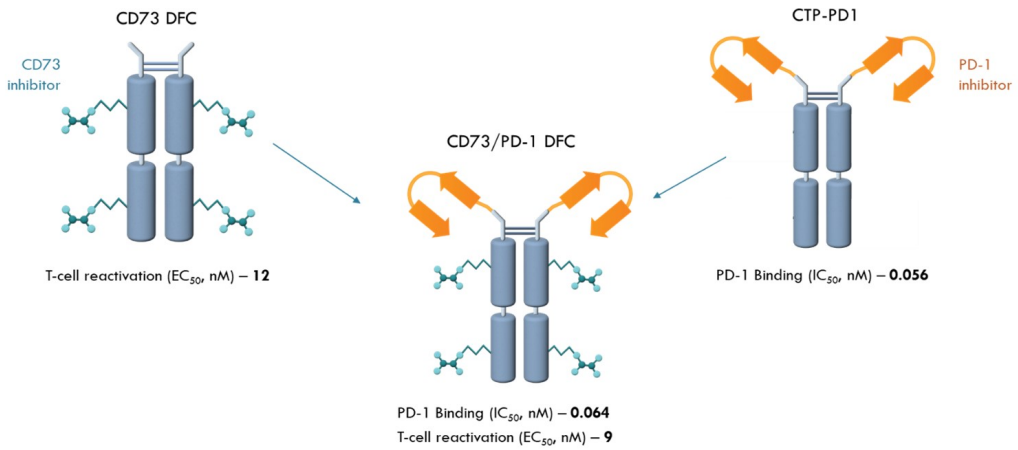
CD73 Internalization in MDA-MB-231 Cells

Test article	Target/Class	Maximum % internalization	EC_{50} [nM]
CBO421	CD73/DFC	50	0.049
AB680*	CD73/small molecule	0*	NA
Oleclumab*	CD73/mAb	18	0.13

*AB680 – Arcus Biosciences CD73 inhibitor, internalization data not shown
Oleclumab – Astra Zeneca biosimilar CD73 inhibitor

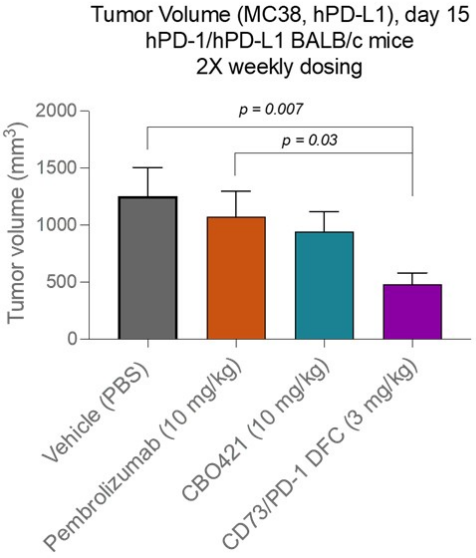
CBO421 demonstrates best in class CD73 downregulation via internalization, which is not achievable with small molecule CD73 inhibitors

CD73/PD-1 DFC potently inhibits both PD-1 and CD73 receptors:



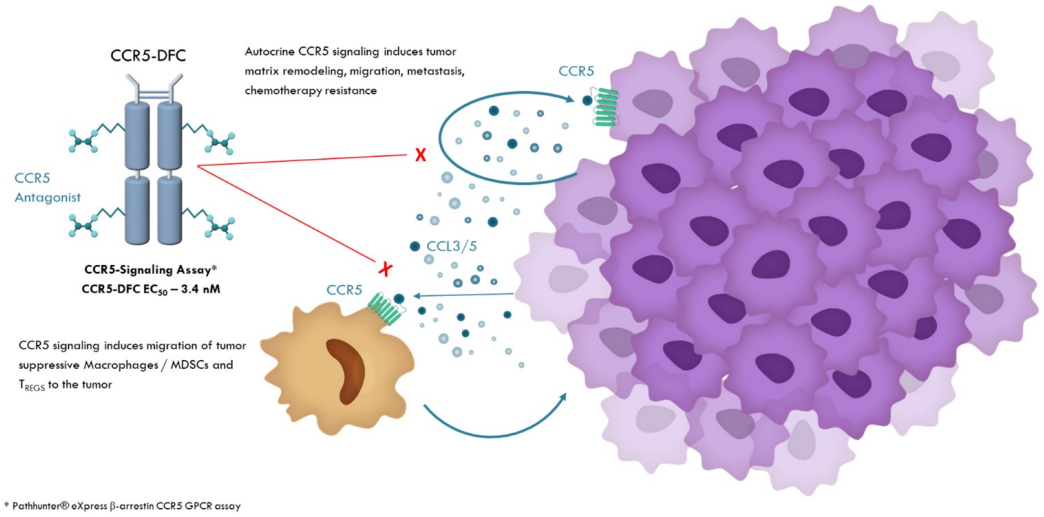
Enhancement of activity in preclinical models observed when CBO421 was combined with PD-1 inhibition inspired the development of a first in class multispecific CD73/PD-1 targeting DFC that potently inhibits both targets simultaneously. Emerging preclinical data is promising. The multispecific DFC retains the full activity of the monotherapy components in functional binding and activity assays. In a murine colorectal carcinoma efficacy model, the multispecific DFC exhibited superior activity compared with CBO421 and the marketed PD-1 inhibitor, pembrolizumab, validating the concept. Optimization and preclinical development of our CD73/PD-1 targeting DFCs is ongoing.

CD73/PD-1 DFC outperforms monotherapies in humanized tumor models:



CCRs are a historically difficult-to-drug receptor family:

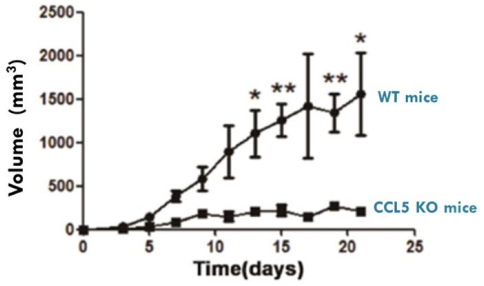
The DFC platform is also being expanded to include a validated, but difficult class of targets to drug, the chemokine receptors, or CCRs. CCR5 is a validated oncology target that can be a major driver in cancers that rely on the CCL5/CCR5 signaling pathway (e.g., breast, pancreatic and renal cell carcinomas). In several cancers, tumors secrete chemokine CCR5 agonists that promote tumor growth, metastasis and chemoresistance, while simultaneously recruiting immuno-suppressive macrophages and myeloid derived suppressor cells, or MDSCs, to the tumor microenvironment. We have rapidly been able to advance highly potent lead DFC CCR5-antagonist drug candidates that demonstrate robust activity as monotherapies in murine colorectal carcinoma models. Further optimization and preclinical characterization of our CCR5-DFC lead candidates including combination therapy studies, is ongoing.

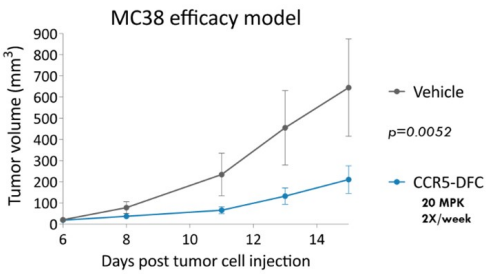


CCR5-DFC shows strong tumor control in preclinical model:

MC38 tumors are unable to proliferate in CCL5 KO mice (MC38 = murine colorectal carcinoma)

CCR5-DFC treatment accomplishes a similar degree of tumor reduction





Zhang et al. Cell Death and Disease (2018) 9:766 DOI 10.1038/s41419-018-0796-2

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.

FDA Approval of Rezafungin for the Treatment of Candidemia and Invasive Candidiasis

In March 2023, the FDA approved REZZAYO 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 15 years, and is the only available once-weekly echinocandin.

EMA and UK MHRA Approval of Rezafungin for the Treatment of Invasive Candidiasis in Adults

In December 2023, the EMA granted approval for REZZAYO in the EU for the treatment of invasive candidiasis in adults. In January 2024, the UK MHRA granted approval for REZZAYO for the treatment of invasive candidiasis in adults.

REZZAYO Commercialization in the U.S. by Melinta

On July 31, 2023, Melinta initiated the commercial launch of REZZAYO in the U.S.

ReSTORE Phase 3 clinical trial in China

In December 2023, enrollment in the ReSTORE Phase 3 trial in China, evaluating the efficacy and safety of rezafungin as a treatment for candidemia and invasive candidiasis, was completed. The portion of the trial conducted in China included 52 patients diagnosed with candidemia and/or invasive candidiasis. ReSTORE (NCT03667690) is a global, randomized, double-blind, controlled Phase 3 pivotal clinical trial evaluating the efficacy and safety of once-weekly intravenous dosing of rezafungin compared to once-daily dosing of caspofungin, the current standard of care, to treat patients with candidemia and/or invasive candidiasis. Data from this study are expected in the second quarter of 2024.

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. A blinded interim analysis is planned in the second quarter of 2024 which will inform the current fungal free survival rates, or FFS. The FFS will determine if the 462 patients planned to be enrolled will be sufficient to power the trial to detect non-inferiority. The study is currently enrolling in the EU, Canada and the U.S.

Melinta License Agreement

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

Melinta is 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 new drug application, or NDA. Both regulatory applications will transfer to Melinta on a transfer date determined based on the status of the ReSPECT trial and the associated supplemental NDA, or sNDA, 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, 2023, we have received the $30.0 million up-front payment and a $20.0 million milestone 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 with Mundipharma, or the Mundipharma Collaboration Agreement, 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. We are also eligible to receive double-digit royalties in the teens on tiers of annual net sales.

As of December 31, 2023, 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). In December 2023, we achieved a milestone of $11.1 million under the Mundipharma Collaboration Agreement for which we have received payment in February 2024. In January 2024, we achieved a milestone of $2.8 million under the Mundipharma Collaboration Agreement for which we have received payment in April 2024.

OUR STRATEGY

Our objective is to become the leading biotechnology company in the discovery, development and commercialization of targeted therapies designed to save lives and improve 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. 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, CBO421, targets CD73 in the adenosine pathway. We have expanded our existing collaboration with WuXi XDC under which WuXi XDC provides 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 further approval.** We are continuing to develop 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 the FDA's approval of REZZAYO for the treatment indication, and we are currently enrolling our ReSPECT Phase 3 prophylaxis clinical trial. Approvals 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, for which it is currently approved, and the prevention of invasive fungal infections in a highly vulnerable population, adults undergoing allogeneic blood and marrow transplantation.

CLOUDBREAK PLATFORM

We believe our Cloudbreak platform has the potential to offer a fundamentally new approach to treat and prevent serious diseases such as solid tumor cancers and viral infections, 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, including ADCs, monoclonal or multispecific 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 to serve as a "drug cocktail" in a single molecule, which may improve response to treatment and prevention; and
- Potential advantages over vaccines irrespective of the immune status of patients.

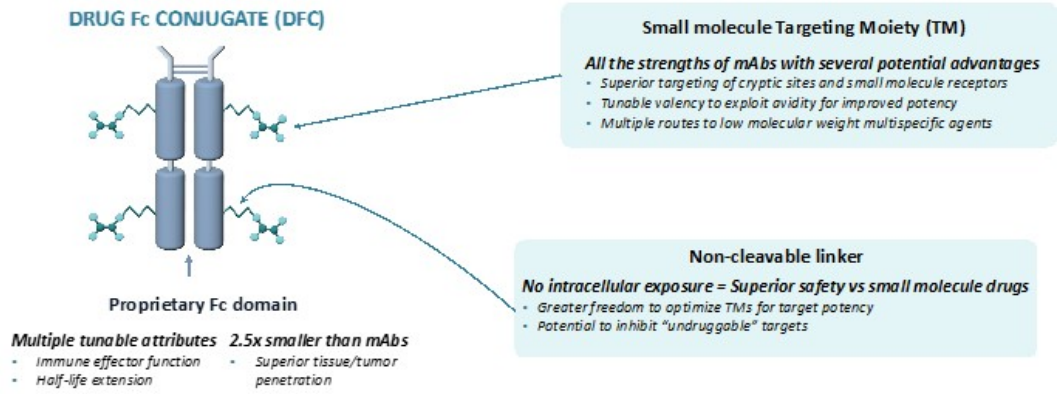
DFCs are fundamentally different from ADCs: DFCs are biologically stable drug-Fc conjugates designed to engage extracellular targets, while ADCs are designed to enter target cells to deliver and release cytotoxic small molecule drugs. In contrast to ADCs and monoclonal antibodies, DFCs are smaller, providing 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.

The Cloudbreak platform has enabled us to expand the development of DFCs to target other life-threatening diseases. We have expanded the Cloudbreak platform beyond infectious diseases to discover and develop highly potent DFCs that can target multiple immune checkpoint pathways within a single DFC for oncologic indications.

Cloudbreak candidates targeting solid tumor cancers and 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

We are leveraging the Cloudbreak platform to address multiple diseases. Each DFC targets a serious disease, focused on solid tumor cancers and viral infections. Our DFC research and development programs include:

- Influenza; and
- Cancer (solid tumors).

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 CBO421

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.

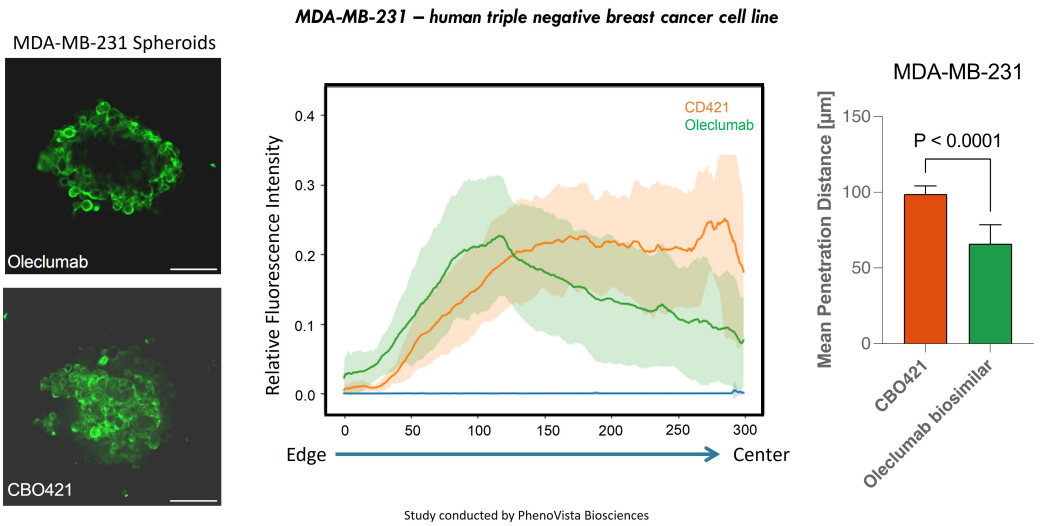
With our Cloudbreak oncology program we seek to develop a new generation of immunotherapies, and our CBO421 DFC is a first-in-class CD73 inhibitor that combines the strengths of small molecules and monoclonal antibodies targeting CD73. We are advancing CBO421 through IND-enabling studies.

CBO421 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. CBO421 is designed to address the potency, efficacy, pharmacokinetic and safety limitations of small molecule and monoclonal antibody candidates targeting CD73 in clinical development. CBO421 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. CBO421 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 CBO421 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. CBO421 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 CBO421 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 CBO421.

In addition, we believe the reduced size of CBO421 compared with conventional monoclonal antibodies is expected to translate to improved anticancer activity via enhanced tissue distribution and tumor penetration. CBO421 demonstrated improved tumor penetration into triple negative breast cancer tumor spheroids compared with the most advanced monoclonal antibody CD73 inhibitor in clinical development, oleclumab.

CBO421 exhibits superior tumor spheroid penetration versus full length CD73-targeting antibodies (oleclumab biosimilar):



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. 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 or those undergoing blood and marrow transplantation 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*. Despite advances achieved in the diagnosis and treatment of candidemia, these infections continue to cause high mortality rates. The current treatment alternatives for systemic fungal infections, including polyenes, azoles and older echinocandins, have limitations that we believe may be addressed. 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.

Rezafungin for the Treatment and Prevention of Serious Fungal Infections

Due to its novel chemical structure, rezafungin has a prolonged half-life, a high maximum plasma concentration and a high area under the plasma concentration-time curve. 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 designed to overcome the limitations of the echinocandin class and other antifungals by offering the following key benefits:

- Potential to treat resistant pathogens.
- Single-agent treatment.
- Shorter and less costly hospital stays, and lower outpatient costs.
- Improved compliance.
- Enabling or improving prophylaxis regimens.

In the U.S., the FDA has granted rezafungin designations as a 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. In March 2023, the FDA approved REZZAYO for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options.

In the EU, the European Commission has granted rezafungin Orphan Drug Designation for the treatment of invasive candidiasis. The Orphan Drug Designation provides 10 years of market exclusivity protection from similar medicines with similar indications upon approval of the marketing authorization, and 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. In December 2023, the EMA granted approval for REZZAYO in the EU for the treatment of invasive candidiasis in adults.

LICENSE AND COLLABORATION AGREEMENTS

Mundipharma Collaboration Agreement

On September 3, 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.

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.

As part of a recent prioritization of its R&D business, in July 2023 Janssen disclosed its intention to discontinue internal development of multiple product candidates in its infectious disease pipeline, including CD388. However, in September 2023 Janssen delivered its Election to Proceed Notice for CD388 whereby Janssen will assume the future development, manufacturing and commercialization activities of CD388 but intends to transfer its rights and obligations under the Janssen Collaboration Agreement to another transferee. We continue to work in collaboration with Janssen to complete the Phase 1 and Phase 2a clinical trials and will be reimbursed for all ongoing development activities by Janssen as per the Janssen Collaboration Agreement.

Following Janssen's Election to Proceed Notice, Janssen, or any third-party transferee, is obligated at its sole expense to diligently continue development and commercialization either itself or through the transferee to whom it sublicenses or assigns the rights. If Janssen sublicenses or assigns the rights to a transferee, then all terms under the current Janssen Collaboration Agreement will survive without modification.

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 were entitled to reimbursement by Janssen of up to $58.2 million in research and development costs incurred in conducting Research Plan activities. We were also 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 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 is 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 sNDA 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 CMC 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 the rezafungin IND and NDA. Both regulatory applications will transfer to Melinta on a transfer date determined based on the status of the ReSPECT trial and the associated sNDA 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 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.

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, CBO421, 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, CBO421, and other product candidates and technology in the U.S. and abroad. As of April 22, 2024, 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 CBO421.

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 CBO421, 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. In March 2023, the FDA approved REZZAYO for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options. 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. In December 2023, the EMA approved REZZAYO in the EU for the treatment of invasive candidiasis in adults.

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 ibrexafungerp, 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 CBO421 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 SAEs 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 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. 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. Even if coverage is obtained for a given product, the resulting reimbursement payment rates may change. 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 2032 unless additional Congressional action is taken. 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 take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs,

promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. 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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs.

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 April 12, 2024, we had 69 total employees, 21 of whom hold Ph.D. or M.D. degrees, 51 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 Our Financial Position and Need for Additional Capital

We need substantial additional funding to complete the development of rezafungin and to advance CD388, CBO421 and our other Cloudbreak programs.

In connection with the preparation of our financial statements for the period ended December 31, 2023, 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, which raises substantial doubt about our ability to continue as a going concern. 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, CBO421 and other product candidates from our other Cloudbreak programs is also dependent on our ability to obtain additional funding.

On September 3, 2019, we entered into a Collaboration and License Agreement, or the Mundipharma Collaboration Agreement, with Mundipharma Medical Company, or Mundipharma, pursuant to which we granted Mundipharma exclusive commercialization rights to rezafungin outside the United States, or 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 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, to develop and commercialize our Cloudbreak drug-Fc conjugates, or 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 $44.5 million as of December 31, 2023. On July 26, 2022, we entered into a License Agreement, or the Melinta License Agreement, with Melinta Therapeutics, LLC, or Melinta, 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 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, CBO421 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, 2023, we had cash and cash equivalents of $35.8 million.

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 and cash equivalents due to market conditions such as recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures, which could have a material adverse effect on our business and financial condition. In addition, if the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could negatively affect our financial condition and our ability to pursue our business strategy.

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, CBO421 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, 2023, we have issued 20,769,854 shares of common stock pursuant to the Sales Agreement with an aggregate offering price of approximately $41.1 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 underwritten 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. We had net loss of $22.9 million and $33.6 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $441.4 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 CBO421. 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 investigational new drug applications, or INDs, to the U.S. Food and Drug Administration, or 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, CBO421 and other product candidates;
- establish or contract for a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;
- maintain, expand and enforce our intellectual property portfolio;
- hire additional manufacturing, clinical, regulatory, quality assurance and scientific personnel;
- add operational, financial and management systems and personnel, including personnel to support product development; and
- acquire or in-license other product candidates and technologies.

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

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the recent global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. This is particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

The 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 Israel-Hamas war and the conflict between Russia and Ukraine could lead to disruption, instability and volatility in global markets and industries that could negatively impact our operations. For example, in connection with the conflict between Russia and Ukraine, 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 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, one of the continued listing requirements for The Nasdaq Capital Market is a minimum bid price of at least $1.00 per share, or the Minimum Bid Price Requirement. We were first notified by the Listing Qualification Staff of the Nasdaq Stock Market LLC, or Nasdaq, on February 28, 2022, that our common stock had failed to maintain the Minimum Bid Price Requirement 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. On November 9, 2023, we were notified by Nasdaq that our common stock had once again failed to maintain the Minimum Bid Price Requirement for the 30 consecutive business days preceding November 6, 2023. On November 17, 2023, Nasdaq granted us a hearing date with the Nasdaq Hearings

Panel on February 1, 2024. The hearing was conducted on February 1, 2024, and on February 8, 2024, the Nasdaq Hearings Panel granted our request for continued listing on The Nasdaq Capital Market, pursuant to an extension, through May 7, 2024, to regain compliance with the Minimum Bid Price Requirement. The extension is subject to certain specified conditions and our submission of certain interim updates to the Nasdaq Hearings Panel. If it were to occur, the delisting of our common stock from trading on Nasdaq could 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 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 approval in U.S. and Europe but are continuing to conduct the ReSTORE China trial 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 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 NDA, 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, CBO421 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 European marketing approval for rezafungin and any marketing approval for 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, CBO421 and any other product candidates we may develop will depend on many factors, including the following:

- our ability to secure adequate additional funding;
- agreement with regulatory authorities on study 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 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.

The COVID-19 global pandemic significantly impacted our ability to activate sites and enroll patients in the ReSPECT trial, resulting in substantial delays and increases in the cost of completing the trial.

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. 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. For example, in the ReSPECT trial, a blinded interim analysis is planned in the first quarter of 2024 which will inform the current fungal free survival rates, or FFS. The FFS will determine if the 462 patients planned to be enrolled will be sufficient to power the trial to maintain non-inferiority. If the number of patients planned to be enrolled are not sufficient, the trial may need to enroll more patients which may potentially impact the overall timing to top-line data and increase trial costs. The study is currently enrolling in the EU, Canada and the U.S.

If clinical trials for rezafungin, CD388, CBO421 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 was severely impacted by the effects of COVID-19. 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 or Phase 2a trials of CD388 will be completed on schedule. We may experience numerous unforeseen events that could delay or prevent our ability to commence or complete our clinical trials, which could then delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

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

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. 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 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.

Any of our product candidates that receive marketing approval 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.

Any of our product candidates that receive marketing approval 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. In addition, if we enter into agreements with third parties to sell and market our product candidates, such third parties may not be successful in commercializing our products.

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.

If we do establish relationships with third parties to sell and market our product candidates, such third parties may not be successful in commercializing those products. For example, in the U.S. we are entirely dependent on Melinta to commercialize rezafungin. While Melinta has significant experience in commercialization of anti-infective drugs, they have limited experience with commercialization of antifungal drugs and may be unable to hire individuals with the requisite expertise or develop and execute an appropriate commercialization plan.

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 ibrexafungerp, 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 solid tumor cancers and viral infections. We are aware of a large number of approved and investigational therapies in these areas also. We expect that CBO421 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, CBO421, 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 face an even greater risk for our products that receive marketing approval. If we cannot successfully defend ourselves against claims that our product candidates and products 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 and various cancers. We have nominated the DFC CD388 as our lead development candidate for influenza, and we have nominated CBO421 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, 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 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 be unable to successfully commercialize rezafungin in one or more territories because, following regulatory approval, they may be unable to obtain formulary pricing approval, reimbursement approval, and/or formulary placement;
- have limited experience commercializing antifungal therapeutics and therefore may be unsuccessful in developing and implementing commercial launch plans for rezafungin;
- may terminate the Mundipharma Collaboration Agreement and the Melinta License Agreement at will;
- may be subject to changes in key personnel or strategic focus, have limited available funding or be subject to other external factors diverting resources or creates competing priorities, all of which could negatively impact the commercialization of rezafungin in 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 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. As part of a recent prioritization of its R&D business, in July 2023 Janssen disclosed its intention to discontinue internal development of multiple product candidates in its infectious disease pipeline, including CD388. However, in September 2023 Janssen delivered its Election to Proceed Notice for CD388 whereby Janssen will assume the future development, manufacturing and commercialization activities of CD388 but intends to transfer its rights and obligations under the Janssen Collaboration Agreement to another transferee.

Following Janssen's Election to Proceed Notice, Janssen, or any third-party transferee, is obligated at its sole expense to diligently continue development and commercialization either itself or through the transferee to whom it sublicenses or assigns the rights. If Janssen sublicenses or assigns the rights to a transferee, then all terms under the current Janssen Collaboration Agreement will survive without modification. However, there is no guarantee that Janssen will execute an agreement with a transferee and may ultimately decide to terminate the Janssen Collaboration Agreement. Additionally, our ability to receive payments from this arrangement will depend in part on Janssen's, or any third-party transferee'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 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, chemistry, manufacturing and controls, or 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.

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, 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 manufacturers and suppliers are located in China. Trade tensions and conflict between the United States and China have been escalating in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations, and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements, or proposed legislation by the U.S. Government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. Such disruption could have adverse effects on the development of our product candidates and our business operations. In addition, the recently proposed BIOSECURE Act introduced in House of Representatives, as well as a substantially similar bill in the Senate, targets certain Chinese biotechnology companies. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to contract with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government.

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 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 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. We 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.

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 created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal anti-kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, also 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 those of third parties upon which we rely, or our data 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, process) personal data and other sensitive information, including 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 data). As a result, we and the third parties upon which we rely face a variety of evolving threats that 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 and 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 evolving threats, including but not limited to, social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, 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, attacks enhanced or facilitated by artificial intelligence, or AI, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to provide our products or services, 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 or past 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 take steps designed to detect, mitigate and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure 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, such as 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; diversion of management attention; 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 data 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. Additionally, sensitive data of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employee's, personnel's, or vendor's use of generative artificial intelligence, or AI, technologies.

We are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, 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 (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we process sensitive data, and as a result, our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the U.S., 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.

In the past few years, at least ten U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, or CPRA, collectively CCPA, applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these states, like the CCPA, may also exempt some data processed in the context of clinical trials, 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 U.S., an increasing number of laws, regulations, and industry standards may govern data 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.

For example, under GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 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.

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. In Canada, the Personal Information Protection and Electronic Documents Act, or PIPEDA, and various related provincial laws, as well as Canada's Anti-Spam Legislation, or CASL, may apply to our operations.

In addition, we may be unable to transfer personal data from Europe, China, and other jurisdictions to the U.S. 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 U.S. and other countries whose privacy laws it generally 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 U.S. in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), 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 U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the U.S., 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 (such as Europe) 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 U.S., 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.

Our employees and personnel may use generative AI technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Any use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

We use AI and machine learning, or ML, to assist us in making certain decisions, which is regulated by certain privacy laws. Due to inaccuracies or flaws in the inputs, outputs, or logic of the AI/ML, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits.

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 (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating 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) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. 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; interruptions or stoppages in our business operations (including, as relevant, clinical trials); 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, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or 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 2032 unless additional Congressional action is taken. Additionally, in January 2013, the President signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. 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 take effect progressively starting in fiscal year 2023. Under the new Drug Price Negotiation Program, the number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The number of drugs with negotiated prices available will accumulate over time. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. The IRA permits HHS to implement many of the statutory provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs. 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, CBO421, 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 federal Anti-Kickback Statute and Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the use and dissemination of information classified for national security purposes and the exportation of certain products and technical data.

Any changes in applicable laws and regulations could restrict our ability to obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our results of operations.

Risks Related to Employee Matters and Managing Growth

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

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

Recruiting and retaining qualified scientific, clinical, manufacturing, regulatory, quality assurance and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisers, including scientific, regulatory, quality assurance and clinical advisers, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisers may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

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

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

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

Risks Related to Ownership of our Common Stock

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

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

- changes in the market valuations of similar companies;
- the commencement, timing, enrollment or results of the current and planned clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter, "complete response" letter, or a request for additional information;

- adverse results, suspensions, terminations or delays in pre-clinical or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial or development program;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to requirements for approvals;
- changes in the structure of healthcare payment systems or limitations on the ability of hospitals and outpatient treatment centers to receive adequate reimbursement for the purchase and use of our products;
- adverse developments concerning our contract manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices or acceptable quality;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates successfully, or at all;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- the introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, government grants or contracts or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our fungal infection, bacterial infection or other target markets;
- our ability to successfully enter new markets or develop additional product candidates;
- actual or anticipated variations in quarterly operating results;
- our cash position and our ability to raise additional capital and the manner and terms on which we raise it, and the expectation of future fundraising activities by us;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports or other media coverage about us or our industry or our therapeutic approaches in particular or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future or the expectation of such sales;
- the trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patent rights, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions including the military conflict in Ukraine and Russia, the Israel-Hamas war 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 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.

The restatement of our consolidated financial statements has subjected us to a number of additional risks and uncertainties, including increased possibility of legal proceedings.

As discussed elsewhere in this Annual Report on Form 10-K, on April 11 and April 15, 2024, the Audit Committee determined, based on management's recommendation, that our Prior Financial Statements filed with the SEC should no longer be relied upon and should be restated. We have restated the Prior Financial Statements in this Annual Report on Form 10-K. The restatement of the Prior Financial Statements has caused us to incur additional expenses for legal, accounting, and other professional services and has diverted our management's attention from our business and could continue to do so. In addition, as a result of the restatement, investors may lose confidence in our financial reporting, the price of our common stock could decline, and we may be subject to litigation or regulatory enforcement actions.

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 December 31, 2023, we determined that we had a material weakness as of December 31, 2023 and in prior periods because our control over the evaluation of applicable indirect taxes in local jurisdictions and assessment of indirect tax accrued liabilities was not appropriately designed, and as a result a material misstatement in the Prior Financial Statements was not 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.

We are in the process of implementing a remediation plan, which includes additional training of existing staff, enhanced use of indirect tax consultants and experts, and designing controls over the completeness and accuracy of the supporting evidence related to indirect tax liabilities. The remediation actions are being monitored by the Audit Committee. 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. Any additional undetected material weaknesses in our internal controls could lead to further 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.

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.

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 90,601,999 shares of common stock outstanding as of December 31, 2023. 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, 2023, we had U.S. federal net operating loss carryforwards of approximately $153.8 million, 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 U.S., 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 U.S., 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 U.S. and over 15 years for research activities conducted outside the U.S. 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 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 1C. Cybersecurity.

Risk management and strategy

We recognize the importance of maintaining the trust and confidence of its customers, clients, business partners and employees. Cybersecurity represents an important component of our overall approach to risk management. We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical trials, employees and contractors, or Information Systems and Data.

The Incident Response Team, or the IRT, is a functional and collaborative team consisting of the Chief Legal and Operating Officer, Chief Financial and Business Officer, Senior Vice President, People and Culture, and Director, Information Technology, or IT. The IRT, together with the wider IT, Legal, and Finance teams, as well as external cybersecurity consultants, help identify, assess, and manage our cybersecurity threats and risks.

The Director, IT plays a pivotal role in our cybersecurity framework, actively identifying and assessing risks from cybersecurity threats. This is achieved through a variety of methods, including but not limited to, extensive audits, detailed assessments, and the engagement of outside cybersecurity consultants. In addition to these existing strategies, we have implemented several processes to increase our ability to identify, monitor, and assess material cybersecurity threats.

We subscribe to specialized reports and services that identify emerging cybersecurity threats, thereby keeping our defenses informed and up-to-date. The IT department systematically analyzes such reports of threats and actors, providing us with a deeper understanding of potential risks. We also conduct regular scans of the threat environment, providing real-time insights into the security landscape.

Evaluating our own and our industry's risk profile is an ongoing process, allowing us to continually tailor our cybersecurity measures to specific needs and vulnerabilities. We also coordinate with law enforcement agencies concerning threats, so that our approach benefits from broader insights and intelligence.

Conducting detailed threat assessments for both internal and external threats form a crucial part of our security strategy. Additionally, we leverage external intelligence feeds, integrating diverse sources of information to strengthen our overall cybersecurity posture. These concerted efforts are designed to achieve a comprehensive, dynamic, and proactive approach to managing and mitigating cybersecurity risks.

Our approach to cybersecurity is tailored to suit the specific environment in which we operate. We implement and maintain an array of technical, physical, and organizational measures, processes, standards, and policies, designed to manage and mitigate material risks arising from cybersecurity threats to our Information Systems and Data. This includes a comprehensive strategy featuring a dedicated cybersecurity staff and a regularly tested IT Security Incident Response Plan. Regular risk assessments, tabletop exercises, threat modeling, and vulnerability testing form the backbone of our technical measures.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. This is exemplified in the way our IT Security Incident Response Plan forms an integral part of the broader risk management framework, so that cybersecurity risks are visible and treated as strategic business risks.

Detailing the integration of cyber risk into our risk management, cybersecurity risk is addressed as a crucial component of our enterprise risk management program. The IT department works in close collaboration with executive management to prioritize risk management processes, with a particular focus on mitigating cybersecurity threats that could have a significant impact on our business. Furthermore, team members from the IT department or a relevant executive committee evaluate material risks from cybersecurity threats in alignment with our overall business objectives. These evaluations are then communicated to the audit committee of the board of directors. The audit committee assesses these risks as part of our overall enterprise risk, ensuring that cybersecurity is given due consideration in line with our strategic goals and governance framework.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example assessors, cybersecurity consultants, auditors, and outside legal counsel.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers and supply chain resources. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. The program includes a risk assessment for each vendor, vulnerability scans related to the vendor, and imposition of information contractual obligations on the vendor. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K.

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The board of directors' and the IRT are responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain members of management, including the Director, IT, Chief Legal and Operating Officer, and Chief Financial and Business Officer. The Chief Legal and Operating Officer and Chief Financial and Business Officer are responsible for providing information on materiality to the Director, IT and producing documentation of known and unknown facts about a cybersecurity incident and factors considered in the materiality assessment. Our Chief Legal and Operating Officer and Chief Financial and Business Officer hold degrees relevant to their areas of expertise and both have over 20 years of experience in their respective fields. The Director, IT is primarily responsible for assessing and managing material risks from cybersecurity threats; they have 23 years of experience in core infrastructure, data infrastructure and analytics, business platforms, and integrations.

The Director, IT is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, and communicating key priorities to relevant personnel. The Director, IT is also responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our IT Security Incident Response Plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including the IRT. The IRT works with the IT department and external cybersecurity experts to help us mitigate and remediate cybersecurity incidents. In addition, our IT Security Incident Response Plan includes reporting to the board of directors for certain cybersecurity incidents.

The audit committee receives quarterly updates from the IRT concerning our cybersecurity threats and risk and the processes we have implemented to address them. On an annual basis the board of directors receives a report from the IRT highlighting any significant cybersecurity threats.

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 2026, 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 April 12, 2024, 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 developing targeted therapies designed to save lives and improve the standard of care for patients facing serious diseases.

Our first commercially approved product in the United States, or U.S., is REZZAYO® (rezafungin for injection) which is indicated for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options. On July 31, 2023, Melinta Therapeutics, LLC, or Melinta, our commercial partner in the U.S., initiated the commercial launch of REZZAYO in the U.S. On October 2, 2023, Melinta announced receipt from the Centers for Medicare & Medicaid Services, or CMS, of both a product-specific J-Code and a new technology add-on payment, or NTAP, for REZZAYO. Outside the U.S. and Japan, our development and commercial partner for REZZAYO is Mundipharma Medical Company, or Mundipharma. In December 2023, the European Medicines Agency, or EMA, granted approval for REZZAYO in the European Union, or EU, for the treatment of invasive candidiasis in adults. In January 2024, the United Kingdom, or UK, Medicines and Healthcare products Regulatory Agency, or MHRA, granted approval for REZZAYO for the treatment of invasive candidiasis in adults.

Although we have shifted our primary research focus to our proprietary Cloudbreak® platform, we continue to execute on the ongoing ReSPECT Phase 3 pivotal clinical trial for the prevention of invasive fungal infections in adult allogeneic blood and marrow transplant recipients. A significant portion of our future royalties and milestones to be received under both Melinta and Mundipharma licensing agreements are tied to the successful completion of the ReSPECT Phase 3 trial.

Our proprietary Cloudbreak platform enables development of novel drug-Fc conjugates, or DFCs, that inhibit specific disease targets while simultaneously engaging the immune system. Our most advanced DFC program is CD388, a highly potent 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 multiple oncology and autoimmune indications.

Cloudbreak Platform

We believe our Cloudbreak platform has the potential to offer a fundamentally new approach to treat and prevent serious diseases such as solid tumor cancers and viral infections, 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 and 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, including antibody drug conjugates, or ADCs, monoclonal or multispecific 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 to serve as a "drug cocktail" in a single molecule, which may improve response to treatment and prevention; and
- Potential advantages over vaccines irrespective of the immune status of patients.

DFCs are fundamentally different from ADCs: DFCs are biologically stable drug-Fc conjugates designed to engage extracellular targets, while ADCs are designed to enter target cells to deliver and release cytotoxic small molecule drugs. In contrast to ADCs and monoclonal antibodies, DFCs are smaller, providing 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 candidate for the prevention of influenza is CD388, a DFC in Phase 1 and Phase 2a clinical trials. Our lead oncology DFC is CBO421, a development candidate targeting CD73 for the treatment of solid tumors, which is in investigational new drug application, or IND, -enabling studies.

Cloudbreak Influenza Program

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. Enrollment of all six planned cohorts has been completed. In addition, a separate Phase 1 Japanese bridging study (NCT05619536) has been initiated and enrollment has been completed.

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. Enrollment has now been completed.

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.

In June 2023, the U.S. Food and Drug Administration, or FDA, granted Fast Track designation to CD388 for the prevention of influenza A and B infection in adults who are at high risk of influenza complications due to underlying immunodeficiency and may not mount an adequate response to influenza vaccine or are at high risk of severe influenza despite influenza vaccination, including those for whom vaccines are contraindicated. Fast Track designation aims to facilitate the development and expedite the review of drugs to treat serious conditions with unmet medical needs. The purpose is to get important new drugs to patients earlier. Companies that are granted this designation are given the opportunity for more frequent interactions with the FDA, and, if relevant criteria are met, eligibility for Priority Review.

Final CD388 Phase 2a Results

In our recent R&D Day, on September 21, 2023, we announced efficacy and safety data from our Phase 1 and Phase 2a trials evaluating the pre-exposure prophylactic activity of CD388 against an H3N2 influenza A virus strain.

CD388 was well-tolerated up to 900 milligrams, or mg:

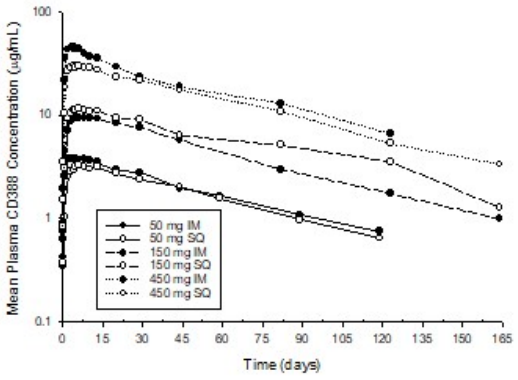
Number of participants that received one dose of CD388 in Phase 1 and Phase 2a trials

	First in Human Study (Phase 1)	Japanese Bridging Study (Phase 1)	Human Challenge Study (Phase 2a)	Total
50 mg	18	7	2	**27**
150 mg	18	7	28	**53**
450 mg	18	7	—	**25**
900 mg	9	—	—	**9**
All Doses[1]	**63**	**21**	**30**	**114**

[1] Safety Summary:

- No treatment-emergent serious adverse events, or SAEs, and no discontinuation of study drug or withdrawals due to safety findings.
- No consistent adverse event, or AE, patterns.
- No hypersensitivity reactions.
- Most treatment-emergent adverse events, or TEAEs, were Grade 1 (90%), few Grade 2, all resolved.
- Incidence of TEAE not dose-dependent.
- Few injection site events (pain, intramuscular, or IM, route mainly), Grade 1, all resolved spontaneously.
- No clinically relevant electrocardiogram, or ECG, vital signs or physical exam abnormalities.

CD388 pharmacokinetics, or PK, profile is that of a long-acting compound, potentially enabling seasonal pre-exposure prophylaxis, or PrEP:



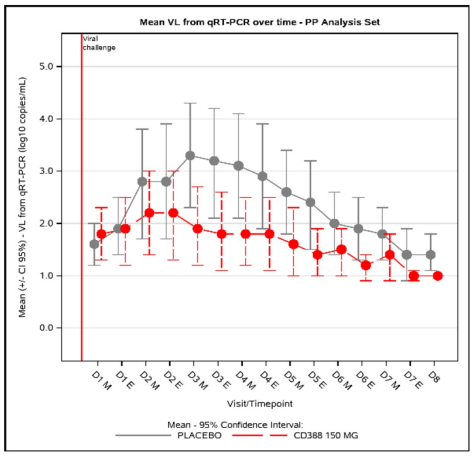
CD388 demonstrates prophylactic reduction of viral replication in the upper respiratory tract, or URT, and the incidence of PCR-confirmed influenza infection:

The Phase 2a prophylactic efficacy results are 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.

	Placebo (n=28)	CD388 150 mg (n=28)	P-value[2]
Quantitative reverse transcriptase polymerase chain reaction, or qRT-PCR, confirmed influenza infection ("attack rate" see Placebo data)	14 (50%)	6 (21%)	0.0248
qRT-PCR confirmed symptomatic influenza infection	9 (32%)	4 (14%)	0.1023
qRT-PCR confirmed moderately to severe symptomatic influenza infection	7 (25%)	3 (11%)	0.1477

[2] Statistical significance was pre-determined using a Wilcoxon rank-sum test with a one-sided type-1 error rate of 0.025.

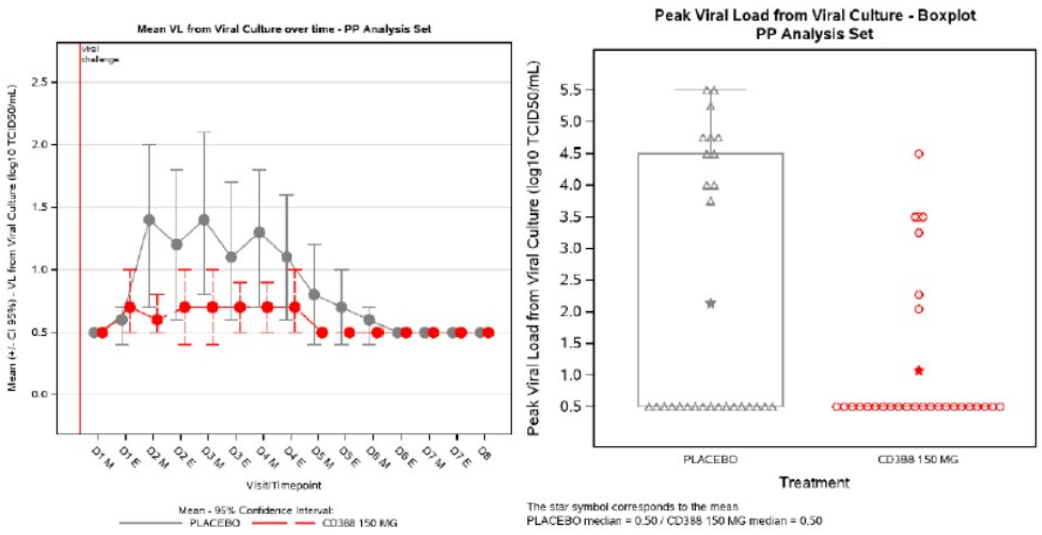
Primary endpoint: AUC viral load-time_ qRT-PCR



Statistical significance was pre-determined using a Wilcoxon rank-sum test with a one-sided type-1 error rate of 0.025

As shown above, despite the small sample size in this analysis, a decrease in viral replication in the URT 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 SAEs were reported in the analysis. All participants included in the analysis received either CD388 or placebo and were then challenged with influenza five days later.

Viral culture data confirmed efficacy seen in early analyses:



Janssen Collaboration Agreement

On March 31, 2021, we 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, 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, or CMC, 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. As part of a recent prioritization of its R&D business, in July 2023 Janssen disclosed its intention to discontinue internal development of multiple product candidates in its infectious disease pipeline, including CD388. However, in September 2023 Janssen delivered its Election to Proceed Notice for CD388 whereby Janssen will assume the future development, manufacturing and commercialization activities of CD388 but intends to transfer its rights and obligations under the Janssen Collaboration Agreement to another transferee. We continue to work in collaboration with Janssen to complete the Phase 1 and Phase 2a clinical trials and will be reimbursed for all ongoing development activities by Janssen as per the Janssen Collaboration Agreement.

Following Janssen's Election to Proceed Notice, Janssen, or any third-party transferee, is obligated at its sole expense to diligently continue development and commercialization either itself or through the transferee to whom it sublicenses or assigns the rights. If Janssen sublicenses or assigns the rights to a transferee, then all terms under the current Janssen Collaboration Agreement will survive without modification.

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 were 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, 2023, we have received the $27.0 million up-front payment, $44.5 million in research and development reimbursements, and $10.0 million in milestone payments.

We are eligible to receive up to an additional $230.0 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 whether to proceed with clinical development and initiation of Phase 2b and Phase 3 trials. 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.

Cloudbreak Oncology Programs

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

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.

Cloudbreak Oncology seeks to develop a new generation of immunotherapies targeting the tumor microenvironment. Our lead oncology DFC candidate, CBO421, is a potential best-in-class CD73 inhibitor that combines the strengths of small molecules and monoclonal antibodies targeting CD73. CBO421 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. The CD73 pathway is clinically validated in early/mid-stage clinical studies to reduce tumor growth in combination with PD-1/ PD-L1 inhibitors in disease areas that do not historically respond to checkpoint inhibition alone, such as advanced colorectal cancer, or CRC, and non-small cell lung cancer, or NSCLC. As a monotherapy and in combination with PD-1 inhibitors, CBO421 has demonstrated formation of immunologic memory in multiple murine tumor models, along with potential best-in-class activity in T-cell reactivation assays and tumor penetration compared with the most advanced CD73 antibody therapeutics in clinical development. We are currently advancing CBO421 through IND-enabling studies and expect to file an IND in mid-2024.

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

CBO421 demonstrates outstanding preclinical performance:

Potential Best-in-Class Activity

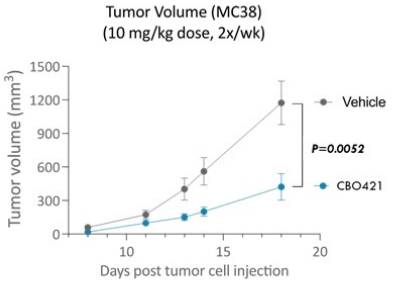
PBMC rescue assay (ATP) vs clinical stage adenosine pathway inhibitors

Test article	Target/Class	EC_{50} [nM]	
		$CD4^+CD25^+$	$CD8^+CD25^+$
CBO421	**CD73/DFC**	**13**	**51**
AB680*	CD73/small molecule	39	73
Oleclumab	CD73/mAb	>1,000	>1,000
IPH5201	CD39/mAb	>1,000	>1,000
AB928	A2AR/small molecule	>1,000	>1,000
CPI-444	A2AR/small molecule	>1,000	>1,000

AB680 – Arcus Biosciences CD73 inhibitor
Oleclumab – Astra Zeneca biosimilar CD73 inhibitor
IPH5201 – Innate Pharma biosimilar CD39 inhibitor
AB928 – Arcus Biosciences A2AR inhibitor
CPI-444 – Corvus A2AR inhibitor

Potent Tumor Activity

MC38 – murine colorectal carcinoma



CBO421 enhances anti-tumor activity of PD-1 inhibitors:

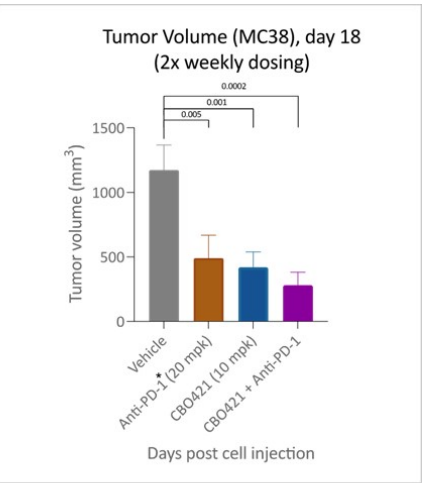
CBO421 and Anti-PD-1 combination improves response rates versus monotherapies.

MC38 – murine colorectal carcinoma

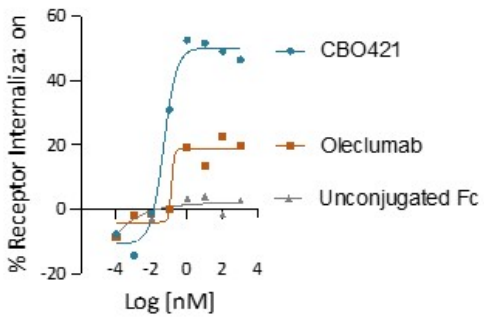
Study Arm	% Responders*
Vehicle	0
CBO421	27
Anti-PD-1	47
CBO421 + Anti-PD-1	60

*Defined as mice that demonstrate cessation of tumor growth or reduction in tumor volume across two or more timepoints

*RMP1-14



CBO421 exhibits a second mechanism of action that differentiates it from small molecule CD73 inhibitors:



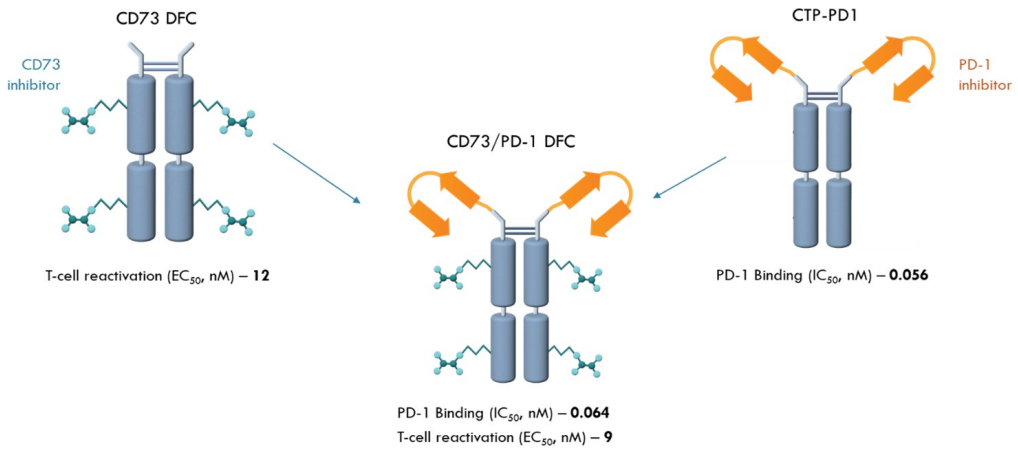
CD73 Internalization in MDA-MB-231 Cells

Test article	Target/Class	Maximum % internalization	EC_{50} [nM]
CBO421	CD73/DFC	50	0.049
AB680*	CD73/small molecule	0*	NA
Oleclumab*	CD73/mAb	18	0.13

*AB680 – Arcus Biosciences CD73 inhibitor, internalization data not shown
Oleclumab – Astra Zeneca biosimilar CD73 inhibitor

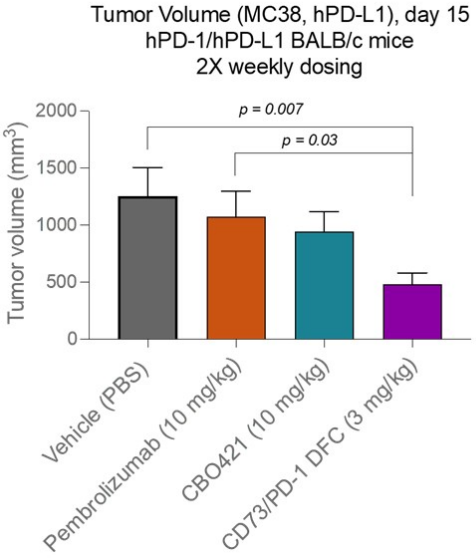
CBO421 demonstrates best in class CD73 downregulation via internalization, which is not achievable with small molecule CD73 inhibitors

CD73/PD-1 DFC potently inhibits both PD-1 and CD73 receptors:



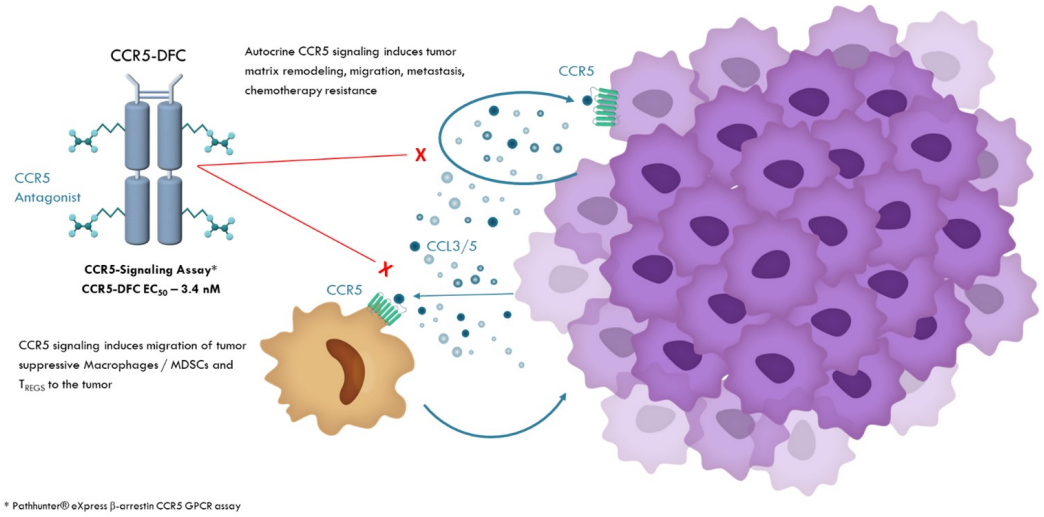
Enhancement of activity in preclinical models observed when CBO421 was combined with PD-1 inhibition inspired the development of a first in class multispecific CD73/PD-1 targeting DFC that potently inhibits both targets simultaneously. Emerging preclinical data is promising. The multispecific DFC retains the full activity of the monotherapy components in functional binding and activity assays. In a murine colorectal carcinoma efficacy model, the multispecific DFC exhibited superior activity compared with CBO421 and the marketed PD-1 inhibitor, pembrolizumab, validating the concept. Optimization and preclinical development of our CD73/PD-1 targeting DFCs is ongoing.

CD73/PD-1 DFC outperforms monotherapies in humanized tumor models:



CCRs are a historically difficult-to-drug receptor family:

The DFC platform is also being expanded to include a validated, but difficult class of targets to drug, the chemokine receptors, or CCRs. CCR5 is a validated oncology target that can be a major driver in cancers that rely on the CCL5/CCR5 signaling pathway (e.g., breast, pancreatic and renal cell carcinomas). In several cancers, tumors secrete chemokine CCR5 agonists that promote tumor growth, metastasis and chemoresistance, while simultaneously recruiting immuno-suppressive macrophages and myeloid derived suppressor cells, or MDSCs, to the tumor microenvironment. We have rapidly been able to advance highly potent lead DFC CCR5-antagonist drug candidates that demonstrate robust activity as monotherapies in murine colorectal carcinoma models. Further optimization and preclinical characterization of our CCR5-DFC lead candidates including combination therapy studies, is ongoing.

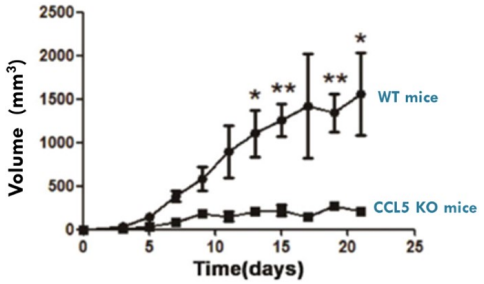


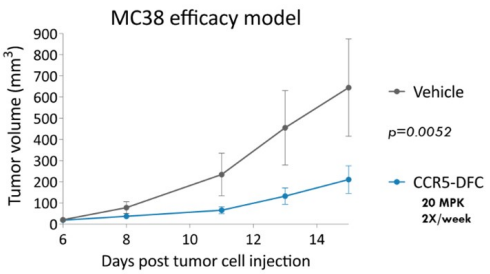
* Pathhunter® eXpress β-arrestin CCR5 GPCR assay

CCR5-DFC shows strong tumor control in preclinical model:

MC38 tumors are unable to proliferate in CCL5 KO mice (MC38 = murine colorectal carcinoma)

CCR5-DFC treatment accomplishes a similar degree of tumor reduction





Zhang et al. Cell Death and Disease (2018) 9:766 DOI 10.1038/s41419-018-0796-2

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.

FDA Approval of Rezafungin for the Treatment of Candidemia and Invasive Candidiasis

In March 2023, the FDA approved REZZAYO 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 15 years, and is the only available once-weekly echinocandin.

EMA and UK MHRA Approval of Rezafungin for the Treatment of Invasive Candidiasis in Adults

In December 2023, the EMA granted approval for REZZAYO in the EU for the treatment of invasive candidiasis in adults. In January 2024, the UK MHRA granted approval for REZZAYO for the treatment of invasive candidiasis in adults.

REZZAYO Commercialization in the U.S. by Melinta

On July 31, 2023, Melinta initiated the commercial launch of REZZAYO in the U.S.

ReSTORE Phase 3 clinical trial in China

In December 2023, enrollment in the ReSTORE Phase 3 trial in China, evaluating the efficacy and safety of rezafungin as a treatment for candidemia and invasive candidiasis, was completed. The portion of the trial conducted in China included 52 patients diagnosed with candidemia and/or invasive candidiasis. ReSTORE (NCT03667690) is a global, randomized, double-blind, controlled Phase 3 pivotal clinical trial evaluating the efficacy and safety of once-weekly intravenous dosing of rezafungin compared to once-daily dosing of caspofungin, the current standard of care, to treat patients with candidemia and/or invasive candidiasis. Data from this study are expected in the second quarter of 2024.

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. A blinded interim analysis is planned in the second quarter of 2024 which will inform the current fungal free survival rates, or FFS. The FFS will determine if the 462 patients planned to be enrolled will be sufficient to power the trial to detect non-inferiority. The study is currently enrolling in the EU, Canada and the U.S.

Melinta License Agreement

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

Melinta is 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 new drug application, or NDA. Both regulatory applications will transfer to Melinta on a transfer date determined based on the status of the ReSPECT trial and the associated supplemental NDA, or sNDA, 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, 2023, we have received the $30.0 million up-front payment and a $20.0 million milestone 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 with Mundipharma, or the Mundipharma Collaboration Agreement, 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. We are also eligible to receive double-digit royalties in the teens on tiers of annual net sales.

As of December 31, 2023, 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). In December 2023, we achieved a milestone of $11.1 million under the Mundipharma Collaboration Agreement for which we have received payment in February 2024. In January 2024, we achieved a milestone of $2.8 million under the Mundipharma Collaboration Agreement for which we have received payment in April 2024.

Compliance with Nasdaq Listing Requirements

Our common stock is listed on The Nasdaq Capital Market, which has as one of its continued listing requirements a minimum bid price of at least $1.00 per share, or the Minimum Bid Price Requirement. On November 9, 2023, we received a notification letter, or the Notice, from the Listing Qualification Staff, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, advising us that for 30 consecutive trading days preceding November 6, 2023, the bid price of our common stock had closed below the Minimum Bid Price Requirement. As a result of the Nasdaq Hearings Panel, or the Panel, imposing the previously disclosed Panel Monitor on the Company until November 9, 2023 pursuant to the February 9, 2023 Hearings Decision of the Panel, the Company was not eligible for a compliance period and the Staff notified us that this matter served as a basis for delisting the Company's securities from The Nasdaq Capital Market.

On November 16, 2023, we requested a hearing before the Panel, which stayed any delisting action in connection with the Notice and allowed the continued listing of our common stock on The Nasdaq Capital Market until the Panel renders a decision subsequent to the hearing. On January 12, 2024, we submitted a pre-hearing submission in which we presented a plan to regain compliance with the Minimum Bid Price Requirement and request that the Panel allow us additional time within which to regain compliance.

The hearing was conducted on February 1, 2024, and on February 8, 2024, the Panel granted our request for continued listing on The Nasdaq Capital Market, pursuant to an extension, through May 7, 2024, to regain compliance with the Minimum Bid Price Requirement. The extension is subject to certain specified conditions and our submission of certain interim updates to the Panel.

Impact of Macroeconomic Conditions

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. We may be impacted by broader macroeconomic conditions, including global pandemics, high inflation, bank failures, labor shortages, supply chain disruptions, recession risks and potential disruptions from the ongoing Russia-Ukraine conflict and related sanctions and the Israel-Hamas war. For example, the closures of Silicon Valley Bank, Signature Bank and First Republic Bank resulted in broader financial institution liquidity risk and concerns in the past. While we did not have deposits with these banks, 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 and cash equivalents may be threatened, which 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.

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, 2023, we had an accumulated deficit of $441.4 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, 2023, 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 consolidated financial statements, which raises substantial doubt about our ability to continue as a going concern. 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 and commercial supply agreements 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 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.

Cost of Product Revenue

Cost of product revenue consists primarily of costs related to materials, third-party contract manufacturing, freight-in and overhead. Prior to regulatory approval, all direct and indirect manufacturing costs were charged to research and development expense in the period incurred.

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 in preclinical development and certain manufacturing expenses before FDA approval, nonclinical and clinical trial costs, and indirect taxes on clinical supplies and development materials. 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 consolidated statements of operations and comprehensive loss 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. 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,	
	2023	2022
		(As Restated)
Rezafungin	$ 24,591	$ 38,207
Cloudbreak platform	25,936	20,271
Personnel costs	15,746	16,705
Other research and development expenses	2,259	2,222
Total research and development expenses	$ 68,532	$ 77,405

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.

Selling, general and administrative expenses

Selling, general and administrative, or SG&A, expenses relate to selling, finance, human resources, legal and other administrative activities. SG&A 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 SG&A expenses include facility and overhead costs not otherwise included in cost of product revenue or research and development expenses, consultant expenses, travel expenses, professional fees for auditing, tax, legal, and other services, the branded prescription drug fee, and any accrued interest and penalties on accrued indirect tax liabilities.

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 accounts for cash and cash equivalents. Interest expense represents interest paid related to term loans, the amortization of debt issuance costs, and interest on finance lease liabilities.

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 *Accounting Standards Codification*, or ASC, 606, *Revenue from Contracts with Customers*, or ASC 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 ASC 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 ASC 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 ASC 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.

Collaboration Revenue

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.

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.

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.

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.

We 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, 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 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 and milestones achieved to date.

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 9 to the financial statements for additional information.

Preclinical and Clinical Trial Accruals

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known 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, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,		
	2023	2022	Change
		(As Restated)	
Collaboration revenue	$ 59,570	$ 64,448	$ (4,878)
Product revenue	4,335	—	4,335
Cost of product revenue	1,523	—	1,523
Research and development	68,532	77,405	(8,873)
Selling, general and administrative	18,333	20,546	(2,213)
Other income, net	1,995	191	1,804
Income tax expense	(443)	(272)	(171)

Collaboration revenue

Collaboration revenue was $59.6 million and $64.4 million for the years ended December 31, 2023 and 2022, respectively. Revenue for the year ended December 31, 2023 related to the achievement of milestones and ongoing research and development and clinical supply services provided to Mundipharma, Janssen and Melinta of $16.4 million, $23.3 million and $19.7 million, respectively, as well as $0.2 million in royalty revenue recognized following initiation of the commercial launch of REZZAYO in the U.S. on July 31, 2023.

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 related to the achievement of milestones and ongoing research and development and clinical supply services provided to Mundipharma, Janssen and Melinta of $14.3 million, $23.5 million and $0.8 million, respectively.

Product revenue

Product revenue was $4.3 million for the year ended December 31, 2023 and related to shipments of REZZAYO naked vials to Melinta and Mundipharma. REZZAYO received approval by the FDA and was launched commercially in the U.S. by Melinta on July 31, 2023. REZZAYO also received approval by the EMA in December 2023.

Cost of product revenue

Cost of product revenue was $1.5 million for the year ended December 31, 2023 and primarily consisted of direct material costs, third-party manufacturing costs and indirect overhead costs associated with the manufacture, quality assessment and delivery of REZZAYO naked vials shipped to Melinta and Mundipharma. Prior to regulatory approval, all direct and indirect manufacturing costs were charged to research and development expense in the period incurred.

Research and development expenses

Research and development expenses were $68.5 million for the year ended December 31, 2023 compared to $77.4 million for the year ended December 31, 2022. The decrease in research and development expenses is primarily due to lower clinical expenses associated with the rezafungin clinical trials and lower consulting and personnel costs, offset by higher clinical expenses associated with our Cloudbreak platform.

Selling, general and administrative expenses

SG&A expenses were $18.3 million for the year ended December 31, 2023 compared to $20.5 million for the year ended December 31, 2022. The decrease in SG&A expenses is primarily due to lower consulting, personnel and legal costs, and lower amortization of contract costs related to obtaining the Melinta License Agreement, offset by higher selling expenses related to REZZAYO.

Other income, net

Other income, net during the year ended December 31, 2023 related primarily to interest income generated from cash held in interest-bearing accounts, offset by interest expense on finance lease liabilities. Other income, net during the year ended December 31, 2022 related primarily to interest income generated from cash held in interest-bearing accounts, offset by interest expense in connection with our loan from Pacific Western Bank.

Income tax expense

Income tax expense for the years ended December 31, 2023 and 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 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 global pandemics, the ongoing Russia-Ukraine conflict and related sanctions, the Israel-Hamas war, and bank failures.

We are eligible to receive up to $470.3 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 $230.0 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 $410.0 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, 2023, the remaining capacity under the Sales Agreement was $37.1 million. We have not sold shares of our common stock under the Sales Agreement since July 2023.

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 approximately $19.5 million.

As of December 31, 2023, we have no outstanding loan balances.

Our lease with Nancy Ridge Technology Center, L.P. expires on December 31, 2026 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, 2023, 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 $5.0 million as of December 31, 2023.

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, or beyond. 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 pandemics, sanctions, or other macroeconomic events 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 SG&A support costs.

As of December 31, 2023, we had $35.8 million in cash and cash equivalents. The following table shows a summary of our cash flows for the years ended December 31, 2023 and 2022 (in thousands):

	Year ended December 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (22,432)	$ (28,473)
Investing activities	(505)	(118)
Financing activities	25,984	(951)
Net increase (decrease) in cash and cash equivalents	$ 3,047	$ (29,542)

Operating activities

Net cash used in operating activities was $22.4 million for the year ended December 31, 2023, compared to $28.5 million for the year ended December 31, 2022. Cash used in operating activities for the year ended December 31, 2023 was primarily attributable to a net loss of $22.9 million, and included $20.0 million for a milestone achieved in March 2023 under the Melinta License Agreement, which was received in April 2023, and $7.0 million for a milestone achieved in September 2023 under the Janssen Collaboration Agreement, which was received in September 2023.

Cash used in operating activities for the year ended December 31, 2022 was primarily attributable to a net loss of $33.6 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.

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, 2023 and 2022 consist of purchases of property and equipment.

Financing activities

Net cash provided by financing activities during the year ended December 31, 2023 consisted primarily of (i) net proceeds of $17.3 million from the sale of 11,086,000 shares of common stock and 286,000 shares of Series X Convertible Preferred Stock pursuant to concurrent but separate underwritten public offerings and (ii) net proceeds of $8.7 million from the sale of 6,231,741 shares of common stock under the Sales Agreement, after deducting placement agent fees.

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.

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, which raises substantial doubt about our ability to continue as a going concern. 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 Stockholders 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, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Restatement of 2022 Financial Statements

As discussed in Note 1 to the consolidated financial statements, the 2022 consolidated financial statements have been restated to correct misstatements.

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

Basis for Opinion

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

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

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

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) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of 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 separate opinions 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 the Matter

As more fully described in Note 9 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, uses 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 collaboration and license agreements.

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.

Accrued indirect tax liabilities

Description of the Matter

As discussed in Notes 1 and 2 to the consolidated financial statements, the Company's purchases of clinical drug supplies and raw materials, inventory transfers, and sales of commercial drug product are subject to accrued indirect tax liabilities in various jurisdictions outside of the United States. The Company evaluated the indirect taxation consequences upon the first commercial sale of REZZAYO in 2023 and determined that it has a liability for indirect taxation in various tax jurisdictions outside of the United States based on its supply chain activities in 2023 and prior years. As of December 31, 2023, the Company recorded $18.0 million of accrued indirect tax liabilities.

Auditing the Company's accrued indirect tax liabilities was challenging because the indirect tax liabilities was dependent upon an accumulation of a high volume of historical information related to the Company's supply chain and clinical supply activities and the application of various international indirect tax laws and regulations, which varied between countries.

How We Addressed the Matter in Our Audit

To test the accrued indirect tax liabilities, we performed audit procedures to test the completeness of the Company's accrued indirect tax liabilities that included, among other procedures, inspecting evidence of supply chain activities for clinical and commercial drug supplies. With the assistance of our indirect tax specialists, we also performed testing of management's determination of transactions subject to indirect taxes and the indirect tax rates applied to those transactions. In addition, we performed testing of the mathematical accuracy of the underlying computation of accrued indirect tax liabilities.

/s/ Ernst & Young LLP

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

San Diego, California

April 22, 2024

Consolidated Balance Sheets

(In thousands, except share and per share data)	December 31, 2023	December 31, 2022 (As Restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,778	$ 32,731
Accounts receivable	16,246	5,833
Inventory	6,097	—
Prepaid expenses and other current assets	2,734	6,530
Total current assets	60,855	45,094
Property and equipment, net	557	222
Finance lease right-of-use asset, net	782	—
Operating lease right-of-use asset	3,788	1,099
Other assets	1,048	1,072
Total assets	$ 67,030	$ 47,487
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 3,772	$ 1,447
Accrued liabilities	14,177	7,672
Accrued indirect tax liabilities	18,040	11,534
Accrued compensation and benefits	5,034	4,922
Current contract liabilities	25,095	14,614
Current portion of finance lease liability	218	—
Current portion of operating lease liability	1,082	1,211
Total current liabilities	67,418	41,400
Long-term contract liabilities	4,245	20,525
Long-term finance lease liability	575	—
Long-term operating lease liability	3,002	—
Total liabilities	75,240	61,925
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2023 and December 31, 2022:		
Series X Convertible Preferred stock, $0.0001 par value; 4,947,759 shares authorized at December 31, 2023 and 2022; 2,156,713 shares issued and 2,104,472 shares outstanding at December 31, 2023 and 1,870,713 shares issued and 1,818,472 shares outstanding at December 31, 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2023 and 2022; 90,601,999 shares issued and outstanding at December 31, 2023; 72,470,440 shares issued and outstanding at December 31, 2022	9	7
Additional paid-in capital	433,212	404,055
Accumulated deficit	(441,431)	(418,500)
Total stockholders' deficit	(8,210)	(14,438)
Total liabilities and stockholders' deficit	$ 67,030	$ 47,487

See accompanying notes.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)	Years ended December 31, 2023	2022 (As Restated)
Revenues:		
Collaboration revenue	$ 59,570	$ 64,448
Product revenue	4,335	—
Total revenues	63,905	64,448
Operating expenses:		
Cost of product revenue	1,523	—
Research and development	68,532	77,405
Selling, general and administrative	18,333	20,546
Total operating expenses	88,388	97,951
Loss from operations	(24,483)	(33,503)
Other income, net:		
Interest income, net	1,995	191
Total other income, net	1,995	191
Loss before income tax expense	(22,488)	(33,312)
Income tax expense	(443)	(272)
Net loss and comprehensive loss	(22,931)	(33,584)
Basic and diluted net loss per common share	$ (0.26)	$ (0.48)
Shares used to compute basic and diluted net loss per common share	87,427,439	69,857,698

See accompanying notes.

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

(In thousands, except share data)	Series X Convertible Preferred Stock		Common Stock		Additional Paid-In Capital (As Restated)	Accumulated Deficit (As Restated)	Total Stockholders' Equity (Deficit) (As Restated)
	Shares	Amount	Shares	Amount			
Balance, December 31, 2021 (As Restated)	1,818,472	$ —	67,863,674	$ 7	$ 398,013	$ (384,916)	$ 13,104
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 (As Restated)	—	—	—	—	—	—	—
Net loss (As Restated)	—	—	—	—	—	(33,584)	(33,584)
Balance, December 31, 2022 (As Restated)	1,818,472	—	72,470,440	7	404,055	(418,500)	(14,438)
Underwritten public offering, net of issuance costs	286,000	—	11,086,000	1	17,255	—	17,256
Public offering of common stock, net of issuance costs	—	—	6,219,741	1	8,698	—	8,699
Issuance of common stock for exercise of stock options	—	—	25,750	—	21	—	21
Issuance of common stock for restricted share units vested	—	—	490,520	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	309,548	—	122	—	122
Stock-based compensation	—	—	—	—	3,061	—	3,061
Net loss	—	—	—	—	—	(22,931)	(22,931)
Balance, December 31, 2023	2,104,472	$ —	90,601,999	$ 9	$ 433,212	$ (441,431)	$ (8,210)

See accompanying notes.

Consolidated Statements of Cash Flows

(In thousands)	Years ended December 31, 2023	2022 (As Restated)
Operating activities:		
Net loss	$ (22,931)	$ (33,584)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,061	3,532
Non-cash operating lease expense	1,158	981
Depreciation and amortization	112	143
Amortization of costs to obtain a contract with a customer	77	—
Amortization of finance lease right-of-use asset	6	—
Non-cash interest expense	5	1
Changes in assets and liabilities:		
Accounts receivable	(10,413)	(477)
Inventory	(6,097)	—
Prepaid expenses, other current assets, and other assets	3,735	(2,440)
Accounts payable and accrued liabilities	8,886	(2,371)
Accrued indirect tax liabilities	6,506	3,945
Accrued compensation and benefits	235	203
Contract liabilities	(5,799)	2,646
Operating lease liabilities	(973)	(1,052)
Net cash used in operating activities	(22,432)	(28,473)
Investing activities:		
Purchases of property and equipment	(505)	(118)
Net cash used in investing activities	(505)	(118)
Financing activities:		
Proceeds from underwritten public offering, net of issuance costs	17,256	—
Proceeds from public offering of common stock, net of issuance costs	8,707	2,362
Proceeds from exercise of stock options	21	—
Issuance costs for underwritten public offering	—	(720)
Principal repayments of Term Loan	—	(2,593)
Net cash provided by (used in) financing activities	25,984	(951)
Net increase (decrease) in cash and cash equivalents	3,047	(29,542)
Cash and cash equivalents at beginning of year	32,731	62,273
Cash and cash equivalents at end of year	$ 35,778	$ 32,731
Supplemental disclosure of cash flows:		
Interest paid	$ —	$ 40
Income taxes paid	$ 797	$ —
Non-cash investing activity:		
Purchases of property and equipment, included in accounts payable and accrued liabilities	$ 11	$ 69
Finance lease right-of-use asset obtained in exchange for lease liability	$ 788	$ —
Operating lease right-of-use asset obtained in exchange for lease liability	$ 3,847	$ —
Non-cash financing activities:		
Purchase of shares pursuant to Employee Stock Purchase Plan	$ 122	$ 140
Proceeds from public offering of common stock, net of issuance costs, included in prepaid expenses, other current assets, and other assets	$ —	$ 8

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 developing targeted therapies designed to save lives and improve the standard of care for patients facing serious diseases. The Company's first commercially approved product in the United States, or U.S., is REZZAYO® (rezafungin for injection) which is indicated for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options. Melinta Therapeutics, LLC, or Melinta, is commercializing REZZAYO in the U.S. The Company's proprietary Cloudbreak® platform enables development of novel drug-Fc conjugates, or DFCs, that inhibit specific disease targets while simultaneously engaging the immune system. The Company's most advanced DFC program is CD388, a highly potent 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 multiple oncology and autoimmune 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, 2023, the Company had an accumulated deficit of $441.4 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, 2023, the Company had cash and cash equivalents of $35.8 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 consolidated financial statements are issued. The consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

The Company plans to continue to fund its losses from operations through cash and cash equivalents on hand, as well as through future equity offerings, debt financings, other third party funding, and potential licensing or collaboration arrangements. There can be no assurance that additional funds will be available when needed from any source or, if available, will be available on terms that are acceptable to the Company. Even if the Company raises additional capital, it may also be required to modify, delay or abandon some of its plans which could have a material adverse effect on the Company's business, operating results and financial condition and the Company's ability to achieve its intended business objectives. Any of these actions could materially harm the Company's business, results of operations and future prospects.

Basis of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. The Company evaluates its estimates and assumptions on an ongoing basis. The most significant estimates in the Company's consolidated financial statements relate to 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.

Restatement of Consolidated Financial Statements

The Company evaluated the indirect taxation consequences upon the first commercial sale of REZZAYO in 2023 and determined that it had a liability for indirect taxation in various tax jurisdictions outside of the U.S. based on its supply chain activities in 2023 and prior years. As a result, it was concluded that in prior years the Company did not appropriately account for indirect taxes which led to understatements of accrued liabilities and operating expenses during the impacted periods. The Company recorded an accrued liability for indirect taxes, and the related interest and penalties, of $11.5 million, an increase in operating expenses of $3.9 million, and an increase in beginning accumulated deficit of $7.6 million, for 2022. The Company recorded an accrued liability for indirect taxes, and the related interest and penalties, of $7.6 million, an increase in operating expenses of $3.7 million, and an increase in beginning accumulated deficit of $3.9 million, for 2021.

The consolidated financial statements (as restated) also include adjustments to correct certain other previously identified misstatements relating to fiscal year 2022 and the quarters within 2023 that the Company had determined to be immaterial, both individually and in the aggregate.

Impact of Restatement

See below for reconciliation from the previously reported amounts to the restated amounts in the consolidated balance sheet, consolidated statement of operations and comprehensive loss, consolidated statement of convertible preferred stock and stockholders' equity (deficit), and consolidated statement of cash flows as of and for the year ended December 31, 2022. The previously reported amounts were derived from the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 23, 2023. These amounts are labeled as "As Previously Reported" in the tables below. The amounts labeled "Restatement Adjustment" represent the effects of this restatement described above.

The following presents a reconciliation of the impacted financial statement line items as previously reported to the restated amounts as of and for the year ended December 31, 2022 (in thousands, except share and per share data):

	Year Ended December 31, 2022		
Corrected Consolidated Balance Sheet	**As Previously Reported**	**Restatement Adjustment**	**As Restated**
Operating lease right-of-use asset	$ 1,205	$ (106)	$ 1,099
Total assets	47,593	(106)	47,487
Accrued indirect tax liabilities	—	11,534	11,534
Current portion of operating lease liability	1,317	(106)	1,211
Total current liabilities	29,972	11,428	41,400
Total liabilities	50,497	11,428	61,925
Accumulated deficit	(406,966)	(11,534)	(418,500)
Total stockholders' deficit	(2,904)	(11,534)	(14,438)
Total liabilities and stockholders' deficit	47,593	(106)	47,487

Corrected Consolidated Statement of Operations and Comprehensive Loss	Year Ended December 31, 2022		
	As Previously Reported	Restatement Adjustment	As Restated
Collaboration revenue	$ 64,288	$ 160	$ 64,448
Total revenues	64,288	160	64,448
Research and development	75,520	1,885	77,405
Selling, general and administrative	18,486	2,060	20,546
Total operating expenses	94,006	3,945	97,951
Loss from operations	(29,718)	(3,785)	(33,503)
Loss before income tax expense	(29,527)	(3,785)	(33,312)
Net loss and comprehensive loss	(29,799)	(3,785)	(33,584)
Basic and diluted net loss per common share	(0.43)		(0.48)
Shares used to compute basic and diluted net loss per common share	69,857,698		69,857,698

Corrected Consolidated Statement of Convertible Preferred Stock and Stockholders' Equity (Deficit)	Additional Paid-In Capital		
	As Previously Reported	Restatement Adjustment	As Restated
Balance, December 31, 2021	$ 398,733	$ (720)	$ 398,013
Issuance costs for underwritten public offering	(720)	720	—
Balance, December 31, 2022	404,055	—	404,055

	Accumulated Deficit		
	As Previously Reported	Restatement Adjustment	As Restated
Balance, December 31, 2021	$ (377,167)	$ (7,749)	$ (384,916)
Net loss	(29,799)	(3,785)	(33,584)
Balance, December 31, 2022	(406,966)	(11,534)	(418,500)

	Total Stockholders' Equity (Deficit)		
	As Previously Reported	Restatement Adjustment	As Restated
Balance, December 31, 2021	$ 21,573	$ (8,469)	$ 13,104
Issuance costs for underwritten public offering	(720)	720	—
Net loss	(29,799)	(3,785)	(33,584)
Balance, December 31, 2022	(2,904)	(11,534)	(14,438)

Corrected Consolidated Statement of Cash Flows	Year Ended December 31, 2022		
	As Previously Reported	Restatement Adjustment	As Restated
Operating activities:			
Net loss	$ (29,799)	$ (3,785)	$ (33,584)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash operating lease expense	1,082	(101)	981
Changes in assets and liabilities:			
Accrued indirect tax liabilities	—	3,945	3,945
Contract liabilities	2,806	(160)	2,646
Operating lease liabilities	(1,153)	101	(1,052)

The remainder of the notes to the Company's consolidated financial statements have been updated and restated, as applicable, to reflect the impacts from the restatement discussed above.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents

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

Accounts Receivable

Accounts receivable is stated at the original invoice amount and consists of amounts due from customers related to milestones achieved, certain research and development and clinical supply costs subject to reimbursement under the collaboration and license agreements, royalties earned, and product sales. 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, 2023 or 2022.

Inventory

The Company began capitalizing inventory for REZZAYO, which received approval by the U.S. Food and Drug Administration, or FDA, in March 2023. REZZAYO (rezafungin for injection) is approved for the treatment of candidemia and invasive candidiasis in adults with limited or no alternative treatment options. Prior to regulatory approval, all direct and indirect manufacturing costs were charged to research and development expense in the period incurred.

Inventory is comprised of raw materials, work-in-process and finished goods, and includes costs related to materials, third-party contract manufacturing, freight-in and overhead. Inventory is stated at the lower of cost or net realizable value with cost based on the first-in-first-out method. The Company performs an assessment of recoverability of capitalized inventory during each reporting period based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life, and writes down any excess, obsolete or unsaleable inventory to its estimated realizable value in the period which the required reserve is first identified. Such write downs, should they occur, are charged to cost of product revenue in the consolidated statements of operations and comprehensive loss. As of December 31, 2023, the Company did not identify any excess, obsolete or unsaleable inventory.

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.

Finance Lease

In accordance with *Accounting Standards Codification*, or ASC, 842, *Leases*, or ASC 842, the Company determines if a contract contains a lease at inception and recognizes finance lease right-of-use assets and finance lease liabilities based on the present value of the future minimum lease payments at the commencement date. The implicit rate within the Company's finance lease was determinable and therefore used in determining the present value of future payments at the commencement date. Lease agreements that have lease and non-lease components are accounted for as a single lease component.

The Company recognizes amortization of the right-of-use assets and interest on the lease liabilities for its finance lease. Finance lease right-of-use assets are amortized on a straight-line basis from the commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. However, if the lease transfers ownership of the underlying asset to the lessee or the lessee is reasonably certain to exercise an option to purchase the underlying asset, the right-of-use assets are amortized to the end of the useful life of the underlying asset.

Operating Lease

In accordance with ASC 842 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 operating 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.

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 selling, general and administrative, or SG&A, expenses in the accompanying statements of operations and comprehensive loss.

Income Taxes

The Company reports deferred income taxes in accordance with ASC 740, *Income Taxes*, or ASC 740. 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.

Indirect Taxes

The Company's purchases of clinical drug supplies and raw materials, inventory transfers, and sales of commercial drug product are subject to indirect taxation in various jurisdictions outside of the U.S. Indirect tax payable is included in accrued indirect tax liabilities, the related expense is included in research and development, or R&D, expenses, and the related interest and penalties are included in SG&A expenses. The accrual is for the indirect tax incurred in various tax jurisdictions outside of the U.S. as a consequence of the Company's supply chain activities or in connection with commercial sales of REZZAYO. To the extent that any accrued indirect taxes are determined to not be due and payable, then any associated liabilities and operating expenses will be reversed in future periods. Indirect tax amounts on commercial sales (product revenue) that can be billed to and recovered from our customers are included in accounts receivables. Indirect tax amounts related to inventory purchases and manufacturing are included within inventory.

Revenue Recognition

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers*, or ASC 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 ASC 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 ASC 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 ASC 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.

Collaboration Revenue

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 development 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.

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.

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.

In July 2022, the Company entered into a License Agreement with Melinta, or the Melinta License Agreement. 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.

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 and milestones achieved to date.

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 9 for additional information.

Product Revenue

In December 2022 and January 2023, the Company entered into separate Commercial Supply Agreements with Mundipharma and Melinta, respectively, for the batch supply of REZZAYO naked vials for commercial use. Under the Commercial Supply Agreements, Mundipharma and Melinta are required to submit purchase orders to the Company for batches of REZZAYO naked vials. The Company concluded that the delivery of each batch of REZZAYO naked vials and the related quality assessment certification represents a distinct performance obligation.

The transaction price to be recognized as revenue for each performance obligation under the Commercial Supply Agreements consists of variable consideration which is determined based on the estimated per vial costs, plus the contractually stated margin rate. The amounts recognized as revenue are adjusted, as needed, each reporting period based on actual costs incurred for each batch. Variable consideration is included in the transaction price only to the extent that it is considered probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. The Company has made an accounting policy election to exclude from the transaction price any indirect taxes collected from customers. As a result, any such collections are recorded as indirect taxes liabilities. The transaction price will be fully allocated to the single performance obligation.

The Company concluded that the performance obligation is satisfied and product revenue is recognized when the customer obtains control of the product, which occurs at a point in time, typically upon the later of (i) completion of a positive quality assessment, or (ii) shipment of the Company's product to the customer.

Shipping and handling activities that are performed after a customer obtains control of the product are treated as activities to fulfill the promise to a customer and any amounts billed to a customer represent revenues for the product provided. Costs related to such shipping and handling billings are classified as cost of product revenue.

Cost of Product Revenue

Cost of product revenue consists primarily of costs related to materials, third-party contract manufacturing, freight-in and overhead. Prior to regulatory approval, all direct and indirect manufacturing costs were charged to research and development expense in the period incurred.

Research and Development Costs

R&D 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 in preclinical development and certain manufacturing expenses before FDA approval, nonclinical and clinical trial costs, and indirect taxes on clinical supplies and development materials. 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.

Selling, General and Administrative Expenses

SG&A expenses relate to selling, finance, human resources, legal and other administrative activities. SG&A 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 SG&A expenses include facility and overhead costs not otherwise included in cost of product revenue or research and development expenses, consultant expenses, travel expenses, professional fees for auditing, tax, legal, and other services, the branded prescription drug fee, and any accrued interest and penalties on accrued indirect tax liabilities.

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. The Company computed 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 does 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 attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and dilutive stock equivalents outstanding for the period determined using the treasury stock method or if-converted method. Under the two-class method, the net loss attributable to common stockholders is not allocated to the Series X Convertible Preferred Stock as the preferred stockholders do not have a contractual obligation to share in the Company's losses. 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.

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

	December 31,	
	2023	2022
Common stock warrants	17,331	12,517,328
Series X Convertible Preferred Stock	21,044,720	18,184,720
Common stock options, RSUs and PRSUs issued and outstanding	12,764,068	9,323,495
Total	33,826,119	40,025,543

Fair Value of Financial Instruments

The Company follows ASC 820-10, *Fair Value Measurements and Disclosures*, or ASC 820-10, 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 liabilities. 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 and Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that are adopted by the Company as of the specified effective date.

In December 2023, the FASB issued *Accounting Standards Update* 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires public entities to disclose disaggregated information about their effective tax rate reconciliation as well as expanded information on income taxes paid by jurisdiction. The disclosure requirements will be applied on a prospective basis, with the option to apply them retrospectively. The standard is effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company plans to adopt this guidance for the fiscal year ending December 31, 2025 and believes, based on its preliminary assessment, that this new guidance will not have a material impact on the Company's consolidated financial statements or related disclosures.

The Company believes, based on its preliminary assessment, that any other recently issued, but not yet adopted, accounting pronouncements will not have a material impact on the Company's consolidated financial statements or related disclosures, or do not apply to the Company.

3. FAIR VALUE MEASUREMENTS

The Company follows ASC 820-10, 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, 2023				
Assets:				
Cash and money market accounts	$ 35,778	$ 35,778	$ —	$ —
Total assets at fair value	$ 35,778	$ 35,778	$ —	$ —
December 31, 2022				
Assets:				
Cash and money market accounts	$ 32,731	$ 32,731	$ —	$ —
Total assets at fair value	$ 32,731	$ 32,731	$ —	$ —

4. INVENTORY

Inventory consisted of the following (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 2,691	$ —
Work-in-process	3,406	—
Finished goods	—	—
Total inventory	$ 6,097	$ —

The Company's capitalized inventory consists of costs incurred subsequent to FDA approval of REZZAYO in March 2023. Prior to regulatory approval, all direct and indirect manufacturing costs were charged to research and development expense in the period incurred. There were no inventory write downs during the year ended December 31, 2023.

5. PROPERTY AND EQUIPMENT

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

	December 31,	
	2023	2022
Laboratory equipment	$ 2,817	$ 2,415
Leasehold improvements	425	425
Computer hardware and software	327	305
Office equipment	36	93
Furniture and fixtures	142	142
	3,747	3,380
Less accumulated depreciation and amortization	(3,190)	(3,158)
Total	$ 557	$ 222

Depreciation and amortization of property and equipment of $0.1 million and $0.1 million were recorded for the years ended December 31, 2023, and 2022, respectively.

6. 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 Company has borrowed $10.0 million from the Lender, or the Term A Loan. The Term A Loan 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%, and matured on July 3, 2022. The Term A Loan had an interest-only period through April 3, 2020, which was followed by equal monthly principal payments and was paid in full on July 5, 2022.

7. 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, 2023 and 2022, the Company sold 6,219,741 and 3,414,926 shares of common stock for net proceeds of approximately $8.7 million and $2.4 million, respectively, after deducting placement agent fees. As of December 31, 2023, the remaining capacity under the Sales Agreement is $37.1 million.

2023 Underwritten Public Offering

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 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.

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, 2023.

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, 2023 and 2022 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, 2023. 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, 2023, warrants to purchase 17,331 shares of the Company's common stock were outstanding with a weighted average exercise price of $11.54 per share. During the year ended December 31, 2023, 12,499,997 common stock warrants expired unexercised.

As of December 31, 2022, 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, 2023 and 2022. 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,	
	2023	2022
Common stock warrants	17,331	12,517,328
Series X Convertible Preferred Stock	21,044,720	18,184,720
Common stock options, RSUs and PRSUs issued and outstanding	12,764,068	9,323,495
Authorized for future stock awards	3,411,463	4,469,969
Awards available under the ESPP	987,756	806,968
Total	38,225,338	45,302,480

8. 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, 2023 and 2022, 309,548 and 363,596 shares, respectively, were issued pursuant to the ESPP.

As of December 31, 2023, total unrecognized compensation expense related to the ESPP was immaterial and is expected to be recognized over approximately 0.4 years.

Restricted Stock Units

The following table summarizes RSU and PRSU activity during the year ended December 31, 2023:

	Number of RSUs and PRSUs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2022	1,223,871	$ 1.47
RSUs and PRSUs granted	1,515,817	1.00
RSUs and PRSUs vested	(490,520)	1.48
RSUs and PRSUs canceled	(151,115)	1.29
Outstanding at December 31, 2023	2,098,053	$ 1.14

The weighted-average grant date fair value of RSUs and PRSUs granted by the Company during the year ended December 31, 2022 was $0.83 per share. The total fair value of RSUs and PRSUs vested during the years ended December 31, 2023 and 2022 was approximately $0.7 million and $1.6 million, respectively.

At December 31, 2023, estimated unrecognized compensation expense related to RSUs and PRSUs granted was approximately $1.7 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 2 years.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Total Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	8,099,624	$ 2.78	6.65	$ 48
Options granted	3,233,558	1.02		
Options exercised	(25,750)	0.83		
Options canceled	(641,417)	3.12		
Outstanding at December 31, 2023	10,666,015	$ 2.23	6.72	$ 57
Vested and expected to vest at December 31, 2023	10,666,015	$ 2.23	6.72	$ 57
Exercisable at December 31, 2023	7,236,987	$ 2.75	5.71	$ 54

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, 2023 and 2022 was $0.72 and $0.51, respectively, per share.

As of December 31, 2023, total unrecognized share-based compensation expense related to unvested stock options was approximately $2.4 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,	
	2023	2022
2015 EIP and 2020 IIP		
Risk-free interest rate	3.58% - 4.61%	1.39% - 4.02%
Expected dividend yield	0%	0%
Expected volatility	82% - 83%	70% - 75%
Expected term (years)	5.50 - 6.08	5.50 - 6.08
2015 ESPP		
Risk-free interest rate	4.29% - 5.43%	1.57% - 2.65%
Expected dividend yield	0%	0%
Expected volatility	64% - 147%	75% - 98%
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 consolidated statements of operations and comprehensive loss as follows (in thousands):

	Years ended December 31,	
	2023	2022
Research and development	$ 1,592	$ 1,760
Selling, general and administrative	1,469	1,945
Total	$ 3,061	$ 3,705

9. 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, 2023, 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, 2023, 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 $25.1 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 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 current contract liabilities as of December 31, 2023 because the rights to consideration is 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. As of December 31, 2023, the Company estimated the uncredited portion to be approximately $10.1 million in December 2024. In December 2021, August 2022, and December 2023, the Company achieved milestones of $2.8 million, $11.1 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 contract liabilities 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 achieved as of December 31, 2023 in January 2022, September 2022, and February 2024, respectively. The Company determined that as of December 31, 2023, 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 milestone 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.

In January 2024, the Company achieved a milestone of $2.8 million under the Mundipharma Collaboration Agreement for which the Company received payment in April 2024.

Royalties. As the license is deemed to be the predominant item to which sales-based royalties relate, the Company will recognize royalty revenue when the related sales occur. No royalty revenue was recognized during the years ended December 31, 2023 and 2022.

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 is 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 is the IND holder for the Research Plan clinical trials. Both parties will be responsible for conducting certain specified CMC 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.

In September 2023 Janssen delivered its Election to Proceed Notice for CD388 whereby Janssen will assume the future development, manufacturing and commercialization activities of CD388 under the Janssen Collaboration Agreement. The Company continues to work in collaboration with Janssen to complete the Phase 1 and Phase 2a clinical trials and will be reimbursed for all ongoing development activities by Janssen as per the Janssen Collaboration Agreement.

Following Janssen's Election to Proceed Notice, Janssen, is obligated at its sole expense to diligently continue development and commercialization.

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 was 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, 2023, the Company determined the transaction price is equal to the up-front fee of $27.0 million, plus the research and development funding of $49.8 million, plus milestones achieved of $10.0 million. The transaction price includes the total estimated costs related to research and development and clinical supply services, which can increase or decrease as costs to continue the research and development efforts become known. No revenue was reversed due to the change in transaction price as revenue is recognized based on actual amounts billed. 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 $26.8 million, as restated, 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 and September 2023, the Company achieved milestones of $3.0 million and $7.0 million, respectively, 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 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 contract liabilities 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 May 2022 and September 2023, respectively. The Company determined that as of December 31, 2023, 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 milestone 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 royalty revenue when the related sales occur. No royalty revenue was recognized during the years ended December 31, 2023 and 2022.

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 is 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 is 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 FDA of a supplemental new drug application, or sNDA, 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 CMC 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 the rezafungin IND and new drug application, or NDA. Both regulatory applications will transfer to Melinta on a transfer date determined based on the status of the ReSPECT trial and the associated sNDA 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 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, 2023, the Company determined the transaction price is equal to the up-front fee of $30.0 million, plus a milestone achieved of $20.0 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 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, 2023 was immaterial.

Milestone Payments. In March 2023, the Company achieved a $20.0 million milestone under the Melinta License 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 contract liabilities 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 April 2023. The Company determined that as of December 31, 2023, 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 milestone 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 royalty revenue when the related sales occur. The Company recognized $0.2 million in royalty revenue during the year ended December 31, 2023 following the commercial launch of REZZAYO by Melinta in the U.S. on July 31, 2023. 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, and capitalized an additional $0.5 million upon achievement of a milestone, in accordance with ASC 340, *Other Assets and Deferred Costs*. 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. The Company recognized expense during the years ended December 31, 2023 and 2022 of $0.5 million and $1.8 million, respectively, and is included within SG&A expenses in the Company's consolidated statements of operations and comprehensive loss. As of December 31, 2023, 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 pertaining to the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement during the year ended December 31, 2023 (in thousands):

Opening balance, December 31, 2022 (As Restated)	$	35,139
Payments received in advance		1,755
Payments receivable		1,488
Revenue from performance obligations satisfied during reporting period		(9,042)
Closing balance, December 31, 2023	$	29,340
Current portion of contract liabilities	$	25,095
Long-term portion of contract liabilities		4,245
Total contract liabilities, December 31, 2023	$	29,340

As of December 31, 2023, the aggregate transaction price allocated to performance obligations that are unsatisfied is $11.5 million, $3.8 million and $3.7 million under the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement, respectively. These amounts are expected to be recognized over 2 years, 0.5 years, 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, 2023, the Company recorded $13.9 million, $1.9 million, and $0.4 million in accounts receivable associated with 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.

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

	Year Ended December 31, 2023		
	Mundipharma	Janssen	Melinta
Revenue from Collaboration and License Agreements:			
Point in Time:			
License of Intellectual Property - upon milestones achieved	$ 3,252	$ 2,347	$ 17,257
Clinical Drug Supply	26	—	—
Royalties	—	—	168
Over Time:			
Research and Development Services	12,303	19,011	2,441
Clinical Supply Services	840	1,925	—
Total Revenue from Collaboration and License Agreements	$ 16,421	$ 23,283	$ 19,866

	Year Ended December 31, 2022		
	Mundipharma	Janssen	Melinta
		(As Restated)	
Revenue from Collaboration and License Agreements:			
Point in Time:			
License of Intellectual Property - upon transfer of license	$ —	$ —	$ 25,885
License of Intellectual Property - upon milestones achieved	3,252	976	—
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	$ 23,496	$ 26,696

10. INCOME TAXES

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

	December 31, 2023	2022
Current tax provision:		
Federal	$ 393	$ 248
State	50	24
Total current tax provision	443	272
Deferred tax provision:		
Federal	—	—
State	—	—
Total deferred tax provision	—	—
Total tax provision	$ 443	$ 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, 2023	2022 (As Restated)
Federal income taxes at 21% for 2023 and 2022	$ (4,723)	$ (7,029)
State income tax, net of federal benefit	(186)	(247)
Nondeductible expenses	260	415
Tax credits	(2,076)	(1,877)
Rate change	(54)	491
Change in valuation allowance	6,373	(19,684)
Reserve for uncertain tax positions	519	(10,423)
162m deferred tax asset limitation	128	82
382 NOL and tax credit limitation	—	37,513
Expired stock awards	174	1,052
Other	28	(21)
Income tax expense	$ 443	$ 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, 2023	2022 (As Restated)
Deferred tax assets:		
Net operating losses	$ 35,506	$ 42,043
Tax credits	9,747	9,327
Intangibles	136	160
Capitalized R&D	25,871	14,706
Stock compensation	1,424	1,385
Lease liabilities	1,112	275
Deferred revenue	5,951	5,620
Accrued indirect tax liabilities	4,114	2,617
Other	725	1,018
Total deferred tax assets	84,586	77,151
Less valuation allowance	(83,086)	(76,713)
Deferred tax assets, net of valuation allowance	1,500	438
Deferred tax liabilities:		
Prepaid expenses	(214)	(189)
Capitalized inventory costs	(244)	—
Right-of-use assets	(1,042)	(249)
Total deferred tax liabilities	(1,500)	(438)
Net deferred tax assets	$ —	$ —

At December 31, 2023, the Company had federal and state tax net operating loss carryforwards of approximately $153.8 million and $131.2 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 $9.5 million and state research and development credit carryforwards totaling $5.3 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 $5.3 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 increased by $6.4 million in 2023 and decreased by $19.7 million in 2022.

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 2023 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, 2023 and 2022, the unrecognized tax benefits recorded were approximately $11.5 million and $11.0 million, respectively. Approximately $9.7 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 2023 and 2022 is as follows (in thousands):

	Years Ended December 31,	
	2023	2022
		(As Restated)
Balance as of the beginning of the year	$ 11,015	$ 23,990
Increases related to current year tax positions	552	497
Decreases related to prior year tax positions	(47)	(13,472)
Balance as of the end of the year	$ 11,520	$ 11,015

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.

11. COMMITMENTS AND CONTINGENCIES

Litigation

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company at December 31, 2023 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.

Finance Lease Obligations

The Company has a finance lease for lab equipment which was entered into in November 2023. The finance lease has a term of 36 months, monthly lease payments of $25,009, and an option to purchase the lab equipment for $1 at the end of the finance lease term. As of December 31, 2023, the Company was reasonably certain that it would exercise the option to purchase the lab equipment at the end of the finance lease term. The useful life of the lab equipment is estimated to be 10 years. The rate implicit to the finance lease used in measuring the Company's finance lease liability was 8.0%.

The following table presents information about the amount, timing and uncertainty of cash flows arising from the Company's finance lease as of December 31, 2023 (in thousands):

2024	$ 275
2025	300
2026	300
2027	25
Total undiscounted finance lease payments	900
Less: Imputed interest	(107)
Present value of finance lease payments	$ 793

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

Balance Sheet Classification:	
Finance lease right-of-use asset	$ 788
Accumulated amortization	(6)
Net finance lease right-of-use asset	$ 782
Current portion of finance lease liability	$ 218
Long-term finance lease liability	575
Total finance lease liabilities	$ 793

As of December 31, 2023, the weighted average remaining finance lease term was 3.1 years.

Cash paid for amounts included in the measurement of finance lease liabilities was zero for the year ended December 31, 2023.

Finance lease costs were immaterial for the year ended December 31, 2023.

Operating Lease Obligations

The Company has an operating lease for laboratory and office space in San Diego, California which was entered into in June 2014. Amendments for additional space were entered into in February 2015, March 2015 and August 2015. On April 20, 2023, the Company entered into a seventh amendment to its operating lease with Nancy Ridge Technology Center, L.P. which extended the term of the operating lease by an additional 36 months and increases the base rent to $133,371 per month effective January 1, 2024, subject to 4% increases every January. The operating lease expires on December 31, 2026 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, 2023, 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 operating lease term for accounting purposes. The incremental borrowing rate used in measuring the Company's operating lease liability was 12.0%.

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, 2023 (in thousands):

2024	$	1,600
2025		1,665
2026		1,731
Total undiscounted operating lease payments		4,996
Less: Imputed interest		(912)
Present value of operating lease payments	$	4,084

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

Balance Sheet Classification:		
Operating lease right-of-use asset	$	3,788
Current portion of operating lease liability	$	1,082
Long-term operating lease liability		3,002
Total operating lease liabilities	$	4,084

As of December 31, 2023, the weighted average remaining operating lease term was 3 years.

Cash paid for amounts included in the measurement of operating lease liabilities was $1.3 million and $1.2 million for the years ended December 31, 2023 and 2022, respectively.

Operating lease costs were $1.6 million and $1.3 million for the years ended December 31, 2023 and 2022, respectively. These costs are primarily related to the Company's 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.

12. SELECTED QUARTERLY FINANCIAL DATA (UNAUDITED)

Restatement of Interim Financial Information (Unaudited)

Due to the misstatements described in Note 1 above, the Company has restated its unaudited condensed consolidated balance sheets, condensed consolidated statements of operations and comprehensive loss, condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit), and condensed consolidated statements of cash flows for the quarterly periods ended March 31, 2022, June 30, 2022, September 30, 2022, March 31, 2023, June 30, 2023 and September 30, 2023.

	March 31, 2023			March 31, 2022		
Corrected Condensed Consolidated Balance Sheets (unaudited)	**As Previously Reported**	**Restatement Adjustment**	**As Restated**	**As Previously Reported**	**Restatement Adjustment**	**As Restated**
ASSETS						
Current assets:						
Cash and cash equivalents	$ 47,976	$ —	$ 47,976	$ 36,488	$ —	$ 36,488
Restricted Cash	—	—	—	1,482	—	1,482
Accounts receivable	25,826	295	26,121	8,783	—	8,783
Prepaid expenses and other current assets	5,686	25	5,711	5,254	—	5,254
Total current assets	79,488	320	79,808	52,007	—	52,007
Property and equipment, net	270	—	270	239	—	239
Operating lease right-of-use asset	917	(81)	836	2,030	(184)	1,846
Other assets	1,061	—	1,061	1,019	—	1,019
Total assets	$ 81,736	$ 239	$ 81,975	$ 55,295	$ (184)	$ 55,111
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)						
Current liabilities:						
Accounts payable	3,980	46	4,026	2,861	—	2,861
Accrued liabilities	9,078	30	9,108	9,234	720	9,954
Accrued indirect tax liabilities	—	11,795	11,795	—	7,942	7,942
Accrued compensation and benefits	5,843	—	5,843	3,079	—	3,079
Current contract liabilities	15,761	29	15,790	14,260	—	14,260
Current portion of operating lease liability	1,001	(81)	920	1,190	(100)	1,090
Current portion of term loan	—	—	—	1,481	—	1,481
Total current liabilities	35,663	11,819	47,482	32,105	8,562	40,667
Long-term contract liabilities	19,236	150	19,386	17,229	—	17,229
Long-term operating lease liability	—	—	—	1,004	(84)	920
Total liabilities	54,899	11,969	66,868	50,338	8,478	58,816
Commitments and contingencies						
Stockholders' equity (deficit):						
Preferred stock (1)						
Series X Convertible Preferred stock (2)	—	—	—	—	—	—
Common stock (3)	9	—	9	7	—	7
Additional paid-in capital	430,585	—	430,585	400,398	(720)	399,678
Accumulated deficit	(403,757)	(11,730)	(415,487)	(395,448)	(7,942)	(403,390)
Total stockholders' equity (deficit)	26,837	(11,730)	15,107	4,957	(8,662)	(3,705)
Total liabilities and stockholders' equity (deficit)	$ 81,736	$ 239	$ 81,975	$ 55,295	$ (184)	$ 55,111

(1) Preferred stock, $0.0001 par value; 10,000,000 shares authorized at March 31, 2023 and March 31, 2022

(2) Series X Convertible Preferred Stock, $0.0001 par value; 4,947,759 shares authorized at March 31, 2023 and March 31, 2022; 2,156,713 shares issued and 2,104,472 shares outstanding at March 31, 2023; 1,870,713 shares issued and 1,818,472 shares outstanding at March 31, 2022

(3) Common stock, $0.0001 par value; 200,000,000 shares authorized at March 31, 2023 and March 31, 2022; 90,024,562 shares issued and outstanding at March 31, 2023 and 69,049,247 shares issued and outstanding at March 31, 2022

Corrected Condensed Consolidated Balance Sheets (unaudited)	June 30, 2023			June 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
ASSETS						
Current assets:						
Cash and cash equivalents	$ 50,430	$ —	$ 50,430	$ 24,637	$ —	$ 24,637
Restricted cash	—	—	—	370	—	370
Accounts receivable	5,483	—	5,483	4,833	—	4,833
Inventory	1,954	434	2,388	—	—	—
Prepaid expenses and other current assets	4,373	—	4,373	6,706	—	6,706
Total current assets	62,240	434	62,674	36,546	—	36,546
Property and equipment, net	297	—	297	201	—	201
Operating lease right-of-use asset	4,388	(81)	4,307	1,764	(162)	1,602
Other assets	1,061	—	1,061	1,013	—	1,013
Total assets	$ 67,986	$ 353	$ 68,339	$ 39,524	$ (162)	$ 39,362
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)						
Current liabilities:						
Accounts payable	1,899	—	1,899	3,091	—	3,091
Accrued liabilities	10,022	—	10,022	8,567	—	8,567
Accrued indirect tax liabilities	—	13,431	13,431	—	10,582	10,582
Accrued compensation and benefits	3,582	—	3,582	3,464	—	3,464
Current contract liabilities	14,975	—	14,975	14,730	—	14,730
Current portion of operating lease liability	942	(81)	861	1,233	(104)	1,129
Current portion of term loan	—	—	—	370	—	370
Total current liabilities	31,420	13,350	44,770	31,455	10,478	41,933
Long-term contract liabilities	17,551	—	17,551	15,351	—	15,351
Long-term operating lease liability	3,601	—	3,601	679	(58)	621
Total liabilities	52,572	13,350	65,922	47,485	10,420	57,905
Commitments and contingencies						
Stockholders' equity (deficit):						
Preferred stock (4)						
Series X Convertible Preferred stock (5)	—	—	—	—	—	—
Common stock (6)	9	—	9	7	—	7
Additional paid-in capital	431,519	—	431,519	400,599	—	400,599
Accumulated deficit	(416,114)	(12,997)	(429,111)	(408,567)	(10,582)	(419,149)
Total stockholders' equity (deficit)	15,414	(12,997)	2,417	(7,961)	(10,582)	(18,543)
Total liabilities and stockholders' equity (deficit)	$ 67,986	$ 353	$ 68,339	$ 39,524	$ (162)	$ 39,362

(4) Preferred stock, $0.0001 par value; 10,000,000 shares authorized at June 30, 2023 and June 30, 2022

(5) Series X Convertible Preferred Stock, $0.0001 par value; 4,947,759 shares authorized at June 30, 2023 and June 30, 2022; 2,156,713 shares issued and 2,104,472 shares outstanding at June 30, 2023; 1,870,713 shares issued and 1,818,472 shares outstanding at June 30, 2022

(6) Common stock, $0.0001 par value; 200,000,000 shares authorized at June 30, 2023 and June 30, 2022; 90,251,746 shares issued and outstanding at June 30, 2023 and 69,238,508 shares issued and outstanding at June 30, 2022

Corrected Condensed Consolidated Balance Sheets (unaudited)	September 30, 2023			September 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
ASSETS						
Current assets:						
Cash and cash equivalents	$ 48,670	$ —	$ 48,670	$ 53,078	$ —	$ 53,078
Accounts receivable	2,855	323	3,178	5,042	—	5,042
Inventory	2,467	434	2,901	—	—	—
Prepaid expenses and other current assets	3,712	—	3,712	5,779	—	5,779
Total current assets	57,704	757	58,461	63,899	—	63,899
Property and equipment, net	580	—	580	173	—	173
Operating lease right-of-use asset	4,131	(81)	4,050	1,491	(137)	1,354
Other assets	1,053	—	1,053	1,295	—	1,295
Total assets	$ 63,468	$ 676	$ 64,144	$ 66,858	$ (137)	$ 66,721
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)						
Current liabilities:						
Accounts payable	3,661	—	3,661	4,244	—	4,244
Accrued liabilities	11,772	—	11,772	8,162	—	8,162
Accrued indirect tax liabilities	—	14,689	14,689	—	11,314	11,314
Accrued compensation and benefits	4,457	—	4,457	4,117	—	4,117
Current contract liabilities	14,679	—	14,679	15,249	—	15,249
Current portion of operating lease liability	1,051	(81)	970	1,277	(108)	1,169
Total current liabilities	35,620	14,608	50,228	33,049	11,206	44,255
Long-term contract liabilities	16,504	—	16,504	24,398	—	24,398
Long-term operating lease liability	3,306	—	3,306	344	(29)	315
Total liabilities	55,430	14,608	70,038	57,791	11,177	68,968
Commitments and contingencies						
Stockholders' equity (deficit):						
Preferred stock (7)						
Series X Convertible Preferred stock (8)	—	—	—	—	—	—
Common stock (9)	9	—	9	7	—	7
Additional paid-in capital	432,315	—	432,315	402,649	—	402,649
Accumulated deficit	(424,286)	(13,932)	(438,218)	(393,589)	(11,314)	(404,903)
Total stockholders' equity (deficit)	8,038	(13,932)	(5,894)	9,067	(11,314)	(2,247)
Total liabilities and stockholders' equity (deficit)	$ 63,468	$ 676	$ 64,144	$ 66,858	$ (137)	$ 66,721

(7) Preferred stock, $0.0001 par value; 10,000,000 shares authorized at September 30, 2023 and September 30, 2022

(8) Series X Convertible Preferred Stock, $0.0001 par value; 4,947,759 shares authorized at September 30, 2023 and September 30, 2022; 2,156,713 shares issued and 2,104,472 shares outstanding at September 30, 2023; 1,870,713 shares issued and 1,818,472 shares outstanding at September 30, 2022

(9) Common stock, $0.0001 par value; 200,000,000 shares authorized at September 30, 2023 and September 30, 2022; 90,415,944 shares issued and outstanding at September 30, 2023 and 71,181,197 shares issued and outstanding at September 30, 2022

Corrected Condensed Consolidated Statement of Operations and Comprehensive Income (Loss) (unaudited)	Three Months Ended March 31, 2023			Three Months Ended March 31, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Revenues:						
Collaboration revenue	$ 25,990	$ 117	$ 26,107	$ 7,109	$ 160	$ 7,269
Total revenues	25,990	117	26,107	7,109	160	7,269
Operating expenses:						
Research and development	18,715	154	18,869	20,166	215	20,381
General and administrative	4,298	159	4,457	5,204	138	5,342
Total operating expenses	23,013	313	23,326	25,370	353	25,723
Income (loss) from operations	2,977	(196)	2,781	(18,261)	(193)	(18,454)
Other income (expense), net:						
Interest income (expense), net	232	—	232	(20)	—	(20)
Total other income (expense), net	232	—	232	(20)	—	(20)
Net income (loss) and comprehensive income (loss)	3,209	(196)	3,013	(18,281)	(193)	(18,474)
Allocation of earnings to participating securities	(677)	41	(636)	—	—	—
Net income (loss) attributable to common stockholders	$ 2,532	$ (155)	$ 2,377	$ (18,281)	$ (193)	$ (18,474)
Basic net earnings (loss) per common share (10)	$ 0.03		$ 0.03	$ (0.27)		$ (0.27)
Diluted net earnings (loss) per common share (10)	$ 0.03		$ 0.03	$ (0.27)		$ (0.27)
Shares used to compute basic net earnings (loss) per common share	78,640,086		78,640,086	68,138,116		68,138,116
Shares used to compute diluted net earnings (loss) per common share	101,189,396		101,189,396	68,138,116		68,138,116

(10) As the Company was in an income position for the three-months ended March 31, 2023, the two-class method was used to compute basic net earnings per share and the Company calculated diluted net earnings per share based on the more dilutive of (1) the treasury stock method, reverse treasury stock method or if-converted method, as applicable, or (2) the two-class method.

Corrected Condensed Consolidated Statement of Operations and Comprehensive Loss (unaudited)	Three Months Ended June 30, 2023			Three Months Ended June 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Revenues:						
Collaboration revenue	$ 7,614	$ (117)	$ 7,497	$ 6,216	$ —	$ 6,216
Total revenues	7,614	(117)	7,497	6,216	—	6,216
Operating expenses:						
Research and development	17,135	421	17,556	15,255	1,375	16,630
General and administrative	3,310	729	4,039	4,074	1,265	5,339
Total operating expenses	20,445	1,150	21,595	19,329	2,640	21,969
Loss from operations	(12,831)	(1,267)	(14,098)	(13,113)	(2,640)	(15,753)
Other income (expense), net:						
Interest income (expense), net	623	—	623	(6)	—	(6)
Total other income (expense), net	623	—	623	(6)	—	(6)
Net loss before income tax expense	(12,208)	(1,267)	(13,475)	(13,119)	(2,640)	(15,759)
Income tax expense	(149)	—	(149)	—	—	—
Net loss and comprehensive loss	$ (12,357)	$ (1,267)	$ (13,624)	$ (13,119)	$ (2,640)	$ (15,759)
Basic and diluted net loss per common share	$ (0.14)		$ (0.15)	$ (0.19)		$ (0.23)
Shares used to compute basic and diluted net loss per common share	90,115,859		90,115,859	69,133,700		69,133,700

Corrected Condensed Consolidated Statement of Operations and Comprehensive Loss (unaudited)	Six Months Ended June 30, 2023			Six Months Ended June 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Revenues:						
Collaboration revenue	$ 33,604	$ —	$ 33,604	$ 13,325	$ 160	$ 13,485
Total revenues	33,604	—	33,604	13,325	160	13,485
Operating expenses:						
Research and development	35,850	575	36,425	35,421	1,590	37,011
General and administrative	7,608	888	8,496	9,278	1,403	10,681
Total operating expenses	43,458	1,463	44,921	44,699	2,993	47,692
Loss from operations	(9,854)	(1,463)	(11,317)	(31,374)	(2,833)	(34,207)
Other income (expense), net:						
Interest income (expense), net	855	—	855	(26)	—	(26)
Total other income (expense), net	855	—	855	(26)	—	(26)
Loss before income tax expense	(8,999)	(1,463)	(10,462)	(31,400)	(2,833)	(34,233)
Income tax expense	(149)	—	(149)	—	—	—
Net loss and comprehensive loss	$ (9,148)	$ (1,463)	$ (10,611)	$ (31,400)	$ (2,833)	$ (34,233)
Basic and diluted net loss per common share	$ (0.11)		$ (0.13)	$ (0.46)		$ (0.50)
Shares used to compute basic and diluted net loss per common share	84,409,667		84,409,667	68,638,651		68,638,651

Corrected Condensed Consolidated Statement of Operations and Comprehensive Income (Loss) (unaudited)	Three Months Ended September 30, 2023			Three Months Ended September 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Revenues:						
Collaboration revenue	$ 11,250	$ —	$ 11,250	$ 40,744	$ —	$ 40,744
Product revenue	1,468	—	1,468	—	—	—
Total revenues	12,718	—	12,718	40,744	—	40,744
Operating expenses:						
Cost of product revenue	387	—	387	—	—	—
Research and development	17,330	59	17,389	20,041	242	20,283
General and administrative	3,556	876	4,432	5,780	490	6,270
Total operating expenses	21,273	935	22,208	25,821	732	26,553
Income (loss) from operations	(8,555)	(935)	(9,490)	14,923	(732)	14,191
Other income, net:						
Interest income, net	613	—	613	55	—	55
Total other income, net	613	—	613	55	—	55
Net income (loss) before income tax expense	(7,942)	(935)	(8,877)	14,978	(732)	14,246
Income tax expense	(230)	—	(230)	—	—	—
Net income (loss) and comprehensive income (loss)	(8,172)	(935)	(9,107)	14,978	(732)	14,246
Allocation of earnings to participating securities	—	—	—	(3,081)	150	(2,931)
Net income (loss) attributable to common stockholders	$ (8,172)	$ (935)	$ (9,107)	$ 11,897	$ (582)	$ 11,315
Basic net earnings (loss) per common share (11)	$ (0.09)		$ (0.10)	$ 0.17		$ 0.16
Diluted net earnings (loss) per common share (11)	$ (0.09)		$ (0.10)	$ 0.17		$ 0.16
Shares used to compute basic net earnings (loss) per common share	90,287,441		90,287,441	70,217,985		70,217,985
Shares used to compute diluted net earnings (loss) per common share	90,287,441		90,287,441	88,592,568		88,592,568

(11) As the Company was in an income position for the three-months ended September 30, 2022, the two-class method was used to compute basic net earnings per share and the Company calculated diluted net earnings per share based on the more dilutive of (1) the treasury stock method, reverse treasury stock method or if-converted method, as applicable, or (2) the two-class method.

Corrected Condensed Consolidated Statement of Operations and Comprehensive Loss (unaudited)	Nine Months Ended September 30, 2023			Nine Months Ended September 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Revenues:						
Collaboration revenue	$ 44,854	$ —	$ 44,854	$ 54,069	$ 160	$ 54,229
Product revenue	1,468	—	1,468	—	—	—
Total revenues	46,322	—	46,322	54,069	160	54,229
Operating expenses:						
Cost of product revenue	387	—	387	—	—	—
Research and development	53,180	634	53,814	55,462	1,832	57,294
General and administrative	11,164	1,764	12,928	15,058	1,893	16,951
Total operating expenses	64,731	2,398	67,129	70,520	3,725	74,245
Loss from operations	(18,409)	(2,398)	(20,807)	(16,451)	(3,565)	(20,016)
Other income, net:						
Interest income, net	1,468	—	1,468	29	—	29
Total other income, net	1,468	—	1,468	29	—	29
Net loss before income tax expense	(16,941)	(2,398)	(19,339)	(16,422)	(3,565)	(19,987)
Income tax expense	(379)	—	(379)	—	—	—
Net loss and comprehensive loss	$ (17,320)	$ (2,398)	$ (19,718)	$ (16,422)	$ (3,565)	$ (19,987)
Basic and diluted net loss per common share	$ (0.20)		$ (0.23)	$ (0.24)		$ (0.29)
Shares used to compute basic and diluted net loss per common share	86,390,446		86,390,446	69,170,865		69,170,865

Corrected Condensed Consolidated Statement of Cash Flows (unaudited)	Three Months Ended March 31, 2023			Three Months Ended March 31, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Operating activities:						
Net income (loss)	$ 3,209	$ (196)	$ 3,013	$ (18,281)	$ (193)	$ (18,474)
Adjustments to reconcile net loss to net cash used in operating activities:						
Stock-based compensation	640	—	640	1,338	—	1,338
Non-cash operating lease expense	288	(26)	262	258	(24)	234
Depreciation and amortization	32	—	32	39	—	39
Amortization of costs to obtain a contract with a customer	475	—	475	—	—	—
Non-cash interest expense	—	—	—	1	—	1
Changes in assets and liabilities:						
Accounts receivable	(19,993)	(295)	(20,288)	(3,427)	—	(3,427)
Prepaid expenses, other current assets, and other assets	872	(24)	848	(1,120)	—	(1,120)
Accounts payable and accrued liabilities	3,116	76	3,192	657	—	657
Accrued indirect tax liabilities	—	261	261	—	353	353
Accrued compensation and benefits	921	—	921	(1,953)	—	(1,953)
Contract liabilities	(142)	178	36	(844)	(160)	(1,004)
Operating lease liabilities	(316)	26	(290)	(276)	24	(252)
Net cash used in operating activities	(10,898)	—	(10,898)	(23,608)	—	(23,608)
Investing activities:						
Purchases of property and equipment	(94)	—	(94)	(84)	—	(84)
Net cash used in investing activities	(94)	—	(94)	(84)	—	(84)
Financing activities:						
Proceeds from underwritten public offering, net of issuance costs	17,593	—	17,593	—	—	—
Proceeds from public offering of common stock, net of issuance costs	8,630	—	8,630	500	—	500
Proceeds from exercise of stock options	14	—	14	—	—	—
Principal repayments of Term Loan	—	—	—	(1,111)	—	(1,111)
Net cash provided by (used in) financing activities	26,237	—	26,237	(611)	—	(611)
Net increase (decrease) in cash and cash equivalents	15,245	—	15,245	(24,303)	—	(24,303)
Cash and cash equivalents at beginning of period	32,731	—	32,731	62,273	—	62,273
Cash and cash equivalents at end of period	$ 47,976	$ —	$ 47,976	$ 37,970	$ —	$ 37,970
Supplemental disclosure of cash flows:						
Interest paid	$ —	$ —	$ —	$ 25	$ —	$ 25
Non-cash investing activity:						
Purchases of property and equipment, included in accounts payable and accrued liabilities	$ 55	$ —	$ 55	$ 16	$ —	$ 16
Non-cash financing activities:						
Issuance costs incurred but not yet paid, included in accounts payable and accrued liabilities	$ 337	$ —	$ 337	$ —	$ 720	$ 720

Corrected Condensed Consolidated Statement of Cash Flows (unaudited)	Six Months Ended June 30, 2023			Six Months Ended June 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Operating activities:						
Net loss	$ (9,148)	$ (1,463)	$ (10,611)	$ (31,400)	$ (2,833)	$ (34,233)
Adjustments to reconcile net loss to net cash used in operating activities:						
Stock-based compensation	1,435	—	1,435	2,016	—	2,016
Non-cash operating lease expense	664	(25)	639	523	(47)	476
Depreciation and amortization	57	—	57	77	—	77
Amortization of costs to obtain a contract with a customer	40	—	40	—	—	—
Non-cash interest expense	—	—	—	1	—	1
Changes in assets and liabilities:						
Accounts receivable	350	—	350	524	—	524
Inventory	(1,954)	(434)	(2,388)	—	—	—
Prepaid expenses, other current assets, and other assets	2,120	—	2,120	(2,567)	—	(2,567)
Accounts payable and accrued liabilities	2,870	—	2,870	(483)	—	(483)
Accrued indirect tax liabilities	—	1,897	1,897	—	2,993	2,993
Accrued compensation and benefits	(1,277)	—	(1,277)	(1,324)	—	(1,324)
Contract liabilities	(2,613)	—	(2,613)	(2,252)	(160)	(2,412)
Operating lease liabilities	(620)	25	(595)	(559)	47	(512)
Net cash used in operating activities	(8,076)	—	(8,076)	(35,444)	—	(35,444)
Investing activities:						
Purchases of property and equipment	(201)	—	(201)	(100)	—	(100)
Net cash used in investing activities	(201)	—	(201)	(100)	—	(100)
Financing activities:						
Proceeds from underwritten public offering, net of issuance costs	17,256	—	17,256	—	—	—
Proceeds from public offering of common stock, net of issuance costs	8,706	—	8,706	500	—	500
Proceeds from exercise of stock options	14	—	14	—	—	—
Principal repayments of Term Loan	—	—	—	(2,222)	—	(2,222)
Net cash provided by (used in) financing activities	25,976	—	25,976	(1,722)	—	(1,722)
Net increase (decrease) in cash and cash equivalents	17,699	—	17,699	(37,266)	—	(37,266)
Cash and cash equivalents at beginning of period	32,731	—	32,731	62,273	—	62,273
Cash and cash equivalents at end of period	$ 50,430	$ —	$ 50,430	$ 25,007	$ —	$ 25,007
Supplemental disclosure of cash flows:						
Interest paid	$ —	$ —	$ —	$ 38	$ —	$ 38
Income taxes paid	$ 588	$ —	$ 588	$ —	$ —	$ —
Non-cash investing activity:						
Operating lease right-of-use asset obtained in exchange for lease liability	$ 3,847	$ —	$ 3,847	$ —	$ —	$ —
Non-cash financing activities:						
Purchase of shares pursuant to Employee Stock Purchase Plan	$ 63	$ —	$ 63	$ 69	$ —	$ 69
Issuance costs incurred but not yet paid, included in accounts payable and accrued liabilities	$ —	$ —	$ —	$ 720	$ —	$ 720

Corrected Condensed Consolidated Statement of Cash Flows (unaudited)	Nine Months Ended September 30, 2023			Nine Months Ended September 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Operating activities:						
Net loss	$ (17,320)	$ (2,398)	$ (19,718)	$ (16,422)	$ (3,565)	$ (19,987)
Adjustments to reconcile net loss to net cash used in operating activities:						
Stock-based compensation	2,231	—	2,231	2,859	—	2,859
Non-cash operating lease expense	921	(26)	895	796	(72)	724
Depreciation and amortization	79	—	79	114	—	114
Amortization of costs to obtain a contract with a customer	53	—	53	1,772	—	1,772
Non-cash interest expense	—	—	—	1	—	1
Changes in assets and liabilities:						
Accounts receivable	2,978	(323)	2,655	314	—	314
Inventory	(2,467)	(434)	(2,901)	—	—	—
Prepaid expenses, other current assets, and other assets	2,776	—	2,776	(1,662)	—	(1,662)
Accounts payable and accrued liabilities	6,204	—	6,204	(1,037)	—	(1,037)
Accrued indirect tax liabilities	—	3,155	3,155	—	3,725	3,725
Accrued compensation and benefits	(402)	—	(402)	(670)	—	(670)
Contract liabilities	(3,956)	—	(3,956)	7,314	(160)	7,154
Operating lease liabilities	(807)	26	(781)	(850)	72	(778)
Net cash used in operating activities	(9,710)	—	(9,710)	(7,471)	—	(7,471)
Investing activities:						
Purchases of property and equipment	(327)	—	(327)	(109)	—	(109)
Net cash used in investing activities	(327)	—	(327)	(109)	—	(109)
Financing activities:						
Proceeds from underwritten public offering, net of issuance costs	17,256	—	17,256	—	—	—
Proceeds from public offering of common stock, net of issuance costs	8,706	—	8,706	1,698	—	1,698
Proceeds from exercise of stock options	14	—	14	—	—	—
Issuance costs for underwritten public offering	—	—	—	(720)	—	(720)
Principal repayments of Term Loan	—	—	—	(2,593)	—	(2,593)
Net cash provided by (used in) financing activities	25,976	—	25,976	(1,615)	—	(1,615)
Net increase (decrease) in cash and cash equivalents	15,939	—	15,939	(9,195)	—	(9,195)
Cash and cash equivalents at beginning of period	32,731	—	32,731	62,273	—	62,273
Cash and cash equivalents at end of period	$ 48,670	$ —	$ 48,670	$ 53,078	$ —	$ 53,078

Corrected Condensed Consolidated Statement of Cash Flows (unaudited)	Nine Months Ended September 30, 2023			Nine Months Ended September 30, 2022		
	As Previously Reported	Restatement Adjustment	As Restated	As Previously Reported	Restatement Adjustment	As Restated
Supplemental disclosure of cash flows:						
Interest paid	$ —	$ —	$ —	$ 40	$ —	$ 40
Income taxes paid	$ 651	$ —	$ 651	$ —	$ —	$ —
Non-cash investing activity:						
Purchases of property and equipment, included in accounts payable and accrued liabilities	$ 178	$ —	$ 178	$ —	$ —	$ —
Operating lease right-of-use asset obtained in exchange for lease liability	$ 3,847	$ —	$ 3,847	$ —	$ —	$ —
Non-cash financing activities:						
Purchase of shares pursuant to Employee Stock Purchase Plan	$ 63	$ —	$ 63	$ 69	$ —	$ 69
Proceeds from public offering of common stock, net of issuance costs, included in prepaid expenses, other current assets, and other assets	$ —	$ —	$ —	$ 10	$ —	$ 10

	Corrected Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)						
	Series X Convertible Preferred Stock		Common Stock				
(In thousands, except share data)	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit (As Restated)	Total Stockholders' Equity (Deficit) (As Restated)
Balance, December 31, 2022 (As Restated)	1,818,472	$ —	72,470,440	$ 7	$ 404,055	$ (418,500)	$ (14,438)
Underwritten public offering, net of issuance costs	286,000	—	11,086,000	1	17,255	—	17,256
Public offering of common stock, net of issuance costs	—	—	6,158,799	1	8,621	—	8,622
Issuance of common stock for exercise of options	—	—	16,250	—	14	—	14
Issuance of common stock for restricted share units vested	—	—	293,073	—	—	—	—
Stock-based compensation	—	—	—	—	640	—	640
Net income (As Restated)	—	—	—	—	—	3,013	3,013
Balance, March 31, 2023 (As Restated)	2,104,472	—	90,024,562	9	430,585	(415,487)	15,107
Public offering of common stock, net of issuance costs	—	—	60,942	—	76	—	76
Issuance of common stock for restricted share units vested	—	—	4,875	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	161,367	—	63	—	63
Stock-based compensation	—	—	—	—	795	—	795
Net loss (As Restated)	—	—	—	—	—	(13,624)	(13,624)
Balance, June 30, 2023 (As Restated)	2,104,472	—	90,251,746	9	431,519	(429,111)	2,417
Issuance of common stock for restricted share units vested	—	—	164,198	—	—	—	—
Stock-based compensation	—	—	—	—	796	—	796
Net loss (As Restated)	—	—	—	—	—	(9,107)	(9,107)
Balance, September 30, 2023 (As Restated)	2,104,472	$ —	90,415,944	$ 9	$ 432,315	$ (438,218)	$ (5,894)

	Corrected Condensed Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)						
	Series X Convertible Preferred Stock		Common Stock				
(In thousands, except share data)	Shares	Amount	Shares	Amount	Additional Paid-In Capital (As Restated)	Accumulated Deficit (As Restated)	Total Stockholders' Equity (Deficit) (As Restated)
Balance, December 31, 2021 (As Restated)	1,818,472	$ —	67,863,674	$ 7	$ 398,013	$ (384,916)	$ 13,104
Public offering of common stock, net of issuance costs	—	—	644,265	—	500	—	500
Issuance of common stock for restricted share units vested	—	—	541,308	—	—	—	—
Stock-based compensation	—	—	—	—	1,165	—	1,165
Net loss (As Restated)	—	—	—	—	—	(18,474)	(18,474)
Balance, March 31, 2022 (As Restated)	1,818,472	—	69,049,247	7	399,678	(403,390)	(3,705)
Issuance of common stock for restricted share units vested	—	—	5,042	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	184,219	—	69	—	69
Stock-based compensation	—	—	—	—	852	—	852
Issuance costs for underwritten public offering (As Restated)	—	—	—	—	—	—	—
Net loss (As Restated)	—	—	—	—	—	(15,759)	(15,759)
Balance, June 30, 2022 (As Restated)	1,818,472	—	69,238,508	7	400,599	(419,149)	(18,543)
Public offering of common stock, net of issuance costs	—	—	1,664,170	—	1,208	—	1,208
Issuance of common stock for restricted share units vested	—	—	278,519	—	—	—	—
Stock-based compensation	—	—	—	—	842	—	842
Net income (As Restated)	—	—	—	—	—	14,246	14,246
Balance, September 30, 2022 (As Restated)	1,818,472	$ —	71,181,197	$ 7	$ 402,649	$ (404,903)	$ (2,247)

13. SUBSEQUENT EVENTS

Reverse Stock Split

At the Company's special meeting of stockholders held on April 4, 2024, the Company's stockholders approved a proposal to (i) amend the Company's Amended and Restated Certificate of Incorporation to effect a reverse stock split of the Company's outstanding common stock at a ratio in the range of 1-for-10 to 1-for-30, inclusive; and (ii) if and only if the reverse stock split is approved and implemented, a reduction in the number of authorized shares of common stock, at a ratio that is equal to half of the reverse stock split ratio, with such ratio to be determined in the discretion of the Company's board of directors and with such reverse stock split to be effected at such time and date, if at all, as determined by the Company's board of directors in its sole discretion.

On April 12, 2024, the Company's board of directors approved a reverse stock split of all outstanding shares of the Company's common stock at a ratio of 1-for-20, or the Reverse Stock Split. The Company's board of directors also approved a reduction in the number of authorized shares of common stock, at a ratio that is equal to half of the Reverse Stock Split ratio. On April 22, 2024, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment of its Amended and Restated Certificate of Incorporation to effect the Reverse Stock Split. As of the date of this filing, the Reverse Stock Split was not effective as trading on the Nasdaq Capital Market did not reflect the Reverse Stock Split.

All shares and per share information presented in these consolidated financial statements does not reflect the upcoming Reverse Stock Split. As of December 31, 2023, adjusting for the Reverse Stock Split will decrease the total number of the Company's authorized shares of common stock from 200,000,000 to 20,000,000; will decrease the number of issued and outstanding shares of common stock from 90,601,999 to approximately 4,530,099; and will decrease the number of outstanding warrants from 17,331 to 866 and will change the exercise price on these warrants from $11.54 to $230.95.

The following unaudited pro forma financial information presents the Company's basic and diluted net loss per share upon effectiveness of the Reverse Stock Split for the periods indicated (in thousands, except share and per share data):

	Years ended December 31,	
	2023	2022
		As Restated
Net loss and comprehensive loss	$ (22,931)	$ (33,584)
Basic and diluted net loss per common share	$ (5.25)	$ (9.61)
Shares used to compute basic and diluted net loss per common share	4,371,371	3,492,884

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, 2023, 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 not effective at the reasonable assurance level as of December 31, 2023, due to a material weakness in internal control over financial reporting described below.

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, 2023. 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, 2023, our internal control over financial reporting was not 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.

Changes in Internal Control over Financial Reporting

Except as discussed below, 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. Our plans for remediating the material weakness, described below, will result in changes in our internal control over financial reporting in future periods when such remediation plans are effectively implemented.

Material Weakness in Internal Control Over Financial Reporting

We determined that our control over the evaluation of applicable indirect taxes in local jurisdictions and assessment of indirect tax accrued liabilities was not appropriately designed. Specifically, we did not design a control to properly evaluate the indirect tax impact of our supply chain activities, and to review the completeness and accuracy of the underlying indirect tax obligation. As a result, a material misstatement in the Prior Financial Statements was not detected and we concluded that the control deficiency noted above represents a material weakness as of December 31, 2023 and in prior periods. This material weakness resulted in the restatement of our financial statements for the years ended December 31, 2021 and 2022, and the quarters ended March 31, 2022, June 30, 2022, September 30, 2022, March 31, 2023, June 30 2023, and September 30, 2023.

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.

Management's Remediation Plan

We have identified and begun to implement steps designed to remediate the foregoing material weakness. However, the material weakness cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

To remediate this material weakness, we are in the process of implementing a remediation plan, which includes additional training to existing staff, enhanced use of indirect tax consultants and experts, and controls over documentation of our indirect tax positions.

While the foregoing measures are intended to effectively remediate the material weakness described in this Item 9A, it is possible that additional remediation steps will be necessary. As such, as we continue to evaluate and implement our plan to remediate the material weakness, our management may decide to take additional measures to address the material weakness or modify the remediation steps described above. Until this material weakness is remediated, we plan to continue to perform additional analyses and other procedures to help ensure that our consolidated financial statements are prepared in accordance with GAAP.

Item 9B. Other Information.

On April 17, 2024 we received notice from the Listing Qualifications Staff of The Nasdaq Stock Market LLC (Nasdaq) advising us that our failure to timely file our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, or the 2023 Form 10-K, with the SEC, in contravention of Nasdaq Listing Rule 5250(c)(1) (the Filing Requirement), could serve as an additional basis for the delisting of our securities from Nasdaq.

We were provided with the opportunity and plans to timely submit our plan to evidence compliance with the Filing Requirement for consideration by the Nasdaq Hearings Panel (the Panel) indicating that we filed the 2023 Form 10-K with the SEC on April 22, 2024, and as announced on April 22, 2024, will implement a reverse stock split of our common stock at a ratio of 1-for-20 shares effective for marketplace purposes with the open of business on Wednesday, April 24, 2024.

As previously disclosed, by letter dated February 8, 2024, the Panel granted our request for continued listing on Nasdaq, subject to us regaining compliance with Nasdaq's $1.00 bid price requirement by May 7, 2024.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

INFORMATION REGARDING THE BOARD OF DIRECTORS AND CORPORATE GOVERNANCE

The Company's Board of Directors, or the Board, is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a three-year term. Vacancies on the Board may be filled only by persons elected by a majority of the remaining directors. A director elected by the Board to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified.

The Board presently has eight members. The names of the members of the Board, their respective ages, their positions with the Company and other biographical information as of April 12, 2024 are set forth below.

Directors Continuing in Office Until the 2024 Annual Meeting of Stockholders

Carin Canale-Theakston, 50, has served as a member of our Board since January 2021. Ms. Canale-Theakston currently serves as an executive biotech advisor for Inizio, a global healthcare commercialization firm that acquired Ms. Canale-Theakston's previous company, Canale Communications Inc., a life sciences communications company that she founded in May 2010. Prior to founding Canale Communications, Ms. Canale-Theakston served as President of the life sciences division of Porter Novelli, an international public relations firm, from May 2005 until May 2010. Prior to Porter Novelli, Ms. Canale-Theakston was a Partner and Managing Director of Atkins + Associates, a life sciences communication firm, from February 2000 until it was acquired by Porter Novelli in May 2005. Since January 2007, Ms. Canale-Theakston has served as a member and vice chair of the board of directors of Biocom and is currently chair of the nominating-governance committee. Ms. Canale-Theakston also currently serves on the board of directors of Peel Therapeutics, a private biotechnology company, on the board of managers for Life Science Cares San Diego, and on the advisory board for Abintus Bio, Inc., a private biotechnology company. Ms. Canale-Theakston holds a B.A. in communications and marketing from the University of Tulsa.

Our Board believes that Ms. Canale-Theakston's experience with business and communication strategies for life science companies provide her with the qualifications and skills to serve on our Board.

Timothy R. Franson, M.D., 72, has served as a member of our Board since March 2015. Currently, Dr. Franson is a Principal in Faegre Drinker Consulting, in the Health and FDA Practice sectors. From April 2014 to July 2019, Dr. Franson served as the Chief Medical Officer for YourEncore, Inc., a consultancy that helps global life sciences and consumer health companies accelerate new product pipelines and bring safer, more effective products to consumers. Dr. Franson was Vice President of Global Regulatory Affairs at Lilly Research Laboratories, a part of Eli Lilly and Company, or Eli Lilly, a publicly-traded pharmaceutical manufacturing company. He joined Eli Lilly and Company in 1986 and retired in 2008. Dr. Franson served as the President of the US Pharmacopeial Convention, which establishes drug quality standards enforced by regulators such as the FDA, from 2010 to 2015, and continued to serve on the organization's Board of Trustees, as immediate Past President until 2020. Dr. Franson previously served on the board of directors of Paratek Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company, or Paratek, from 2015 to 2023, and as past Chair of the Board of the Critical Path Institute from 2016 to 2021, which collaborates with FDA and industry in innovation advances. Dr. Franson has authored more than 50 articles in the fields of infectious disease, epidemiology, pharmacoeconomics and antibiotic utilization, as well as four book chapters relating to innovation policy topics. Dr. Franson currently serves as Adjunct Professor of Medicine in the Division of Clinical Pharmacology of the Indiana University School of Medicine. He also served as a director of Myrexis, Inc. (formerly Myriad Pharmaceuticals, Inc.), from 2010 to 2012. Dr. Franson holds a B.S. in pharmacy from Drake University and an M.D. from the University of Illinois, College of Medicine. He is Board Certified in Internal Medicine and Infectious Diseases.

Our Board believes that Dr. Franson's extensive expertise in the areas of pharmaceutical development and regulatory affairs provide him with the qualifications and skills to serve on our Board.

Chrysa Mineo, 59, has served as a member of our Board since March 2018. From 2009 to 2015, Ms. Mineo led corporate development at Receptos, Inc., or Receptos, a biotechnology company acquired in 2015 by Celgene Corporation, now a Bristol-Myers Squibb company. Prior to Receptos, from 1997 to 2009 Ms. Mineo held roles of increasing business development responsibility at Neurocrine Biosciences, Inc., or Neurocrine, a publicly-traded biotechnology company. Prior to Neurocrine, Ms. Mineo served in various capacities in research, marketing and business development for such companies as Amgen Inc., a publicly-traded biotechnology company, DNAX Research Institute, Schering-Plough Corporation, now a subsidiary of Merck & Co., Inc., a publicly-traded global health care company, and Baxter Biotech. Ms. Mineo holds a B.S. in Zoology from the University of California, Davis and an M.B.A. from Duke University's Fuqua School of Business. In addition, Ms. Mineo is a co-founder of Alume Biosciences, Inc., a private biotechnology company, a member of the Director's Council at the Scripps Institution of Oceanography, and a member of the Board of Directors at the San Diego Natural History Museum.

Our Board believes that Ms. Mineo's expertise and experience as an executive in the pharmaceutical industry, particularly with respect to evaluation and execution of strategic transactions, provide her with the qualifications and skills to serve on our Board.

Directors Continuing in Office Until the 2025 Annual Meeting of Stockholders

Jeffrey Stein, Ph.D., 68, has served as a member of our Board and as President and Chief Executive Officer since January 2014. In addition to serving on the board of Cidara, Dr. Stein is currently a director of Ideaya Biosciences (IDYA), a public precision medicine oncology company, and previously served as a director of Paratek from 2014 to 2023. Prior to co-founding Cidara, Dr. Stein was Chief Executive Officer of Trius Therapeutics from its founding in 2007 until its acquisition by Cubist Pharmaceuticals in September of 2013. Dr. Stein was also the founding Chairman and President of the Antibiotics Working Group. Previously, Dr. Stein was a Venture Partner and Kauffman Fellow with Sofinnova Ventures and opened the firm's San Diego office in 2005. Prior to joining Sofinnova, Dr. Stein was co-founder and Chief Scientific Officer of Quorex Pharmaceuticals which was acquired by Pfizer Pharmaceuticals in 2005. He has also served as a Principal Scientist with Diversa Corporation and the Agouron Institute. Dr. Stein conducted his postdoctoral research as an Alexander Hollaender Distinguished Postdoctoral Fellow at the California Institute of Technology and his graduate work as a NASA Graduate Student Researcher Fellow at UCSD.

Our Board believes that Dr. Stein's expertise and experience as our President and Chief Executive Officer, his perspective and experience as a founder and executive at public and private pharmaceutical companies and his expertise in life sciences and venture capital industries provide him with the qualifications and skills to serve on our Board.

Bonnie Bassler, Ph.D., 61, has served as a member of our Board since January 2021. Dr. Bassler also currently serves in several roles at Princeton University, including, Chair of the Department of Molecular Biology since 2013, associated faculty member of the Department of Chemistry since 2010, Investigator at the Howard Hughes Medical Institute since 2005, Professor in the Department of Molecular Biology since 1994, and associate faculty member of the Princeton Environmental Institute since 1996. Previously, Dr. Bassler served as the Director of the Council on Science and Technology at Princeton University from July 2008 to June 2013. Dr. Bassler currently serves as a board member of Royalty Pharma plc, a publicly-traded biopharmaceutical company, since June 2020, as a board member of Regeneron Pharmaceuticals, Inc. since 2016, a publicly-traded biotechnology company, and as a Trustee of the Alfred P. Sloan Foundation, since 2014. Dr. Bassler previously served as a board member of Kaleido Biosciences, Inc, a publicly-traded health care company, from 2018 to 2022, as a board member of Sanofi, a publicly-traded global health care company, from November 2014 to September 2016, and as a board member of the American Association for the Advancement of Science, from January 2012 to December 2016. She was a member of the National Science Board from January 2010 until May 2016. Dr. Bassler has been elected to the National Academy of Sciences, the National Academy of Medicine, and the Royal Society, among other honorific organizations. She received a B.S. in biochemistry from the University of California-Davis and a Ph.D. in biochemistry from the John Hopkins University.

Our Board believes that Dr. Bassler's expertise in molecular biology and experience serving on boards across academia and the biotech industry provide her with the qualifications and skills to serve on our Board.

David Gollaher, Ph.D., 74, has served as a member of our Board since September 2018. Dr. Gollaher was Senior Vice President of Policy and Government Affairs at Vir Biotechnology, Inc., a publicly-traded infectious disease company, between 2019 and 2021. From February 2014 to June 2018, he served as the head of global government affairs and policy for Gilead Sciences, Inc., a publicly-traded biopharmaceutical company, or Gilead. Before joining Gilead, Dr. Gollaher was cofounder and Chief Executive Officer of the California Healthcare Institute from 1993 to 2013. In 2018, Dr. Gollaher was appointed a Senior Fellow at the Leonard D. Schaeffer Center for Health Policy and Economics at the University of Southern California. He currently serves on the Board of Overseers for The Scripps Research Institute and on the board of Vision Robotics Corporation. Earlier in his career, Dr. Gollaher was a member of the History and Literature faculty at Harvard University and, subsequently, vice president at Scripps Clinic and Research Foundation, responsible for managed care, corporate strategy and public affairs. He earned his B.A. from the University of California Santa Barbara and his master's and Ph.D. degrees, concentrating in the history of science and medicine, from Harvard University.

Our Board believes that Dr. Gollaher's expertise and experience as an executive in the pharmaceutical industry, as a founder of a pharmaceutical company and his educational background provide him with the qualifications and skills to serve on our Board.

Directors Continuing in Office Until the 2026 Annual Meeting of Stockholders

Daniel Burgess, 62, has served as a member of our Board since April 2014. Mr. Burgess is currently Chairman and Chief Executive Officer of Pulmocide Ltd., a private biopharmaceutical company, a position he has held since May 2021. Mr. Burgess is currently President and Chief Executive Officer of Tripex Pharmaceuticals LLC, a private biopharmaceutical company, since December 2014. He is also a venture partner at SV Health Investors, a position he has held since June 2014. Mr. Burgess served as President and Chief Executive Officer of Therini Bio, Inc., a private biotechnology company, on a part-time basis from May 2019 to December 2021, and now serves as a board member. From June 2011 until its acquisition in December 2013 by The Medicines Company, now a subsidiary of Novartis AG, he was the co-founder, President and Chief Executive Officer of Rempex Pharmaceuticals, Inc., or Rempex, a private biopharmaceutical company. Prior to that, Mr. Burgess was President and Chief Executive Officer of Mpex Pharmaceuticals, Inc., or Mpex, a private biopharmaceutical company, from May 2007 until its acquisition by Aptalis Pharma Inc., now a subsidiary of Abbvie, Inc., a publicly-traded pharmaceutical company, in April 2011. Mr. Burgess currently serves as a director of Arbutus Biopharma Corporation, a publicly-traded biopharmaceutical company, since March 2017, Chairman of the board of Nabriva Therapeutics plc, or Nabriva, a formerly publicly-traded biopharmaceutical company, since June 2017, as well as a director of several private biotechnology companies. He is also Chairman of the Joint Oversight Board of CARB-X, a global non-profit partnership accelerating antibacterial products to address drug-resistant bacteria, on the board of advisors for Life Science Cares San Diego, and a board member of Biocom, the California life sciences trade association. Mr. Burgess holds a B.A. in economics from Stanford University and an M.B.A. from Harvard Business School.

Our Board believes Mr. Burgess's expertise and experience as an executive in the pharmaceutical industry and his educational background provide him with the qualifications and skills to serve on our Board.

Theodore R. Schroeder, 68, has served as a member of our Board since April 2014. From June 2015, Mr. Schroeder served as President, Chief Executive Officer and a member of the board of directors of Zavante Therapeutics, Inc., a private biopharmaceutical company that he founded, until its acquisition by Nabriva in July 2018, where he served as Chief Executive Officer until January 2023 and continues to serve as a member of the board of directors. Mr. Schroeder co-founded Cadence Pharmaceuticals, Inc., a publicly-traded biopharmaceutical company, in May 2004 and served as its President and Chief Executive Officer, and a member of the board of directors, until its acquisition in March 2014 by Mallinckrodt plc, a publicly-traded global biopharmaceutical company. From August 2002 to February 2004, Mr. Schroeder served as Senior Vice President, North American Sales and Marketing, of Elan Pharmaceuticals, Inc., or Elan, a neuroscience-based pharmaceutical company. From October 2000 to August 2002, Mr. Schroeder served as General Manager of the Hospital Products Business Unit at Elan. From May 1999 to October 2000, Mr. Schroeder held the position of Senior Director of Marketing Hospital Products at Dura Pharmaceuticals, Inc., or Dura, a specialty respiratory pharmaceutical and pulmonary drug delivery company, until its acquisition by Elan. Prior to joining Dura, Mr. Schroeder held several sales and marketing positions with Bristol-Myers Squibb Company, a global pharmaceutical company. Mr. Schroeder is the former chairman of Biocom, the California life sciences trade association. Mr. Schroeder served as a director of Otonomy, Inc., a public biopharmaceutical company, from August 2015 until January 2023, subsequent to Otonomy ceasing operations. He was the chairman of the board of the Antimicrobials Working Group, a not-for-profit 501(c)(6) organization, from May 2021 until the end of his term in December 2022. Mr. Schroeder previously served as a director of Collegium Pharmaceutical, a publicly-traded pharmaceutical company. He also served on the board of directors of Hyperion Therapeutics, Inc., Incline Therapeutics, Inc. and Trius Therapeutics, Inc. until their respective acquisitions. Mr. Schroeder received a B.S. in management from Rutgers University.

Our Board believes that Mr. Schroeder's expertise and experience as an executive in the pharmaceutical industry, as a founder of a pharmaceutical company and his educational background provide him with the qualifications and skills to serve on our Board.

Independence of the Board of Directors

As required under the Nasdaq Stock Market, or Nasdaq, listing standards, a majority of the members of a listed company's board of directors must qualify as "independent," as affirmatively determined by the board of directors. Our Board consults with the Company's counsel to ensure that the Board's determinations are consistent with relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and the Company, its senior management, and its independent auditors, the Board has affirmatively determined that all of our directors, except Dr. Stein who is not considered independent because he is an executive officer of the Company, are independent directors as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules. In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with the Company.

Board Leadership Structure

Daniel Burgess currently serves as the Chairman of our Board, and has authority, among other things, to call and preside over Board meetings, to set meeting agendas and to determine materials to be distributed to the Board. Accordingly, the Chairman has substantial ability to shape the work of the Board. We believe that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the Board in its oversight of our business and affairs. In addition, we have a separate chair for each committee of the Board. The chair of each committee is expected to report to the Board from time to time, or whenever so requested by the Board, on the activities of his or her committee in fulfilling its responsibilities as detailed in its respective charter or specify any shortcomings should that be the case. In addition, we believe that having a separate Chairman creates an environment that is more conducive to objective evaluation and oversight of management's performance, increasing management accountability and improving the ability of the Board to monitor whether management's actions are in the best interests of Cidara and our stockholders. As a result, we believe that having a separate Chairman can enhance the effectiveness of the Board as a whole.

Role of the Board in Risk Oversight

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board, as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure, and our Audit Committee has the responsibility to consider and discuss our major financial and other significant risk exposures, such as cybersecurity risk, and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee reviews cybersecurity risk, as part of its review of our cybersecurity framework, measures, tools, and compliance, on at least an annual basis. The Audit Committee also monitors compliance with legal and regulatory requirements. Our Nominating and Governance Committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our Compensation and Human Capital Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Diversity

The Board Diversity Matrix below presents the Board's diversity statistics in the format prescribed by Nasdaq rules.

Board Diversity Matrix (As of April 12, 2024)

Total Number of Directors	8			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	3	5	0	0
Part II: Demographic Background				
African American or Black	0	0	0	0
Alaskan Native or Native American	0	0	0	0
Asian	0	0	0	0
Hispanic or Latinx	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0
White	3	4	0	0
Two or More Races or Ethnicities	0	1	0	0
LGBTQ+			1	
Did not Disclose Demographic Background			0	

Commitment to Corporate Responsibility

As a company focused on improving the standard of care for patients facing serious diseases, we strive to identify ways to enhance and deliver on our commitment to patients, the medical community, our employees, our investors and our other stakeholders. Accordingly, we recognize the intersection between environmental, social and governance practices and these objectives. Given this, in 2023 we focused on the following areas:

Environmental Impact. We are cognizant of the impact we have on our broader environment and have supported several green measures in an effort to reduce our carbon footprint, including providing reusable dishes and cutlery to employees, and making available electric car chargers.

Social Impact. Our future performance depends significantly upon the continued service of our key scientific, technical and senior management personnel and our continued ability to attract and retain highly skilled employees. We provide our employees with competitive compensation, development programs that enable continued learning and growth and a robust employment package that promotes well-being across all aspects of their lives. In addition to salaries, these programs include potential annual discretionary bonuses, stock option and restricted stock unit awards, a 401(k) plan, healthcare and insurance benefits, flexible spending accounts, paid time off, family leave and flexible work schedules, among other benefits. We are committed to patients and to the communities in which we operate.

Diversity and Inclusion. We strive to invest in and create ongoing opportunities for employee development in a diverse and inclusive environment in which each team member plays a unique and vital role. We currently have three female directors (38%). We believe that a diverse workforce not only positively impacts our performance and strengthens our culture, but also cultivates an essential pipeline of experienced leaders for management. Hiring for diversity of skills, background and perspective, and diversity of personal characteristics such as age, gender, race and ethnicity continues to be an area of focus as we grow. As of April 12, 2024, women make up approximately 55% of our workforce. We are also committed to building a racially and ethnically diverse workforce. As of April 12, 2024, racially diverse employees (those self-identifying as Black or African American, Hispanic or Latino, Asian, or being two or more races) make up approximately 39% of our workforce.

Ethics and Corporate Governance. We aspire to maintain the highest standards of business conduct and ethics. All of our employees are required to adhere to our Code of Business Conduct and Ethics, which provides, among other things, that all of our employees, officers and directors must be honest and ethical both internally and in our business dealings, understanding that unyielding personal integrity is the foundation of corporate integrity.

Meetings of the Board of Directors

The Board met five times and acted by unanimous written consent seven times during 2023. All directors attended at least 75% of the aggregate number of meetings of the Board and of the committees on which they served during 2023.

In 2023, the Company's independent directors met four times in an executive session at which only independent directors were present.

INFORMATION REGARDING COMMITTEES OF THE BOARD OF DIRECTORS

The Board has an Audit Committee, a Compensation and Human Capital Committee and a Nominating and Governance Committee. The Board previously had a Science and Technology Committee which was decommissioned in December 2023. The Board has adopted a written charter for each committee all of which are available to stockholders on the Company's website at www.cidara.com. The information on our website is not incorporated by reference into this proxy statement or our Annual Report. The following table provides current membership information and fiscal year 2023 meeting and consent information for each of these committees of the Board:

Name	Audit	Compensation and Human Capital	Nominating and Corporate Governance
Bonnie Bassler, Ph.D.			X
Daniel Burgess	X*		X
Carin Canale-Theakston		X	
Timothy R. Franson, M.D.		X	X*
David Gollaher, Ph.D.			X
Chrysa Mineo	X	X	
Theodore R. Schroeder	X	X*	
Jeffrey Stein, Ph.D			
Total meetings and consents in 2023	4	4	1

* Committee Chairperson

Below is a description of each committee of the Board. Each of the committees has authority to engage legal counsel or other experts or consultants, as it deems appropriate to carry out its responsibilities. The Board has determined that each member of each committee meets the applicable rules and regulations regarding "independence" and that each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to the Company.

Audit Committee

The Audit Committee of the Board was established by the Board in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, to oversee the Company's corporate accounting and financial reporting processes and audits of its financial statements. For this purpose, the Audit Committee performs several functions, including, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law;
- prior to engagement of any independent auditor, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditor;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing, with our independent auditors and management, significant issues that arise regarding accounting principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness of our financial controls;
- reviewing with management and our independent auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-party transactions in accordance with our related-party transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing and discussing with management and our auditors, as appropriate, our guidelines and policies with respect to risk assessment and risk management, including our major financial risk exposures, and the steps taken by management to identify, monitor and control exposures to strategic, financial, operational, regulatory and other risks inherit in our business, such as cybersecurity risks and vulnerabilities;
- reviewing, on a periodic basis, our investment policy; and
- reviewing and evaluating, on an annual basis, the performance of the Audit Committee and the Audit Committee charter.

The Audit Committee is currently composed of three directors: Messrs. Burgess (Chair) and Schroeder and Ms. Mineo.

The Board reviews the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of the Company's Audit Committee are independent (as independence is currently defined in the applicable Nasdaq listing standards and Rule 10A-3 of the Exchange Act).

The Board has also determined that Mr. Burgess qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made a qualitative assessment of Mr. Burgess' level of knowledge and experience based on a number of factors, including his formal education and previous and current experience in financial roles.

Compensation and Human Capital Committee

The Compensation and Human Capital Committee of the Board was comprised of four directors for 2023: Mr. Schroeder (Chair), Dr. Franson and Mses. Canale-Theakston and Mineo. Our Board has determined that each of the members of our Compensation and Human Capital Committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act and satisfies the Nasdaq independence requirements.

The Compensation and Human Capital Committee acts on behalf of the Board to review, adopt or recommend to the Board for adoption, and oversee the Company's compensation strategy, policies, plans and programs. For this purpose, the Compensation and Human Capital Committee performs several functions, including, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board regarding) our overall compensation strategy and policies;
- making recommendations to the full Board regarding the compensation and other terms of employment of our Chief Executive Officer;
- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full Board regarding) the compensation and other terms of employment of our other executive officers;
- reviewing and making recommendations to the full Board regarding performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full Board regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full Board regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation to the extent required by Section 14A of the Exchange Act and, if applicable, determining our recommendations regarding the frequency of advisory votes on executive compensation;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisers as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to Cidara;
- review and discuss matters relating to human capital management, including the Company's policies and strategies regarding recruiting, retention, career development and progression, culture, diversity and inclusion, and other employment practices, including their implementation and effectiveness;
- overseeing our compensation clawback policy;
- reviewing with management and approving our disclosures under the caption "Compensation Discussion and Analysis" in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement; and
- reviewing and evaluating, on an annual basis, the performance of the Compensation and Human Capital Committee and the Compensation and Human Capital Committee charter.

Compensation and Human Capital Committee Processes and Procedures

Typically, the Compensation and Human Capital Committee meets approximately three to four times per year, with greater frequency if necessary. The agenda for each meeting is usually developed by the Chair of the Compensation and Human Capital Committee, in consultation with management. The Compensation and Human Capital Committee meets regularly in executive session. However, from time to time, various members of management and other employees as well as outside advisors or consultants may be invited by the Compensation and Human Capital Committee to make presentations, to provide financial or other background information or advice or to otherwise participate in Compensation and Human Capital Committee meetings. The Chief Executive Officer does not participate in, and is not present during, any deliberations or determinations of the Compensation and Human Capital Committee regarding his compensation. The

charter of the Compensation and Human Capital Committee grants the Compensation and Human Capital Committee full access to all books, records, facilities and personnel of the Company. In addition, under its charter, the Compensation and Human Capital Committee has the authority to obtain, at the expense of the Company, advice and assistance from internal and external legal, accounting or other advisers and other external resources that the Compensation and Human Capital Committee considers necessary or appropriate in the performance of its duties. The Compensation and Human Capital Committee has direct responsibility for the oversight of the work of any advisers engaged for the purpose of advising the Compensation and Human Capital Committee. In particular, the Compensation and Human Capital Committee has the sole authority to retain compensation consultants to assist in its evaluation of executive and director compensation, including the authority to approve the consultant's reasonable fees and other retention terms. Under its charter, to the extent required by SEC and Nasdaq rules, the Compensation and Human Capital Committee may select, or receive advice from, a compensation consultant, legal counsel or other adviser to the Compensation and Human Capital Committee, other than in-house legal counsel and certain other types of advisers, only after taking into consideration six factors, prescribed by the SEC and Nasdaq, that bear upon the adviser's independence; however, there is no requirement that any adviser be independent.

In 2023, the Company engaged Aon Consulting, Inc., or Aon, as its compensation consultant. Aon was retained to provide an assessment of the Company's executive and director compensation programs in comparison to executive and director compensation programs at selected publicly-traded peer companies. As part of its engagement, Aon was requested by the Compensation and Human Capital Committee to develop the peer group of comparative companies and to perform analyses of compensation levels for that group. Aon developed peer group and related recommendations that were presented to the Compensation and Human Capital Committee for its consideration.

The Compensation and Human Capital Committee holds one or more meetings during the first quarter of the year to discuss and make recommendations to the Board for annual compensation adjustments, annual bonuses, annual equity awards, and new corporate performance objectives. However, the Compensation and Human Capital Committee also considers matters related to individual compensation, such as compensation for new executive hires, as well as high-level strategic issues, such as the effectiveness of the Company's compensation strategy, potential modifications to that strategy and new trends, plans or approaches to compensation, at periodic meetings throughout the year on an as-needed basis. Generally, the Compensation and Human Capital Committee's process comprises two related elements: the determination of compensation levels and the establishment of performance objectives for the current year. For executives other than the Chief Executive Officer, the Compensation and Human Capital Committee solicits and considers evaluations and recommendations submitted to the Compensation and Human Capital Committee by the Chief Executive Officer. In the case of the Chief Executive Officer, the evaluation of his performance is conducted by the Compensation and Human Capital Committee, which determines recommendations to the Board regarding any adjustments to his compensation as well as awards to be granted. For all executives and directors as part of its deliberations, the Compensation and Human Capital Committee may review and consider, as appropriate, materials such as analyses of historical executive compensation levels and current Company-wide compensation levels, compensation data from comparative companies, compensation surveys, and recommendations of any compensation consultant, if applicable.

Nominating and Governance Committee

The Nominating and Governance Committee of the Board is responsible for identifying, reviewing and evaluating candidates to serve as directors of the Company (consistent with criteria approved by the Board), reviewing and evaluating incumbent directors, selecting or recommending to the Board for selection candidates for election to the Board, making recommendations to the Board regarding the membership of the committees of the Board, assessing the performance of the Board, and developing a set of corporate governance principles for the Company.

The Nominating and Governance Committee was comprised of four directors for 2023: Drs. Franson (Chair), Bassler and Gollaher and Mr. Burgess. All members of the Nominating and Governance Committee are independent (as independence is currently defined under applicable Nasdaq listing standards). The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our Board;
- determining the minimum qualifications for service on our Board;
- evaluating director performance on the Board and applicable committees of the Board and determining whether continued service on our Board is appropriate;
- nominating and recommending individuals for membership on our Board;
- evaluating nominations by stockholders of candidates for election to our Board;
- considering and assessing the independence of members of our Board;
- developing, if and when it deems appropriate, a set of corporate governance policies and principles and recommending to our Board any changes to such policies and principles;

- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and evaluating on an annual basis the performance of the Nominating and Governance Committee and the Nominating and Governance Committee charter.

The Nominating and Governance Committee believes that candidates for director should have certain minimum qualifications, including the ability to read and understand basic financial statements and possessing the highest personal integrity and ethics. The Nominating and Governance Committee also considers such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to the affairs of the Company, demonstrated excellence in his or her field, having the ability to exercise sound business judgment and having the commitment to rigorously represent the long-term interests of the Company's stockholders. However, the Nominating and Governance Committee retains the right to modify these qualifications from time to time. Candidates for director nominees are reviewed in the context of the current composition of the Board, the operating requirements of the Company and the long-term interests of stockholders. In conducting this assessment, the Nominating and Governance Committee typically considers diversity of skills, background and perspective (such as age, gender, race and specialized experience) and such other factors as it deems appropriate, given the current needs of the Board and the Company, to maintain a balance of knowledge, experience and capability. In the case of incumbent directors whose terms of office are set to expire, the Nominating and Governance Committee reviews these directors' overall service to the Company during their terms, including the number of meetings attended, level of participation, quality of performance and any other relationships and transactions that might impair the directors' independence. In the case of new director candidates, the Nominating and Governance Committee also determines whether the nominee is independent for Nasdaq purposes, which determination is based upon applicable Nasdaq listing standards, applicable SEC rules and regulations and the advice of counsel, if necessary. The Nominating and Governance Committee then compiles a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm. The Nominating and Governance Committee conducts any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. The Nominating and Governance Committee meets to discuss and consider the candidates' qualifications and selects candidates for recommendation to the Board by majority vote.

The Nominating and Governance Committee will consider director candidates recommended by stockholders. The Nominating and Governance Committee does not intend to alter the manner in which it evaluates candidates, including the minimum criteria set forth above, based on whether or not the candidate was recommended by a stockholder. Stockholders who wish to recommend individuals for consideration by the Nominating and Governance Committee to become nominees for election to the Board may do so by delivering a written recommendation to the Nominating and Governance Committee at the following address: Cidara Therapeutics, Inc., 6310 Nancy Ridge Drive, Suite 101, San Diego, CA 92121, Attn: Corporate Secretary, no later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting. Submissions must include the name and address of the Company stockholder on whose behalf the submission is made; the number of Company shares that are owned beneficially by such stockholder as of the date of the submission; the full name of the proposed candidate; a description of the proposed candidate's business experience for at least the previous five years; complete biographical information for the proposed candidate; and a description of the proposed candidate's qualifications as a director. Any such submission must be accompanied by the written consent of the proposed nominee to be named as a nominee and to serve as a director if elected.

Science and Technology Committee

In March 2021, our Board formed the Science and Technology Committee, which was comprised of four directors for 2023: Drs. Bassler (Chair), Franson, Gollaher and Stein. The Science and Technology Committee acted on behalf of our Board to, among other things, review and evaluate the Company's scientific research programs on behalf of our Board and make recommendations to our Board regarding strategic and tactical scientific issues and decisions regarding advancement of our technology. The functions of this committee included, among other things:

- developing and participating in a process for periodic review of our scientific research programs and technology;
- evaluating the long-term strategic value of the Company's scientific research programs and technology, making recommendations to the Board regarding acquisition, disposition and/or development of our scientific and technology assets and advising the Board on scientific aspects of business development matters;
- reviewing and evaluating on an annual basis the performance of the Science and Technology Committee and the Science and Technology Committee charter; and
- upon request, assisting in setting annual scientific research performance goals and assessing achievement of such goals.

In December 2023 the Science and Technology Committee was decommissioned.

CODE OF ETHICS

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.

EXECUTIVE OFFICERS

Jeffrey Stein, Ph.D. has served as our President, Chief Executive Officer and a member of our Board of Directors since January 2014. For additional information regarding Dr. Stein's industry experience and education, see above under "Directors Continuing in Office Until the 2025 Annual Meeting of Stockholders."

Taylor Sandison, M.D., 52, has been with Cidara since October 2015 and became our Chief Medical Officer in January 2017. Prior to joining the Company, he served as senior medical director at Merck and prior to that held the same position at Cubist Pharmaceuticals, Inc. Dr. Sandison has also held positions at Trius Therapeutics, Inc., a publicly-traded biopharmaceutical company, and Novartis Diagnostics, and served as a member of the faculty in the Department of Medicine at both Stanford University and the University of Washington. He received B.S. and B.A. degrees from Dartmouth College, M.D. and M.P.H. degrees from the University of Washington, and a Diploma in Tropical Medicine and Hygiene from the London School of Hygiene and Tropical Medicine. He completed internal medicine residency training at the University of Colorado and infectious diseases fellowship training at the University of Washington. Dr. Sandison currently holds board certifications in Infectious Diseases and Internal Medicine.

Preetam Shah, Ph.D., MBA, 51, has served as our Chief Financial Officer and Chief Business Officer since September 2021. Prior to joining the Company, Dr. Shah served as Executive Vice President, Chief Financial Officer and Treasurer at Brainstorm Cell Therapeutics, Inc., or Brainstorm, a publicly-traded biotechnology company, since September 2019. Prior to Brainstorm, Dr. Shah spent over six years as an investment banker advising healthcare companies on equity, debt and M&A transactions; holding senior roles at banks, including Barclays Capital PLC., from June 2016 to September 2019, and Canaccord Genuity Inc., from July 2013 to May 2016. From 2010 to 2013, Dr. Shah founded Saisarva LLC, a healthcare consulting firm. During this period, he also acted as a consultant for healthcare-focused private equity firms and hedge funds. From 2006 to 2009, Dr. Shah served as Vice President, U.S. Operations and Investments at Reliance Capital USA Ventures LLC, an affiliate of Reliance ADA Group Companies, where he was responsible for making early-stage venture investments in healthcare companies. Dr. Shah completed his post-doctoral fellowship in Infectious Diseases from Stanford University School of Medicine. He holds a Ph.D. in Microbiology from the University of Mississippi Medical Center, an M.B.A. in Finance from the Wharton School, University of Pennsylvania, and a B.A. in Mathematics and in Biology from McDaniel College.

Leslie Tari, Ph.D., 57, has served as our Chief Scientific Officer since July 2021. Previously, he served as our Senior Vice President, Research from March 2019 to July 2021, and as our Vice President, Discovery, from July 2014 to March 2019. Prior to joining Cidara, Dr. Tari held various leadership positions at Trius Therapeutics, Inc., a publicly-traded biopharmaceutical company, from March 2007 until its acquisition by Cubist Pharmaceuticals, Inc. in September 2013. Prior to Trius Therapeutics, Dr. Tari co-founded and served as a Director of Structural Biology at ActiveSight, Inc. from 2003 to 2007. From 2001 until 2003, Dr. Tari served as Associate Director of Structural Biology at Syrrx Inc. Dr. Tari also served as a Professor and Alberta Heritage Foundation Scholar for Medical Research at the University of Calgary from 1998 to 2001, where he conducted research focused on antibiotic discovery. Dr. Tari serves on the board of advisors of Life Science Cares San Diego. Dr. Tari received a B.S. degree in Chemistry and a Ph.D. in Chemistry and Structural Biology from the University of Manitoba.

Shane Ward, 49, has served as our Chief Operating Officer, Chief Legal Officer and Corporate Secretary since September 2022. Previously Mr. Ward served as our Chief Legal Officer and Corporate Secretary since August 2021. From December 2020 to August 2021, Mr. Ward was an independent biotechnology consultant. From May 2018 to December 2021, he served as the Chief Legal and Strategy Officer for Bellicum Pharmaceuticals, Inc. a publicly-traded biopharmaceutical company developing controllable cell therapies. Earlier in his career, Mr. Ward was a senior in-house attorney with commercial pharmaceutical companies Gilead Sciences, Abbott Laboratories and Human Genome Sciences. He began his legal career as an associate for the international law firm Sidley Austin LLP. Mr. Ward earned his B.A from the University of Virginia, and his J.D. from Georgetown University Law Center.

DELINQUENT SECTION 16(A) REPORTS

Section 16(a) of the Exchange Act requires the Company's directors and executive officers, and persons who own more than ten percent of a registered class of the Company's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file.

To the Company's knowledge, based solely on a review of the copies of such reports furnished to the Company and written representations that no other reports were required, during the fiscal year ended December 31, 2023, all Section 16(a) filing requirements applicable to its officers, directors and greater than ten percent beneficial owners were complied with, except for one Form 4 for Dr. Tari, an officer of the Company, relating to shares sold on January 12, 2023. The Form 4 was filed on January 27, 2023.

Item 11. Executive Compensation.

EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2023, which consist of our principal executive officer and our two other most highly compensated executive officers, are:

- Jeffrey Stein, Ph.D., our President and Chief Executive Officer;
- Taylor Sandison, M.D., M.P.H., our Chief Medical Officer; and
- Shane Ward, Chief Operating Officer, Chief Legal Officer and Corporate Secretary.

Summary Compensation Table

NAME AND PRINCIPAL POSITION	YEAR	SALARY	STOCK AWARDS (1)	OPTION AWARDS (2)	NON-EQUITY INCENTIVE PLAN COMPENSATION (3)	ALL OTHER COMPENSATION (4)	TOTAL
Jeffrey Stein, Ph.D. President and Chief Executive Officer	2023	$ 593,800	$ 274,468	$ 388,276	$ —	$ 9,900	$ 1,266,444
	2022	$ 565,500	$ 209,755	$ 173,943	$ 298,600	$ 9,150	$ 1,256,948
Taylor Sandison, M.D., M.P.H. Chief Medical Officer	2023	$ 487,100	$ 90,900	$ 128,592	$ —	$ 9,900	$ 716,492
	2022	$ 457,500	$ 41,635	$ 52,710	$ 165,400	$ 9,150	$ 726,395
Shane Ward Chief Operating Officer Chief Legal Officer and Corporate Secretary (5)	2023	$ 454,640	$ 127,934	$ 180,981	$ —	$ 9,900	$ 773,455

(1) The amount reported in this column for 2023 represents the aggregate grant date fair value of restricted stock unit awards granted during 2023 under our 2015 Plan, computed in accordance with ASC Topic 718. The assumptions used in calculating the grant date fair value of these equity awards reported in this column are set forth in Note 8 to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023. This amount does not reflect the actual economic value that may be realized by Drs. Stein and Sandison and Mr. Ward.

(2) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during 2023 computed in accordance with ASC 718. Assumptions used in the calculation of these amounts are included in Note 8 to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023. This amount does not reflect the actual economic value that may be realized by Drs. Stein and Sandison and Mr. Ward.

(3) Reflects amounts earned pursuant to our annual performance-based cash bonus program, amounts for fiscal year 2023 have not yet been determined. We expect to be able to determine the annual performance-based cash bonuses for each named executive officer by mid-2024.

(4) Represents Company 401(k) plan matching contributions to each named executive officer.

(5) Mr. Ward was not a named executive officer in 2022.

COMPENSATION PROGRAM OVERVIEW

Our compensation program for executive officers is designed to encourage our management team to achieve our short-term and long-term corporate objectives while effectively managing business risks and challenges. We provide what we believe is a competitive total compensation package to our management team through a combination of base salary, an annual performance-based bonus and long-term equity-based incentives.

The compensation of our named executive officers other than our Chief Executive Officer is generally determined and approved by the Compensation and Human Capital Committee of our Board, and the compensation of our Chief Executive Officer is approved by our Board based upon the recommendations of the Compensation and Human Capital Committee.

Annual Base Salary

Base salaries established for our named executive officers are paid to attract and retain talent and are set at a level that is commensurate with each executive's duties and authority, contributions, prior experience and sustained performance. The 2023 base salaries for our named executive officers were as follows:

NAME		2023 BASE SALARY
Jeffrey Stein, Ph.D.	$	593,800 (1)
Taylor Sandison, M.D., M.P.H.	$	487,100 (1)
Shane Ward	$	454,640 (1)

(1) Drs. Stein and Sandison and Mr. Ward received base salary increases in March 2023 which were applied retroactively to January 1, 2023.

Annual Bonus Opportunity

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our named executive officers to achieve defined annual corporate and individual goals and to reward them for achievement towards these goals. The annual performance-based bonus that each named executive officer is eligible to receive is generally based on the extent to which we achieve the corporate goals the Board establishes each year, the extent to which the executive achieves any related individual goals and each executive's target bonus opportunity.

The target bonus percentages that Drs. Stein and Sandison and Mr. Ward will be eligible for under the bonus plan for 2023 are 60%, 40% and 40% of their base salaries, respectively. Dr. Stein's bonus award will be weighted 100% for our achievement of corporate goals established by the Board. The bonus awards for Dr. Sandison and Mr. Ward will be weighted 80% for our achievement of corporate goals and 20% for achievement of individual goals approved by our Chief Executive Officer. Our corporate goals for 2023, established by our Board upon recommendation of the Compensation and Human Capital Committee, were a mix of clinical, research and development and financial goals. For our executive officers, including our named executive officers, the actual bonus award for any year, if any, may be more or less than the applicable target, depending primarily on the Board's determination of the extent to which we achieved the corporate goal component, and, other than for Dr. Stein, the executive's individual performance with respect to such corporate goals. There is no minimum bonus percentage or amount established for the named executive officers and, as a result, the bonus amounts vary from year to year based on corporate and/or individual performance. Payments under the bonus plan may be made in cash, through the issuance of stock, stock options or another form of equity award, or by a combination thereof. The Compensation and Human Capital Committee has the right to terminate or change the bonus plan at any time and for any reason.

Annual performance-based cash bonuses have not yet been determined for 2023. We expect to be able to determine the annual performance-based cash bonuses by mid-2024.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align the interests of our employees, including our named executive officers, with our stockholders' interests. The Compensation and Human Capital Committee is responsible for approving equity grants, other than those for our Chief Executive Officer and directors which are approved by our Board based upon the recommendation of the Compensation and Human Capital Committee. Our executives generally are awarded an initial new hire equity grant upon commencement of employment. Additional annual grants may also be made at the discretion of the Compensation and Human Capital Committee or Board in order to specifically incentivize executives with respect to achieving certain corporate goals, reward executives for exceptional performance, or to ensure executives' equity holdings are consistent with our compensation philosophy.

Prior to our initial public offering, we granted all equity awards pursuant to our 2013 Stock Option and Grant Plan, or the 2013 Plan. Upon and following our initial public offering, all equity awards are granted under our 2015 Equity Incentive Plan, or the 2015 Plan, and, starting in December 2020, new hire equity awards to individuals who were not previously employees or directors of the Company, may be granted under our 2020 Inducement Incentive Plan, or the 2020 Plan. The terms of our 2013 Plan, 2015 Plan and 2020 Plan are described below under "Equity Benefit Plans." All options are granted with a per share exercise price equal to the fair market value of a share of our common stock on the date of the grant of such award, as determined by the Compensation and Human Capital Committee or the Board. Generally, our new hire equity awards vest over a four-year period and our annual equity awards vest over a three-year period, in each case subject to the holder's continuous service to Cidara.

We granted annual equity awards to each of our named executive officers in March 2023. Our annual equity awards for Drs. Stein and Sandison and Mr. Ward consisted of stock options and RSUs. All stock options were granted and approved on the same date with an exercise price equal to the fair value of the Company's common stock on the date of grant. All stock options are time-based awards, which vest monthly, on a pro-rata basis, over three years, and have a term of ten years. The RSUs vest in three annual installments on March 10, 2024, 2025, and 2026, contingent on each officer's continued employment with the Company through the applicable vesting date.

Clawbacks

As a public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws as a result of misconduct, the Chief Executive Officer and Chief Financial Officer may be legally required to reimburse our Company for any bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of section 304 of the Sarbanes-Oxley Act of 2002, as amended. Additionally, we have implemented a Dodd-Frank Act-compliant clawback policy, as required by SEC rules.

As discussed elsewhere in this Annual Report on Form 10-K, on April 11 and April 15, 2024, the Audit Committee determined, based on management's recommendation, that our Prior Financial Statements filed with the SEC should no longer be relied upon and should be restated. We have restated the Prior Financial Statements in this Annual Report on Form 10-K. In accordance with our Incentive Compensation Recoupment Policy that was adopted on December 1, 2023, as required by the listing standards adopted pursuant to 17 CFR 240.10D–1, management concluded that recovery of erroneously awarded compensation was not required. This conclusion was reached because during the period relevant to the restatement, no compensation paid to our executives was granted, earned, or vested based wholly or in part upon the attainment of any measure that is determined and presented in accordance with the accounting principles used in preparing our financial statements.

Agreements with our Named Executive Officers

In September 2016 we entered into an amended and restated employment agreement with Dr. Stein. In March 2017 we entered into an employment agreement with Dr. Sandison. In August 2021 we entered into an employment agreement with Mr. Ward. The agreements govern the terms of their at-will employment with us and provide for certain severance and change of control benefits, the terms of which are described below under "—Potential Payments Upon Termination or Change of Control."

Potential Payments Upon Termination or Change of Control

Regardless of the manner in which a named executive officer's service terminates, the named executive officer is entitled to receive amounts earned during his term of service, including salary and unused vacation pay. In addition, each of our named executive officers is eligible to receive certain benefits pursuant to his agreement with us. The benefits described below are contingent on the officer's execution and non-revocation of a general release of claims against us and certain related parties.

Dr. Stein

In the event that we terminate the employment of Dr. Stein other than for cause or if Dr. Stein resigns with good reason, in each case as defined in Dr. Stein's amended and restated employment agreement, and provided such event occurs outside of the period beginning three months before and ending 12 months after a change of control transaction involving us, Dr. Stein will receive 12 months of salary, payable in a lump sum, and 12 months of health care benefits continuation at our expense.

In the event that we terminate the employment of Dr. Stein other than for cause or if Dr. Stein resigns with good reason, in each case as defined in Dr. Stein's amended and restated employment agreement, and provided such event occurs during the period beginning three months before and ending 12 months after a change of control transaction involving us, Dr. Stein will receive 18 months of salary, payable in a lump sum, 1.5 times the amount of Dr. Stein's target bonus level for the year in which the termination occurs, and 18 months of health care benefits continuation at our expense. In addition, all of Dr. Stein's unvested stock awards will immediately become vested on the date of termination.

In addition, in the event we undertake a change of control transaction in which Dr. Stein is subject to excise taxes under Section 280G of the Internal Revenue Code of 1986, as amended, or the Code, Dr. Stein will receive a gross-up payment, payable in a lump sum, to fully compensate Dr. Stein for any such taxes imposed by Section 280G of the Code.

Dr. Sandison and Mr. Ward

In the event that we terminate the employment of either Dr. Sandison or Mr. Ward other than for cause or if such executive resigns with good reason, in each case as defined in his employment agreement, and provided such event occurs outside of the period beginning three months before and ending 12 months after a change of control transaction involving us, such executive will receive nine months of salary, payable in a lump sum, and nine months of health care benefits continuation at our expense.

In the event we terminate the employment of either Dr. Sandison or Mr. Ward other than for cause or if such executive resigns with good reason, in each case as defined in his employment agreement, and provided such event occurs during the period beginning three months before and ending 12 months after a change of control transaction involving us, such executive will receive 12 months of salary, payable in a lump sum, an amount equal to his target bonus level for the year in which the termination occurs, and 12 months of health care benefits continuation at our expense. In addition, all of such executive's unvested stock awards will immediately become vested on the date of termination.

In addition, in the event we undertake a change of control transaction in which either Dr. Sandison or Mr. Ward is subject to excise taxes under Section 280G of the Code, Dr. Sandison and Mr. Ward, as applicable, will receive a gross-up payment, payable in a lump sum, to compensate such executive officer for any taxes imposed by Section 280G of the Code, provided that each such gross-up payment will be capped at $1.0 million.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth certain information regarding equity awards granted to our named executive officers that remain outstanding as of December 31, 2023:

			OPTION AWARDS [1]				STOCK AWARDS			
NAME	GRANT DATE	VESTING COMMENCEMENT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) EXERCISABLE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) UNVESTED AND UNEXERCISABLE	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE	NUMBER OF SHARES OR UNITS OF STOCK THAT HAVE NOT VESTED (#)	MARKET VALUE OF SHARES OR UNITS OF STOCK THAT HAVE NOT VESTED ($) [2]	EQUITY INCENTIVE PLAN AWARDS: NUMBER OF UNEARNED SHARES, UNITS, OR OTHER RIGHTS THAT HAVE NOT VESTED (#)	EQUITY INCENTIVE PLAN AWARDS: MARKET OR PAYOUT VALUE OF UNEARNED SHARES, UNITS OR OTHER RIGHTS THAT HAVE NOT VESTED ($) [2]
Jeffrey Stein, Ph.D.	9/9/2014 [3]	5/30/2014	153,443	—	$ 2.29	9/8/2024				
	2/19/2015 [4]	2/19/2015	205,511	—	$ 6.86	2/18/2025				
	3/16/2016 [4]	3/16/2016	159,000	—	$ 9.89	3/15/2026				
	3/31/2017 [4]	3/31/2017	220,000	—	$ 7.80	3/30/2027				
	3/29/2018 [4]	3/29/2018	235,000	—	$ 4.00	3/28/2028				
	3/21/2019 [4]	3/21/2019	265,000	—	$ 2.61	3/20/2029				
	3/19/2020 [4]	3/19/2020	330,000	—	$ 1.98	3/18/2030				
	3/17/2021 [4]	3/17/2021	481,250	43,750	$ 2.55	3/16/2031				
	3/31/2022 [4]	3/31/2022	192,500	137,500	$ 0.83	3/30/2032				
	3/31/2022 [9]	3/31/2022					108,900	$ 86,031		
	3/27/2023 [4]	3/27/2023	135,875	407,625	$ 1.01	3/26/2033				
	3/27/2023 [10]	3/27/2023					271,750	$ 214,683		
	9/18/2017 [5]								12,500	$ 9,875
Taylor Sandison, M.D., M.P.H.	3/29/2018 [4]	3/29/2018	70,000	—	$ 4.00	3/28/2028				
	3/21/2019 [4]	3/21/2019	65,000	—	$ 2.61	3/20/2029				
	12/18/2019 [6]	12/18/2019	61,925	—	$ 2.45	12/17/2026				
	12/18/2019 [7]	12/18/2019	4,075	—	$ 2.45	12/17/2026				
	3/19/2020 [4]	3/19/2020	145,000	—	$ 1.98	3/18/2030				
	3/17/2021 [4]	3/17/2021	132,917	12,083	$ 2.55	3/16/2031				
	9/30/2021 [8]	9/30/2021					50,200	$ 39,658		
	3/31/2022 [4]	3/31/2022	58,333	41,667	$ 0.83	3/30/2032				
	3/31/2022 [9]	3/31/2022					33,000	$ 26,070		
	3/27/2023 [4]	3/27/2023	45,000	135,000	$ 1.01	3/26/2033				
	3/27/2023 [10]	3/27/2023					90,000	$ 71,100		
Shane Ward	8/25/2021 [3] [11]	8/25/2021	145,833	104,167	$ 2.16	8/24/2031				
	3/31/2022 [4]	3/31/2022	40,833	29,167	$ 0.83	3/30/2032				
	3/31/2022 [9]	3/31/2022					23,100	$ 18,249		
	3/27/2023 [4]	3/27/2023	63,333	190,000	$ 1.01	3/26/2033				
	3/27/2023 [10]	3/27/2023					126,667	$ 100,067		

(1) Options granted prior to April 2015 were granted under the 2013 Plan, and options granted after April 2015 were granted under the 2015 Plan. Options granted under the 2013 Plan are immediately exercisable subject to a repurchase right held by us, which lapses as the shares vest. Options granted under the 2015 Plan become exercisable as they vest. The terms of the 2013 Plan and 2015 Plan are described below under "Equity Benefit Plans." All equity award vesting is subject to continued service of the executive.

(2) The amount shown is determined by multiplying the number of unvested restricted stock units, or RSUs, and performance restricted stock units, or PRSUs, by $0.79, the closing price of the Company's common stock on December 29, 2023, the last trading day of the Company's fiscal year.

(3) Stock options have a four-year vesting schedule, with 25% vesting on the one-year anniversary of the vesting commencement date, and monthly thereafter in equal increments over the remaining 36 months.

(4) Stock options have a three-year vesting schedule, vesting in equal monthly increments.

(5) Awards include PRSUs that are subject to performance-based vesting conditions and are scheduled to vest on the achievement of various clinical and corporate milestones, subject to the officer's continued service with the Company through the satisfaction of such performance conditions. As of December 31, 2023, none of the performance criteria underlying these PRSUs have been achieved.

(6) Represents stock options granted in our 2019 Option Exchange described in our proxy statement for our 2020 Annual Meeting of Stockholders, which vested in full on the first anniversary of the grant date.

(7) Represents stock options granted in our 2019 Option Exchange, which vest over three years, with 1/3 vesting on the one-year anniversary of the vesting commencement date, and monthly thereafter in equal increments over the remaining 24 months.

(8) Represents RSUs that are subject to time-based vesting conditions and are scheduled to vest in three equal installments on September 10, 2022, 2023 and 2024, contingent on the officer's continued service with the Company through the applicable vesting date.

(9) Represents RSUs that are subject to time-based vesting conditions and are scheduled to vest in three equal installments on March 10, 2023, 2024 and 2025, contingent on the officer's continued service with the Company through the applicable vesting date.

(10) Represents RSUs that are subject to time-based vesting conditions and are scheduled to vest in three equal installments on March 10, 2024, 2025 and 2026, contingent on the officer's continued service with the Company through the applicable vesting date.

(11) Options were granted under the 2020 Plan and become exercisable as they vest. The terms of the 2020 Plan are described below under "Equity Benefit Plans." All equity award vesting is subject to continued service of the executive.

Option Repricings

We did not engage in any repricings, modifications or cancellations of any of our named executive officers' outstanding equity awards during the year ended December 31, 2023.

Perquisites: Health, Welfare and Retirement Benefits

All of our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, group life, disability and accidental death and dismemberment insurance plans, in each case on the same basis as our other employees. We also provide a 401(k) plan to our employees, including our named executive officers, as discussed in the section below entitled "401(k) Plan."

We do not provide any other perquisites or personal benefits to our named executive officers. We do, however, pay the premiums for term life insurance and disability insurance for all of our employees, including our current named executive officers.

401(k) Plan

We maintain a defined contribution employee retirement plan, or the 401(k) Plan, for our employees. Our named executive officers are eligible to participate in the 401(k) Plan on the same basis as our other employees. The 401(k) Plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The 401(k) plan provides that each participant may contribute a portion of his or her eligible compensation, up to the statutory annual limit, which was $22,500 for employees under age 50 and was $30,000 for employees age 50 and over in 2023. All contributions made by participants are either pre-tax contributions or after-tax "Roth 401(k) contributions," as elected by the participant. The plan permits us to make discretionary contributions, including matching contributions and discretionary profit-sharing contributions. In 2024 we made an employer matching contribution for 2023 employee pre-tax and Roth 401(k) contributions of fifty cents for every employee dollar electively deferred under the 401(k) Plan, limited to six percent of the participant's compensation and further subject to any limitations set forth by the Internal Revenue Service. The 401(k) Plan currently does not offer the ability to invest in Cidara's securities.

Nonqualified Deferred Compensation

None of our named executive officers participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. The Board may elect to provide our officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Tax Deductibility of Executive Compensation

Under Section 162(m) of the Code, or Section 162(m), compensation paid to each of our "covered employees" that exceeds $1.0 million per taxable year is generally non-deductible unless the compensation qualifies for certain grandfathered exceptions (including the "performance-based compensation" exception) for certain compensation paid pursuant to a written binding contract in effect on November 2, 2017 and not materially modified on or after such date.

Although the Compensation and Human Capital Committee will continue to consider tax implications as one factor in determining executive compensation, the Compensation and Human Capital Committee also looks at other factors in making its decisions and retains the flexibility to provide compensation for the Company's named executive officers in a manner consistent with the goals of the Company's executive compensation program and the best interests of the Company and its stockholders, which may include providing for compensation that is not deductible by the Company due to the deduction limit under Section 162(m). The Compensation and Human Capital Committee also retains the flexibility to modify compensation that was initially intended to be exempt from the deduction limit under Section 162(m) if it determines that such modifications are consistent with the Company's business needs.

EQUITY BENEFIT PLANS

2020 Inducement Incentive Plan

Our Board adopted the 2020 Plan in December 2020.

Eligible Award Recipients. Grantees under the 2020 Plan must be 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.

Stock Awards. The 2020 Plan provides for the grant of nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards to eligible employees as an inducement material to such persons entering into employment with the Company.

Administration. Our Board administers the 2020 Plan. Awards may be granted under the 2020 Plan by either a majority of the Board's independent members or the independent members of the Compensation and Human Capital Committee. Subject to the terms of the 2020 Plan, our Board or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and the vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2020 Plan. Subject to the terms of our 2020 Plan, the plan administrator may not reduce the exercise, purchase or strike price of any outstanding stock award, but may cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. Nonstatutory stock options, or NSOs, are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2020 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2020 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2020 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Restricted Stock Unit Awards. RSU awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. RSU awards may be granted in consideration for any form of legal consideration. An RSU award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by an RSU award. Except as otherwise provided in the applicable award agreement, RSUs that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination at or prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as the Board may deem appropriate; or
- make a payment equal to the excess of (1) the value of the property the participant would have received upon exercise of the stock award over (2) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2020 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our consolidated assets, (2) a sale or other disposition of at least 90% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change of Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. For example, certain of our employees may receive an award agreement that provides for vesting acceleration upon the individual's termination without cause or resignation for good reason (including a material reduction in the individual's base salary, duties, responsibilities or authority, or a material relocation of the individual's principal place of employment with us) in connection with a change of control. Under the 2020 Plan, a change of control is generally (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (2) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; or (3) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

Amendment and Termination. Our Board has the authority to amend, suspend, or terminate our 2020 Plan, subject to stockholder approval.

2015 Equity Incentive Plan

Our Board adopted the 2015 Plan in March 2015 and our stockholders approved the 2015 Plan in April 2015. The 2015 Plan became effective upon the execution and delivery of the underwriting agreement related to our initial public offering. Once the 2015 Plan became effective, no further grants were made under the 2013 Plan.

Stock Awards. The 2015 Plan provides for the grant of incentive stock options, or ISOs, NSOs, stock appreciation rights, restricted stock awards, RSUs, performance-based stock awards, and other forms of equity compensation, or collectively, stock awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2015 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

Administration. Our Board, or a duly authorized committee thereof, has the authority to administer the 2015 Plan. Our Board may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain stock awards, and (2) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2015 Plan, our Board or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and the vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2015 Plan. Subject to the terms of our 2015 Plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2015 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2015 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2015 Plan, up to a maximum of ten years. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of shares of our common stock previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Restricted Stock Unit Awards. RSU awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. RSU awards may be granted in consideration for any form of legal consideration. An RSU award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by an RSU award. Except as otherwise provided in the applicable award agreement, RSUs that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

- arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the stock award and provide for its termination at or prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as the Board may deem appropriate; or
- make a payment equal to the excess of (1) the value of the property the participant would have received upon exercise of the stock award over (2) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2015 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our consolidated assets, (2) a sale or other disposition of at least 90% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change of Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. For example, certain of our employees may receive an award agreement that provides for vesting acceleration upon the individual's termination without cause or resignation for good reason (including a material reduction in the individual's base salary, duties, responsibilities or authority, or a material relocation of the individual's principal place of employment with us) in connection with a change of control. Under the 2015 Plan, a change of control is generally (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (2) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; or (3) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets.

Amendment and Termination. Our board of directors has the authority to amend, suspend, or terminate our 2015 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the tenth anniversary of the date our Board adopted our 2015 Plan.

2013 Stock Option Plan

Our Board initially adopted and our stockholders approved the 2013 Plan in February 2013. The 2013 Plan provides for the grant of stock options (ISOs and NSOs), restricted stock awards, unrestricted stock awards and RSU awards to our employees, directors, and consultants. Only stock options were awarded under the 2013 Plan. Our Board, or a duly authorized committee thereof, has the authority to administer the 2013 Plan. Subject to the terms of the 2013 Plan, our Board determined recipients, dates of grant, the number of and types of awards granted and the terms and conditions of awards made, including any applicable vesting schedule. Awards under the 2013 Plan were granted pursuant to award agreements adopted by the plan administrator. No additional awards may be granted under the 2013 Plan. However, any outstanding awards already granted under the 2013 Plan will remain outstanding, subject to the terms of such plan and the applicable award agreements, until such outstanding awards are exercised or until they terminate or expire by their terms.

2015 Employee Stock Purchase Plan

Our Board adopted the 2015 Employee Stock Purchase Plan, or the ESPP, in March 2015 and our stockholders approved the ESPP in April 2015. The ESPP became effective immediately upon the execution and delivery of the underwriting agreement related to our initial public offering. The purpose of the ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

Administration. Our Board has delegated its authority to administer the ESPP to our Compensation and Human Capital Committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our Board, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (1) 85% of the fair market value of a share of our common stock on the first date of an offering or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

Corporate Transactions. In the event of certain significant corporate transactions, including the consummation of: (1) a sale of all our assets, (2) the sale or disposition of 90% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued

or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately.

Plan Amendments, Termination. Our Board has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides certain information with respect to all of the Company's equity compensation plans in effect as of December 31, 2023.

Equity Compensation Plan Information

Plan Category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights		(b) Weighted-average exercise price of outstanding options, warrants and rights [3]	(c) Number of securities remaining available for issuance under equity compensation plans, excluding securities reflected in column (a) [4]
Equity compensation plans approved by security holders:	11,785,218	[1]	$ 2.26	4,072,069
Equity compensation plans not approved by security holders:	978,850	[2]	$ 1.86	327,150
Total	12,764,068			4,399,219

(1) Includes 9,814,165 shares subject to outstanding stock options and 1,971,053 shares subject to outstanding RSUs under our 2015 Plan and 2013 Plan.

(2) Includes 851,850 shares subject to outstanding stock options and 127,000 shares subject to outstanding RSUs under our 2020 Plan.

(3) The weighted-average exercise price is calculated based solely on the exercise prices of the outstanding stock options and does not reflect the shares that will be issued upon the vesting of outstanding awards of RSUs or PRSUs, which have no exercise price.

(4) Includes our 2013 Plan, 2015 Plan, 2020 Plan, and our ESPP. 987,756 shares in "Equity compensation plans approved by security holders" under column (c) were subject to purchase under our ESPP.

PAY VERSUS PERFORMANCE

We are providing the following information about the relationship between executive compensation actually paid and certain financial performance of our company as required by Section 953(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act and Item 402(v) of Regulation S-K. The disclosure included in this section is prescribed by SEC rules and does not necessarily align with how the Company or the Compensation and Human Capital Committee view the link between the Company's performance and named executive officer, or NEO, pay. This disclosure is intended to comply with the requirements of Item 402(v) of Regulation S-K applicable to "smaller reporting companies." For additional information about our compensation philosophy and how we seek to align executive compensation with the Company's performance, refer to "Executive and Director Compensation" section above.

Required Tabular Disclosure of Pay Versus Performance

The amounts set forth below under the headings "Compensation Actually Paid to PEO" and "Average Compensation Actually Paid to Non-PEO NEOs" have been calculated in a manner consistent with Item 402(v) of Regulation S-K. Use of the term "compensation actually paid" is required by the SEC's rules and as a result of the calculation methodology required by the SEC, such amounts differ from compensation actually received by the individuals and the compensation decisions described in the "Executive and Director Compensation" section above. Our Chief Executive Officer is our principal executive officer and is referred to as PEO in the headers in the following tables.

Year	Summary Compensation Table Total for PEO [1]	Compensation Actually Paid to PEO [2]	Average Summary Compensation Table Total for Non-PEO NEOs [3]	Average Compensation Actually Paid to Non-PEO NEOs [4]	Value of Initial Fixed $100 Investment Based on Total Stockholder Return ("TSR") [5]	Net Loss (thousands) [6]
(a)	(b)	(c)	(d)	(e)	(f)	(g)
2023	$ 1,266,444	$ 1,309,657	$ 744,974	$ 745,897	$ 39.70	$ (22,931)
2022	$ 1,256,948	$ 1,040,138	$ 705,055	$ 594,360	$ 37.82	$ (33,584)
2021	$ 1,630,620	$ 1,140,100	$ 1,090,413	$ 806,943	$ 63.50	$ (46,288)

(1) The dollar amounts reported in column (b) are the amounts of total compensation reported for Dr. Stein for each corresponding year in the "Total" column of the Summary Compensation Table. Refer to "Executive and Director Compensation—Summary Compensation Table".

(2) The dollar amounts reported in column (c) represent the amount of "compensation actually paid" to Dr. Stein, as computed in accordance with Item 402(v) of Regulation S-K. The dollar amounts do not reflect the actual amount of compensation earned by or paid to Dr. Stein during the applicable year. In accordance with the requirements of Item 402(v) of Regulation S-K, the following adjustments were made to Dr. Stein's total compensation for each year to determine the compensation actually paid:

Year	Reported Summary Compensation Table Total for PEO	Subtract: Reported Value of Equity Awards [a]	Add: Equity Award Adjustments [b]	Compensation Actually Paid to PEO
2023	$ 1,266,444	$ 662,744	$ 705,957	$ 1,309,657
2022	$ 1,256,948	$ 383,698	$ 166,888	$ 1,040,138
2021	$ 1,630,620	$ 794,220	$ 303,700	$ 1,140,100

(a) The grant date fair value of equity awards represents the sum of the totals of the amounts reported in the "Stock Awards" and "Option Awards" columns in the Summary Compensation Table for the applicable year.

(b) The equity award adjustments for each applicable year include the addition (or subtraction, as applicable) of the following: (i) the year-end fair value of any equity awards granted in the applicable year that are outstanding and unvested as of the end of the year; (ii) the amount of change as of the end of the applicable year (from the end of the prior fiscal year) in fair value of any awards granted in prior years that are outstanding and unvested as of the end of the applicable year; (iii) for awards that are granted and vest in same applicable year, the fair value as of the vesting date; (iv) for awards granted in prior years that vest in the applicable year, the amount equal to the change as of the vesting date (from the end of the prior fiscal year) in fair value; (v) for awards granted in prior years that are determined to fail to meet the applicable vesting conditions during the applicable year, a deduction for the amount equal to the fair value at the end of the prior fiscal year; and (vi) the dollar value of any dividends or other earnings paid on stock or option awards in the applicable year prior to the vesting date that are not otherwise reflected in the fair value of such award or included in any other component of total compensation for the applicable year. The amounts deducted or added in calculating the equity award adjustments are as follows:

Year	Add: Year End Fair Value of Outstanding and Unvested Equity Awards Granted in the Year	Add: Year over Year Change in Fair Value of Outstanding and Unvested Equity Awards Granted in Prior Years	Add: Fair Value as of Vesting Date of Equity Awards Granted and Vested in the Year	Add: Year over Year Change in Fair Value of Equity Awards Granted in Prior Years that Vested in the Year	Subtract: Fair Value at the End of the Prior Year of Equity Awards that Failed to Meet Vesting Conditions in the Year	Add: Value of Dividends or other Earnings Paid on Stock or Option Awards not Otherwise Reflected in Fair Value or Total Compensation	Total Equity Award Adjustments
2023	$ 438,873	$ 16,849	$ 88,719	$ 161,515	—	$ —	$ 705,957
2022	$ 243,913	$ (76,495)	$ 102,459	$ (102,990)	—	$ —	$ 166,888
2021	$ 225,505	$ (90,254)	$ 119,488	$ 48,961	—	$ —	$ 303,700

(3) The dollar amounts reported in column (d) represent the average of the amounts reported for our company's named executive officers as a group (excluding our PEO) in the "Total" column of the Summary Compensation Table in each applicable year. The names of each of the named executive officers (excluding our PEO) included for purposes of calculating the average amounts in each applicable year are as follows: for 2023, Dr. Sandison and Mr. Ward, for 2022, Drs. Sandison and Shah, and for 2021, Drs. Sandison and Tari.

(4) The dollar amounts reported in column (e) represent the average amount of "compensation actually paid" to the named executive officers as a group (excluding our PEO), as computed in accordance with Item 402(v) of Regulation S-K. The dollar amounts do not reflect the actual average amount of compensation earned by or paid to the named executive officers as a group (excluding our PEO) during the applicable year. In accordance with the requirements of Item 402(v) of Regulation S-K, the following adjustments were made to average total compensation for the named executive officers as a group (excluding our PEO) for each year to determine the compensation actually paid, using the same methodology described above in Note (2):

Year	Average Reported Summary Compensation Table Total for Non-PEO NEOs	Subtract: Average Reported Value of Equity Awards	Add: Average Equity Award Adjustments[(a)]	Average Compensation Actually Paid to Non-PEO NEOs
2023	$ 744,970	264,200	265,127	745,897
2022	$ 705,055	100,105	(10,590)	594,360
2021	$ 1,090,413	548,438	264,968	806,943

(a) The amounts deducted or added in calculating the total average equity award adjustments are as follows:

Year	Add: Average Year End Fair Value of Outstanding and Unvested Equity Awards Granted in the Year	Add: Year over Year Average Change in Fair Value of Outstanding and Unvested Equity Awards Granted in Prior Years	Add: Average Fair Value as of Vesting Date of Equity Awards Granted and Vested in the Year	Add: Year over Year Average Change in Fair Value of Equity Awards Granted in Prior Years that Vested in the Year	Subtract: Average Fair Value at the End of the Prior Year of Equity Awards that Failed to Meet Vesting Conditions in the Year	Add: Average Value of Dividends or other Earnings Paid on Stock or Option Awards not Otherwise Reflected in Total Fair Value or Total Compensation	Average Equity Award Adjustments
2023	$ 174,959	5,926	35,368	48,880	— $	— $	265,127
2022	$ 74,837	(67,038)	13,815	(32,204)	— $	— $	(10,590)
2021	$ 255,936	(35,111)	32,408	11,744	— $	— $	264,968

(5) TSR is determined based on the value of an initial fixed investment of $100 on December 31, 2020. Cumulative TSR reported in column (f) is calculated by dividing the sum of the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and the difference between our company's share price at the end and the beginning of the measurement period by our company's share price at the beginning of the measurement period. No dividends were paid on stock or option awards in 2023, 2022 or 2021.

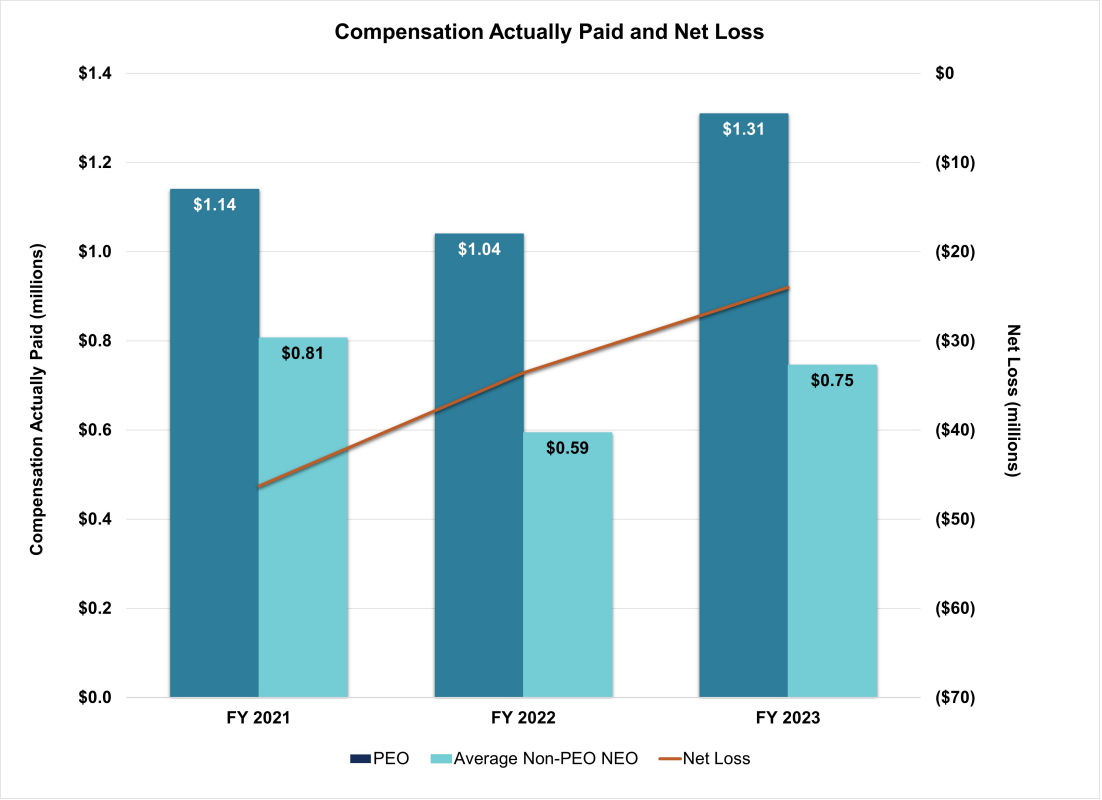
(6) The dollar amounts reported in column (g) represent the amount of net loss reflected in our consolidated audited financial statements for the applicable years, as restated for 2022 and 2021.

Required Disclosure of the Relationship Between Compensation Actually Paid and Financial Performance Measures

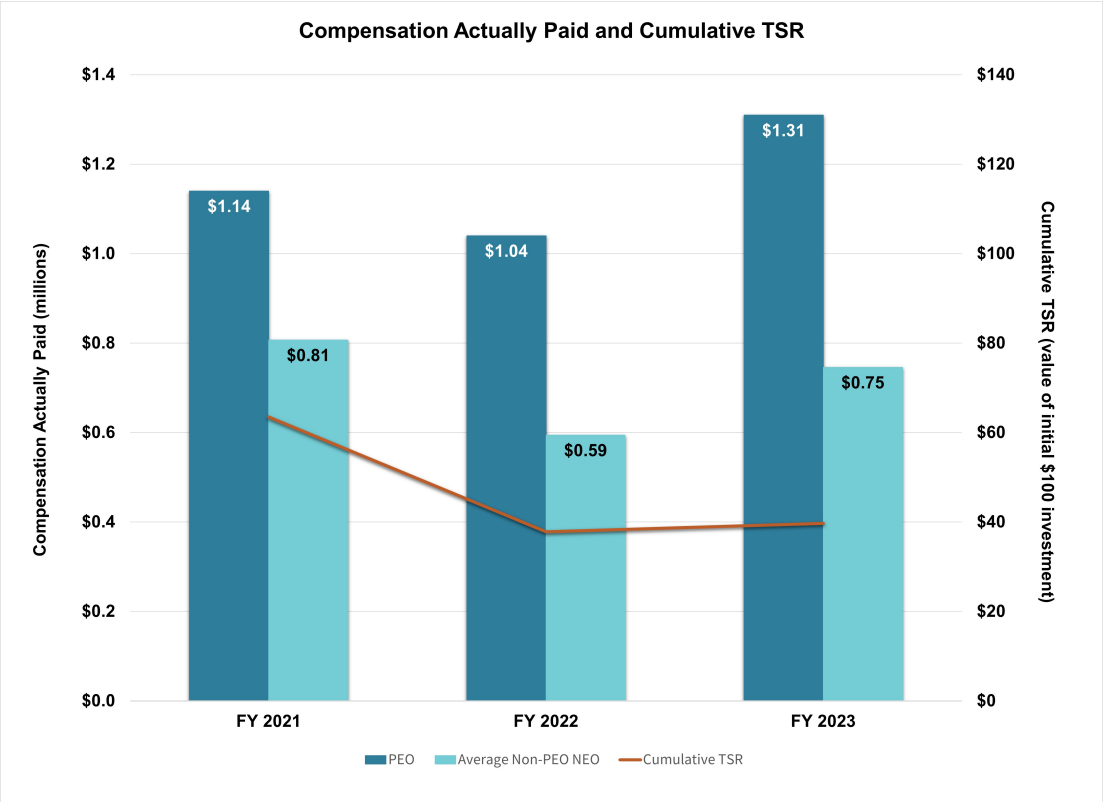
We generally seek to incentivize long-term performance, and therefore do not specifically align our performance measures with "compensation actually paid" (as computed in accordance with Item 402(v) of Regulation S-K) for a particular year. In accordance with Item 402(v) of Regulation S-K, we are providing the following descriptions of the relationships between information presented in the Pay Versus Performance table.

Compensation Actually Paid and Net Loss

We had revenue in 2023, 2022 or 2021 associated with the Company's collaboration agreements with Mundipharma Medical Company, or Mundipharma, and Janssen Pharmaceuticals, Inc., and license agreement with Melinta Therapeutics, LLC, or Melinta, as well as revenue in 2023 associated with commercial supply of REZZAYO® shipped to Mundipharma, our licensee outside the U.S. and Japan, and Melinta, our licensee in the U.S. Consequently, we do not use net loss as a performance measure in our executive compensation program. Moreover, with only limited license, partnership and commercial supply revenue, we do not believe there is any meaningful relationship between our net loss and compensation actually paid to our NEOs during the periods presented. Our net loss was $22.9 million in 2023, $33.6 million in 2022, as restated, and $46.3 million in 2021, as restated.



Compensation Actually Paid and Cumulative TSR



All information provided above under the "Item 402(v) Pay Versus Performance" heading will not be deemed to be incorporated by reference in any filing of our company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing, except to the extent the Company specifically incorporates such information by reference.

NON-EMPLOYEE DIRECTOR COMPENSATION

We maintain a non-employee director compensation policy approved by our Board based on the recommendation of the Compensation and Human Capital Committee. The policy originally became effective in 2015 and was amended by the Board, upon the recommendation of the Compensation and Human Capital Committee, in December 2016, in December 2019, in December 2020, in March 2021 (added Science and Technology Committee compensation), in December 2021, in December 2022, and in December 2023.

The policy, as amended in December 2023, provides that each non-employee director will receive the following compensation for service on the Board:

- an annual cash retainer of $40,000, or $70,000 for the Chairman of the Board;
- an additional annual cash retainer of $9,000, $7,500 and $4,000 for service as a member of the Audit Committee, Compensation and Human Capital Committee, and Nominating and Governance Committee, respectively;
- an additional annual cash retainer of $18,000, $15,000 and $8,000 for service as Chairman of the Audit Committee, Compensation and Human Capital Committee, and Nominating and Governance Committee, respectively (in lieu of the committee member retainer above);

- an initial option grant to purchase 85,000 shares of our common stock on the date of each non-employee director's initial appointment to the Board, with 1/3rd of the shares vesting on the first anniversary of the date of grant and the remaining shares vesting in equal monthly installments over the next two years, subject to acceleration of vesting in full upon a change of control; and
- an annual option grant to purchase 42,500 shares of our common stock on the date of each of our annual stockholder meetings, which vests in one installment on the earlier of the first anniversary of the date of grant and the day prior to the date of our first annual stockholder meeting held after the date of grant, subject to acceleration of vesting in full upon a change of control.

The policy in place during 2023 until amendment in December 2023 provided that each non-employee director would receive the following compensation for service on the Board:

- an annual cash retainer of $40,000, or $70,000 for the Chairman of the Board;
- an additional annual cash retainer of $9,000, $7,500, $4,000 and $4,000 for service as a member of the Audit Committee, Compensation and Human Capital Committee, Nominating and Governance Committee, and Science and Technology Committee, respectively;
- an additional annual cash retainer of $18,000, $15,000, $8,000 and $8,000 for service as Chairman of the Audit Committee, Compensation and Human Capital Committee, Nominating and Governance Committee, and Science and Technology Committee, respectively (in lieu of the committee member retainer above);
- an initial option grant to purchase 85,000 shares of our common stock on the date of each non-employee director's initial appointment to the Board, with 1/3rd of the shares vesting on the first anniversary of the date of grant and the remaining shares vesting in equal monthly installments over the next two years, subject to acceleration of vesting in full upon a change of control; and
- an annual option grant to purchase 42,500 shares of our common stock on the date of each of our annual stockholder meetings, which vests in one installment on the earlier of the first anniversary of the date of grant and the day prior to the date of our first annual stockholder meeting held after the date of grant, subject to acceleration of vesting in full upon a change of control.

We provide reimbursement to all of our non-employee directors for their travel, lodging and other reasonable expenses incurred in attending meetings of the Board and committees of the Board.

The following table sets forth in summary form information concerning the compensation that was earned by each of our non-employee directors during the year ended December 31, 2023:

NAME	FEES EARNED OR PAID IN CASH	OPTION AWARDS ($)[1]	TOTAL ($)
Bonnie Bassler, Ph.D.	$ 52,000	$ 34,837	$ 86,837
Daniel Burgess	$ 92,000	$ 34,837	$ 126,837
Carin Canale-Theakston	$ 47,500	$ 34,837	$ 82,337
Timothy R. Franson, M.D.	$ 59,500	$ 34,837	$ 94,337
David Gollaher, Ph.D.	$ 48,000	$ 34,837	$ 82,837
Chrysa Mineo	$ 56,500	$ 34,837	$ 91,337
Theodore R. Schroeder	$ 64,000	$ 34,837	$ 98,837

(1) The amounts reported reflect the aggregate grant date fair value of each equity award granted to our non-employee directors during the fiscal year ended December 31, 2023, as computed in accordance with FASB ASC 718. Assumptions used in the calculation of these amounts are included in Note 8 to our consolidated financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023. As of December 31, 2023, the aggregate number of options held by our non-employee directors was as follows: Dr. Bassler, 123,000; Mr. Burgess, 187,011; Ms Canale-Theakston, 123,000; Dr. Franson, 176,185; Dr. Gollaher, 136,500; Ms. Mineo, 147,500; Mr. Schroeder, 187,011. As of December 31, 2023, none of our non-employee directors held other unvested stock awards.

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the ownership of the Company's common stock as of April 12, 2024 by: (i) each director; (ii) each of our named executive officers; (iii) all executive officers and directors of the Company as a group; and (iv) all those known by the Company to be beneficial owners of more than 5% of its common stock.

The following table is based upon information supplied by officers, directors and principal stockholders and Schedules 13G or 13D filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, the Company believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 91,235,020 shares outstanding on April 12, 2024, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address for the following stockholders is: c/o Cidara Therapeutics, Inc., 6310 Nancy Ridge Drive, Suite 101, San Diego, CA 92121.

	Beneficial Ownership	
Beneficial Owner	**Number of Shares (#)**	**Percent of Total (%)**
Greater than 5% stockholders		
Biotechnology Value Fund, L.P. and its affiliates (1) 44 Montgomery Street, 40th Floor San Francisco, CA 94104	9,364,457	9.99 %
Mundipharma AG (2) St. Alban-Rheinweg 74 Basel 4020, Switzerland	4,781,408	5.24 %
Named Executive Officers and Directors		
Jeffrey Stein, Ph.D. (3)	3,892,114	4.15 %
Taylor Sandison, M.D., M.P.H. (4)	866,700	*
Shane Ward (5)	437,614	*
Daniel Burgess (6)	147,511	*
Timothy R. Franson, M.D. (7)	144,685	*
Theodore R. Schroeder (8)	144,511	*
Chrysa Mineo (9)	105,000	*
David Gollaher, Ph.D. (10)	94,000	*
Bonnie Bassler, Ph.D. (11)	80,812	*
Carin Canale-Theakston (12)	80,500	*
All current executive officers and directors as a group (12 persons) (13)	7,198,955	7.46 %

* Less than one percent.

(1) Based upon a Schedule 13G/A filed with the SEC on February 14, 2024 by Biotechnology Value Fund, L.P., on behalf of itself, BVF I GP LLC, Biotechnology Value Fund II, L.P., BVF II GP LLC, Biotechnology Value Trading Fund OS LP, BVF Partners OS Ltd., BVF GP Holdings LLC, BVF Partners L.P., BVF Inc., and Mark N. Lampert. Represents 6,861,127 shares of common stock held by Biotechnology Value Fund, L.P. and its affiliates and 2,503,330 shares of common stock issuable upon conversion of 250,333 shares of Series X Preferred Stock. Excludes 18,541,390 shares of common stock issuable upon conversion of 1,854,139 shares of Series X Preferred Stock, as applicable, due to a 9.99% beneficial ownership limit as outlined in the Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock filed as Exhibit 3.1 to our Form 8-K filed with the SEC on May 21, 2018. Biotechnology Value Fund, L.P., BVF I GP LLC, Biotechnology Value Fund II, L.P., BVF II GP LLC, Biotechnology Value Trading Fund OS LP, BVF Partners OS Ltd., BVF GP Holdings, LLC, BVF Partners L.P., BVF Inc., and Mark N. Lampert have shared voting and investment power over the shares.

(2) Based upon a Schedule 13G filed with the SEC on September 13, 2019 by Mundipharma AG. Represents 4,781,408 shares of common stock held by Mundipharma AG.

(3) Includes 2,600,426 shares of common stock that Dr. Stein has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options and vesting of RSUs, as applicable; also includes 331,602 shares of common stock held by the Jeff Stein and Catherine Naughton Revocable Trust, 918,077 shares of common stock held by Dr. Stein and 42,009 shares of common stock held by Dr. Stein's son.

(4) Includes 220,395 shares of common stock held by Dr. Sandison and 646,305 shares of common stock that Dr. Sandison has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options and vesting of RSUs, as applicable.

(5) Includes 102,776 shares of common stock held by Mr. Ward and 334,838 shares of common stock that Mr. Ward has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options and vesting of RSUs, as applicable.

(6) Includes 3,000 shares of common stock held by Mr. Burgess' spouse and 144,511 shares of common stock that Mr. Burgess has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options.

(7) Includes 11,000 shares of common stock held by Dr. Franson and 133,685 shares of common stock that Dr. Franson has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options.

(8) Represents 144,511 shares of common stock that Mr. Schroeder has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options.

(9) Represents 105,000 shares of common stock that Ms. Mineo has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options.

(10) Represents 94,000 shares of common stock that Dr. Gollaher has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options.

(11) Includes 312 shares of common stock held by Dr. Bassler and 80,500 shares of common stock that Dr. Bassler has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options.

(12) Represents 80,500 shares of common stock that Ms. Canale-Theakston has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options.

(13) Includes the shares reflected in footnotes (3) – (12) above and (a) 132,023 shares of common stock held by Dr. Tari, 1,484 shares of common stock held by Dr. Tari's spouse and 551,195 shares of common stock that Dr. Tari has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options and vesting of RSUs, as applicable, and (b) 150,298 shares of common stock held by Dr. Shah and 370,508 shares of common stock that Dr. Shah has the right to acquire from us within 60 days of April 12, 2024 pursuant to the exercise of stock options and vesting of RSUs, as applicable.

EQUITY COMPENSATION PLANS

For information regarding the equity compensation plans of the Company, please see the section above headed "Executive Compensation—Equity Benefit Plans," which is incorporated into this section headed "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" by reference.

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

RELATED-PERSON TRANSACTIONS POLICY AND PROCEDURES

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of "related-person transactions." For purposes of our policy only, a "related-person transaction" is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds $120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-party transaction to our Audit Committee (or, where review by our Audit Committee would be inappropriate, to another independent body of our Board) for review. The presentation must include a description of, among other things, all of the parties, the direct and indirect interests of the related parties, the purpose of the transaction, the material facts, the benefits of the transaction to us and whether any alternative transactions are available, an assessment of whether the terms are comparable to the terms available from unrelated third parties and management's recommendation.

To identify related-party transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-party transactions, our Audit Committee or another independent body of our Board takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

CERTAIN RELATED-PERSON TRANSACTIONS

The following includes a summary of transactions since January 1, 2022 to which we have been a party, in which the amount involved in the transaction exceeded the lesser of $120,000 or one percent of the average of the Company's total assets at year-end for the last two completed fiscal years. Since January 1, 2022, the Company has engaged in the following transactions with related persons:

Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers or as a director or executive officer of any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may decline in value to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

DIRECTOR INDEPENDENCE

For information regarding our director and committee member independence, please see the sections above headed "Information Regarding the Board of Directors and Corporate Governance—Independence of the Board of Directors" and "Information Regarding Committees of the Board of Directors," which are incorporated into this section headed "Certain Relationships and Related Party Transactions, and Director Independence" by reference.

Item 14. Principal Accountant Fees and Services.

PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table represents aggregate fees billed to the Company by Ernst & Young LLP, or Ernst & Young, for the fiscal years ended December 31, 2023 and 2022:

	Fiscal Year Ended December 31,	
	2023	2022
Audit Fees [1]	$ 669,312	$ 580
Audit Related Fees	—	
Tax Fees [2]	36,050	30
All Other Fees	—	
Total Fees	$ 705,362	$ 611

(1) Audit fees consist of fees billed for professional services by Ernst & Young for audit and quarterly review of our financial statements and review of our registration statements and other documents in connection with our at the market offerings and related issuances of consents, and related services that are normally provided in connection with statutory and regulatory filings or engagements.

(2) Tax fees consist of services related to tax compliance, tax planning and tax advice.

All fees described above were pre-approved by the Audit Committee.

In connection with the audit of the 2023 financial statements, the Company entered into an engagement agreement with Ernst & Young that sets forth the terms by which Ernst & Young will perform audit services for the Company.

PRE-APPROVAL POLICIES AND PROCEDURES

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by the Company's independent registered public accounting firm, Ernst & Young. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of services other than audit services by Ernst & Young is compatible with maintaining the principal accountant's independence.

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:

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID:42)	89
Consolidated Balance Sheets	91
Consolidated Statements of Operations and Comprehensive Loss	92
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)	93
Consolidated Statements of Cash Flows	94
Notes to Consolidated Financial Statements	95

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 Offering℠ 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	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Cidara Therapeutics, Inc.
3.3	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).
3.4	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).

10.28	Seventh Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated April 20, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on May 11, 2023).
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.
97.1	Cidara Therapeutics, Inc. Incentive Compensation Recoupment Policy.
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: April 22, 2024 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)*	April 22, 2024
/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)*	April 22, 2024
/s/ Daniel D. Burgess **Daniel D. Burgess**	Chairman of the Board of Directors	April 22, 2024
/s/ Bonnie Bassler, Ph.D. **Bonnie Bassler, Ph.D.**	Member of the Board of Directors	April 22, 2024
/s/ Carin Canale-Theakston **Carin Canale-Theakston**	Member of the Board of Directors	April 22, 2024
/s/ Timothy R. Franson, M.D. **Timothy R. Franson, M.D.**	Member of the Board of Directors	April 22, 2024
/s/ David Gollaher, Ph.D. **David Gollaher, Ph.D.**	Member of the Board of Directors	April 22, 2024
/s/ Chrysa Mineo **Chrysa Mineo**	Member of the Board of Directors	April 22, 2024
/s/ Theodore R. Schroeder **Theodore R. Schroeder**	Member of the Board of Directors	April 22, 2024

CERTIFICATE OF AMENDMENT TO

THE AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF CIDARA THERAPEUTICS, INC.

Cidara Therapeutics, Inc. (the "***Company***"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "***DGCL***"), hereby certifies that:

First: The name of the Company is Cidara Therapeutics, Inc. The Company's Certificate of Incorporation was originally filed with the Secretary of State of the State of Delaware on December 6, 2012, under the name of K2 Therapeutics, Inc.

Second: The Amended and Restated Certificate of Incorporation of the Company (the "***Charter***") was filed with the Secretary of State of the State of Delaware on April 20, 2015.

Third: The Board of Directors of the Company (the "***Board***"), acting in accordance with the provisions of Sections 141 and 242 of the DGCL, duly adopted resolutions to amend the Charter as follows:

1. Article IV, Section A shall be amended and restated to read in its entirety as follows:

   "The Company is authorized to issue two classes of stock to be designated, respectively, "***Common Stock***" and "***Preferred Stock***." The total number of shares which the Company is authorized to issue is 30,000,000 shares. 20,000,000 shares shall be Common Stock, each having a par value of $0.0001. 10,000,000 shares shall be Preferred Stock, each having a par value of $0.0001."

2. Effective as of 5:00 p.m., Eastern time, on April 23, 2024 (the ***"Effective Time"***), each 20 shares of Common Stock, par value $0.0001 per share, issued and outstanding shall, automatically and without any action on the part of the respective holders thereof, be combined and converted into one share of Common Stock, par value $0.0001 per share; provided, however, that the Company shall issue no fractional shares as a result of the actions set forth herein but shall instead pay to the holder of such fractional share a sum in cash equal to such fraction multiplied by the closing sales price of the Common Stock as reported on the Nasdaq Capital Market at the Effective Time.

Fourth: Thereafter pursuant to a resolution of the Board, this Certificate of Amendment was submitted to the stockholders of the Company for their approval, and was duly adopted at a special meeting of the stockholders of the Company, in accordance with the provisions of Section 242 of the DGCL.

Fifth: All other provisions of the Charter as currently on file with the Secretary of State of the State of Delaware shall remain in full force and effect.

IN WITNESS WHEREOF, the Company on has caused this Certificate of Amendment to be signed by its Chief Executive Officer this 22nd day of April, 2024.

Cidara Therapeutics, Inc.

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

Name: Jeffrey Stein, Ph.D.

Title: President and Chief Executive Officer

Cidara Therapeutics, Inc.
Amended and Restated Non-Employee Director Compensation Policy

Approved by Board of Directors: December 4, 2023

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

Annual Cash Compensation

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

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $30,000

2. Annual Committee Member Service Retainer (non-Chairman):
    a. Member of the Audit Committee: $9,000
    b. Member of the Compensation Committee: $7,500
    c. Member of the Nominating and Governance Committee: $4,000

3. Annual Committee Chairman Service Retainer:
    a. Chairman of the Audit Committee: $18,000
    b. Chairman of the Compensation Committee: $15,000
    c. Chairman of the Nominating and Governance Committee: $8,000

Equity Compensation

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

1. Initial Grant: On the date of the Eligible Director's initial election to the Board, for each Eligible Director who is first elected to the Board following the Effectiv Date (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option for 85,000 shares of Common Stock (the "***Initial Grant***"). The shares subject to each Initial Grant will vest as follows: (i) 1/3rd of the shares will vest on the first anniversary of the date of grant and (ii) the remaining 2/3rds of the shares will vest in equal monthly installments over a two year period such that each Initial Grant is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: On the date of each Cidara annual stockholder meeting held after the Effective Date, for each Eligible Director who continues to serve as a non employee member of the Board (or who is first elected to the Board at such annual stockholder meeting), the Eligible Director will be automatically, and withou further action by the Board or Compensation Committee of the Board, granted a stock option for 42,500 shares of Common Stock (the "***Annual Grant***"). The shares subject to the Annual Grant will vest in one installment on the earlier of (i) the first anniversary of the date of grant and (ii) the day prior to the date of Cidara's first annual stockholder meeting held after the date of grant, such that each Annual Grant is fully vested on the earlier of (i) the first anniversary of the date of grant and (ii) the day prior to the date of Cidara's first annual stockholder meeting held after the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

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

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

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

(1) Registration Statement (Form S-3 No. 333-260970) of Cidara Therapeutics, Inc., and

(2) Registration Statements (Form S-8 Nos. 333-203434, 333-210263, 333-216722, 333-228282, 333-231326, 333-236874, 333-253545, 333-259219, 333-263350 and 333-270781) pertaining to the Cidara Therapeutics, Inc. 2013 Stock Option and Grant Plan, Cidara Therapeutics, Inc. 2015 Equity Incentive Plan, Cidara Therapeutics, Inc. 2015 Employee Stock Purchase Plan and Cidara Therapeutics, Inc. 2020 Inducement Incentive Plan;

of our report dated April 22, 2024, with respect to the consolidated financial statements of Cidara Therapeutics, Inc. included in this Annual Report (Form 10-K) of Cidara Therapeutics, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP

San Diego, California

April 22, 2024

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: April 22, 2024

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

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

Exhibit 31.2

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

I, Preetam Shah, Ph.D., MBA, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: April 22, 2024 By: /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)

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Cidara Therapeutics, Inc. (the "Company") for the period ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof and to which this certification is attached as an exhibit (the "Report"), I, Jeffrey Stein, Ph.D., President and Chief Executive Officer of the Company, certify, pursuant to the requirement in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act; and

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

Date: April 22, 2024 By: /s/ Jeffrey Stein, Ph.D.

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

This certification accompanies the Form 10-K to which it relates, is being furnished solely pursuant to 18 U.S.C. § 1350 and is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cidara Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Cidara Therapeutics, Inc. (the "Company") for the period ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof and to which this certification is attached as an exhibit (the "Report"), I, Preetam Shah, Ph.D., MBA, Chief Financial Officer and Chief Business Officer of the Company, certify, pursuant to the requirement in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), that, to the best of my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act; and

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

Date: April 22, 2024 By: /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)

This certification accompanies the Form 10-K to which it relates, is being furnished solely pursuant to 18 U.S.C. § 1350 and is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cidara Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Cidara Therapeutics, Inc.

Incentive Compensation Recoupment Policy

adopted December 1, 2023

1. Introduction

The Board of Directors (the "***Board***") of Cidara Therapeutics, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have th meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunde ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award i attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. Definitions

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation and Human Capital Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Compensation and Human Capital Committee***" means the Compensation and Human Capital Committee of the Board.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total shareholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure. Examples of "Incentive Compensation" include, but are not limited to: non-equity incentive plan awards that are earned based wholly or in part on satisfying a Financial Reporting Measure performance goal; bonuses paid from a "bonus pool," the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal; other cash awards based on satisfaction of a Financial Reporting Measure performance goal; restricted stock, restricted stock units, performance share units, stock options, and SARs that are granted or become vested based wholly or in part on satisfying a Financial Reporting Measure goal; and proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or in part on satisfying a Financial Reporting Measure goal. "Incentive Compensation" excludes, for example, time-based awards such as stock options or restricted stock units that are granted or vest *solely* upon completion of a service period; awards based on non-financial strategic or operating metrics such as the consummation of a merger or achievement of non-financial business goals; service-based retention bonuses; discretionary compensation; and salary.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive

Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation and Human Capital Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable (as explained below). Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action,

determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 (***SOX 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law.

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Covered Person Acknowledgement and Agreement

All Covered Officers subject to this Policy must acknowledge their understanding of, and agreement to comply with, the Policy by executing the Form attached hereto as Exhibit A.

Notwithstanding the foregoing, this Policy will apply to Covered Officers whether or not they execute such certification.

10. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

11. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

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Cidara Therapeutics, Inc.

Incentive Compensation Recoupment Policy

Form of Executive Acknowledgment

I, the undersigned, agree and acknowledge that I am bound by, and subject to, the Cidara Therapeutics, Inc. Incentive Compensation Recoupment Policy, as may b amended, restated, supplemented or otherwise modified from time to time (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with Cidara Therapeutics, Inc. (the "***Company***") to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Administrator (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

__

Name: __

Title: __

Date: __