UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

OR

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

Commission File Number 001-36912

CIDARA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

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

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

Title of each class	Trading symbol	Name of each exchange on which is registered
Common Stock, $0.0001 Par Value	"CDTX"	The Nasdaq Stock Market LLC

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

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

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

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

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Capital Market on June 28, 2024 (the last trading day of the Registrant's most recently completed second quarter), was approximately $53.3 million. Shares of the Registrant's common stock held by executive officers, directors and the Registrant's affiliates have been excluded from this calculation. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's common stock outstanding as of February 27, 2025 was 10,953,490.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, pursuant to Schedule 14A in connection with the Registrant's 2025 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Annual Report on Form 10-K. Such definitive proxy statement will be filed with the SEC not later than 120 days following the end of the Registrant's fiscal year ended December 31, 2024.

CIDARA THERAPEUTICS, INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our anticipated timing for preclinical development, regulatory submissions, commencement and completion of clinical trials and product approvals;
- our plans to research, develop and commercialize our product candidates;
- our ability to fund our working capital requirements;
- our expected clinical trial designs and regulatory pathways;
- our ability to obtain and maintain regulatory approval of our product candidates and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to successfully commercialize, and our expectations regarding future therapeutic and commercial potential with respect to, our product candidates;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our products that are approved;
- our ability to develop sales and marketing capabilities, whether alone or with 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, inflation, bank failures, labor shortages, supply chain disruptions, recession risks, potential tariffs 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.

- Due to the delayed filing with the SEC of our Annual Report on Form 10-K for the year ended December 31, 2023, we are not currently eligible to use a registration statement on Form S-3 to register the offer and sale or resale of securities, which may adversely affect our ability to raise future capital.
- We need substantial additional funding to advance CD388 beyond Phase 2b, and to advance CBO421 and our other Cloudbreak programs.
- We depend heavily on the success of CD388, which has completed 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 CD388 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 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 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 unable to resume our preclinical Cloudbreak programs.
- The price of our stock may be volatile, and you could lose all or part of your investment.

PART I

Item 1. Business.

OVERVIEW

We are a biotechnology company using our proprietary Cloudbreak® platform to develop drug-Fc conjugate, or DFC, immunotherapies designed to save lives and improve the standard of care for patients facing serious diseases.

Our lead clinical-stage asset is CD388, a DFC intended for influenza prophylaxis, which we discovered and advanced to the clinic under a partnership with J&J Innovative Medicine, previously Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, or Janssen. To date, we have completed two Phase 1 studies and one Phase 2a study of CD388 under our prior license and collaboration agreement we entered into with Janssen in March 2021, or Janssen Collaboration Agreement. In 2023, as part of a prioritization of its research and development, or R&D, business, Janssen disclosed its intention to discontinue internal development of multiple product candidates in its infectious disease pipeline, including CD388. Through a competitive process, we reacquired all rights to develop and commercialize CD388 by executing a license and technology transfer agreement with Janssen, or the Janssen License Agreement, in April 2024. Under the terms of the Janssen License Agreement, we received an exclusive, worldwide, fee-bearing but royalty-free license under certain Janssen-controlled technology to develop, manufacture and commercialize compounds, including CD388.

Concurrent with the CD388 reacquisition, we completed a private placement pursuant to which we sold an aggregate of 240,000 shares of our Series A Convertible Voting Preferred Stock to certain institutional and other accredited investors, or the April 2024 Private Placement, which was led by RA Capital Management, with significant participation from Bain Capital Life Sciences, Biotech Value Fund, or BVF, and Canaan Partners. The April 2024 Private Placement provided $240.0 million in gross proceeds, of which we used $85.0 million to fund the upfront payment under the Janssen License Agreement. The remainder of the gross proceeds of $155.0 million are being utilized to develop CD388 as a universal preventative against seasonal and pandemic influenza A and B, beginning with the current CD388 Phase 2b NAVIGATE study that we initiated in September 2024. We believe the reacquisition of CD388 is transformational for Cidara and potentially for those who could benefit from a long-acting, universal preventative against known forms of influenza.

In addition, in April 2024 we simultaneously divested rezafungin, our sole non-Cloudbreak asset, to enable us to focus our resources on the development of CD388. We entered into an Asset Purchase Agreement, or Napp Purchase Agreement, with Napp Pharmaceutical Group Limited, or Napp, an affiliate of Mundipharma Medical Company, or Mundipharma, our licensee for the asset in all territories other than the U.S. and Japan, pursuant to which we sold to Napp all of our rezafungin assets, including our right to receive future milestones and royalties under the License Agreement between us and Melinta Therapeutics, LLC, or Melinta (our U.S. licensee), or the Melinta License Agreement, and the License and Collaboration Agreement between us and Mundipharma, or the Mundipharma Collaboration Agreement.

Following these transactions, our sole R&D focus has now shifted to our proprietary Cloudbreak platform, which enables the development of novel DFCs that inhibit specific disease targets while simultaneously engaging the immune system. With the reacquisition of CD388, it is now our most advanced DFC program. CD388 is a highly potent antiviral designed to deliver universal prevention and treatment of seasonal and pandemic influenza.

In November 2024, we completed a private placement pursuant to which we sold an aggregate of 3,892,274 shares of our common stock and pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of common stock to certain institutional and other accredited investors, or the November 2024 Private Placement. The November 2024 Private Placement provided $105.0 million in gross proceeds.

Cloudbreak Platform

We believe our Cloudbreak platform has the potential to offer a fundamentally new approach to treat and prevent serious diseases such as viral infections and solid tumors, 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 multi-specific 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 targeting 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 highly potent antiviral designed to deliver universal prevention and treatment of seasonal and pandemic influenza. Our lead oncology DFC is CBO421, a development candidate targeting CD73 for the treatment of solid tumors, which received investigational new drug application, or IND, clearance in July 2024. We do not plan to initiate clinical trials for any oncology product candidates at this time but continue business development discussions for our oncology DFC programs, including CBO421.

Cloudbreak Influenza Program (CD388)

We have completed two Phase 1 studies and one Phase 2a study of CD388, our influenza DFC:

- A randomized, double-blind, dose-escalation Phase 1 study to determine the safety, tolerability and pharmacokinetics of intramuscular and subcutaneous administration of CD388 in healthy subjects (NCT05285137);
- A separate Phase 1 Japanese bridging study (NCT05619536); and
- A Phase 2a study (NCT05523089) to evaluate the pre-exposure prophylactic activity of CD388 against influenza.

We initiated the CD388 Phase 2b NAVIGATE study in September 2024.

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 1 and Phase 2a Results

On September 21, 2023, we announced efficacy and safety data from our Phase 1 and Phase 2a studies 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 (maximum dose tested):

In total, 108 subjects were dosed in our Phase 1 and Phase 2a studies, 84 of which were dosed subcutaneously, or SQ, and 24 were dosed intramuscularly, or IM.

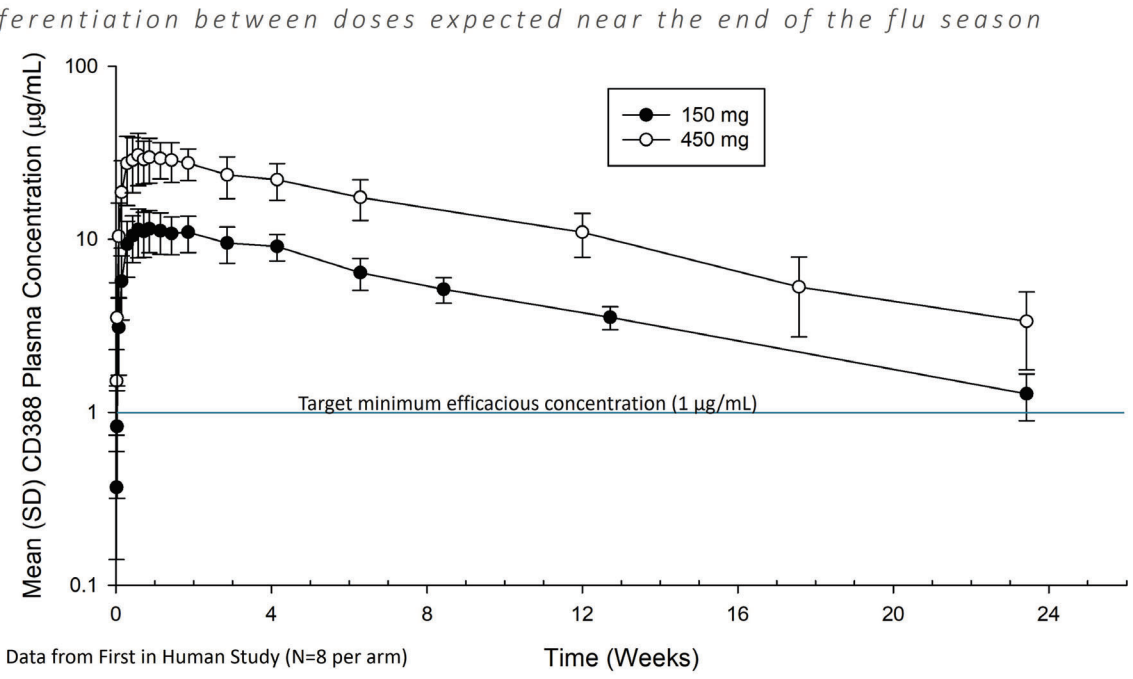
Percent of SQ CD388 or Placebo Treatment Related Adverse Events in Phase 1 and Phase 2a studies

Dose	First in Human Study (Phase 1) CD388 N=8/dose; Placebo N=12	Japanese Bridging Study (Phase 1) CD388 N=7*/dose; Placebo N=6	Human Challenge Study (Phase 2a) 50mg N=2; 150mg N=28; Placebo N=29
Placebo	33.3	16.7	—
50 mg	62.5	28.6	—
150 mg	12.5	12.5	—
450 mg	—	—	N/A
900 mg	25.0	N/A	N/A

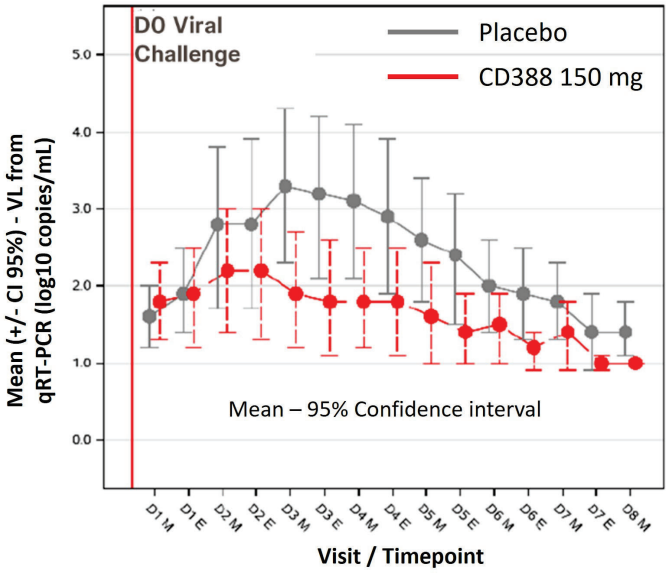
Safety Summary:
- No treatment-emergent serious adverse events, or SAEs, and no discontinuation of study drug or withdrawals due to safety findings.
- No consistent adverse event, or AE, patterns.
- No hypersensitivity reactions.
- Most treatment-emergent adverse events, or TEAEs, were Grade 1 (90%),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

* 150mg N=8

First in Human - single CD388 dose of 150 mg to 450 mg potentially provides seasonal coverage:



CD388 demonstrated protection in Phase 2a Human Challenge Model:



Primary endpoint: AUC viral load-time_ qRT-PCR

One sided p-value Wilcoxon rank sum test: 0.0390

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
Quantitative reverse transcriptase polymerase chain reaction, or qRT-PCR, confirmed influenza infection *	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

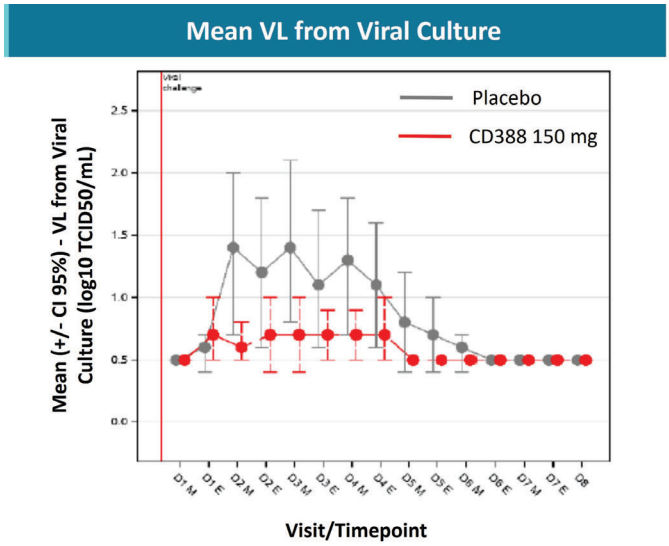
*RT-PCR-confirmed influenza infection: two quantifiable (≥ lower limit of quantification, or LLOQ) qRT-PCR measurements (reported on two or more independent samples over two days), from Day 1 (pm) up to Day 8 (am).

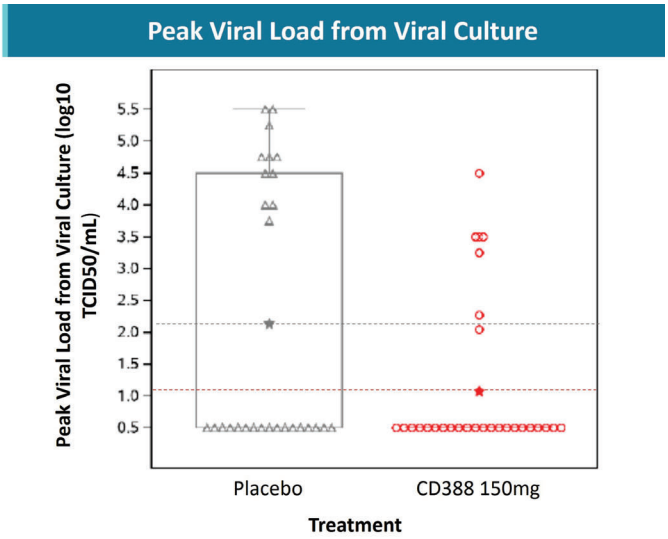
**RT-PCR-confirmed symptomatic influenza infection: RT-PCR-confirmed influenza infection (two quantifiable (≥LLOQ) qRT-PCR measurements (reported on two or more independent samples over two days)), from Day 1 (pm) up to Day 8 (am), and symptoms ≥2 at a single time point.

***RT-PCR-confirmed moderate to severe symptomatic influenza infection: RT-PCR confirmed influenza infection (two quantifiable (≥LLOQ) qRT-PCR measurements (reported on two or more independent samples over two days)), from Day 1 (pm) up to Day 8 (am), and any symptoms of grade ≥2 at a single time point.

As shown above, despite the small sample size in this analysis, a decrease in viral replication in the upper respiratory tract and influenza infection was observed in participants receiving a single dose of CD388 when compared to placebo. No treatment emergent adverse events leading to study discontinuation or 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 from Phase 2a Human Challenge Study confirmed efficacy seen in early analyses:





*, * = mean peak viral load

CD388 Phase 2a and Phase 1 Data Presentations at 34th European Society of Clinical Microbiology and Infectious Diseases (ESCMID) conference:

In April 2024, we presented data from the Phase 2a study of CD388 in various poster presentations at the 34th ESCMID conference. The first presentation showed CD388 was well-tolerated and demonstrated statistically significant antiviral effects when administered as a single subcutaneous dose in healthy volunteers challenged with influenza. The second presentation highlighted data from a Phase 1 single ascending dose study of CD388 which showed the drug has an extended half-life of 6-8 weeks. These data underscore the potential of CD388 to provide patients with seasonal influenza prevention.

CD388 Phase 2a and Phase 1 Data Presentations at the Options XII conference:

In October 2024, we presented data from the Phase 2a study and the two Phase 1 studies. The first presentation was an oral presentation and showed the comprehensive safety data from all completed studies in the CD388 development program, demonstrating that CD388 appears to be well-tolerated at single doses up to 900 mg and repeat doses up to 450 mg. The second presentation was a poster presentation of the Phase 1 Japanese Bridging study that demonstrated that the pharmacokinetics of CD388 were similar between Japanese and Western participants and required no dose changes.

CD388 Phase 2a and Phase 1 Data Presentations at the ID Week conference:

In October 2024, we presented additional data from the Phase 2a study and the Phase 1 First-in-Human study. The first presentation was an oral presentation that showed that among those participants who had serology confirmation of influenza infection in the Phase 2a study the rates of symptomatic clinical influenza and viral load AUC were significantly lower for CD388 participants versus placebo participants. The second presentation was a poster presentation that showed comprehensive safety and pharmacokinetic data from the First-in-Human Phase 1 study. This poster demonstrated that a single dose of CD388 should be sufficient to last through an entire influenza season and the lack of hypersensitivity or anti-drug antibodies with repeat dosing of CD388.

Peer-reviewed Manuscript on CD388 Preclinical Data Accepted for Publication:

A peer-reviewed manuscript describing the design and preclinical characterization of CD388 has been accepted for publication and is expected to appear in print in the first half of 2025. The manuscript highlights the potent, universal antiviral activity of CD388 in cell-based assays and lethal mouse infection models, and low potential for resistance development.

CD388 Phase 2b NAVIGATE Study Timeline

We initiated the CD388 Phase 2b NAVIGATE study during the 2024-25 Northern Hemisphere influenza season, with dosing of the first subjects on September 20, 2024. The CD388 Phase 2b NAVIGATE study is a randomized, double-blinded, controlled trial with single doses of CD388 or placebo administered at the beginning of the influenza season with subjects followed for the influenza season to monitor for breakthrough cases of influenza. The primary endpoint of this study will compare the rates of laboratory-confirmed clinical influenza between different single dose levels of CD388 and placebo over an influenza season. The patient population in this study will be healthy adults who have not received an influenza vaccination for the upcoming season. In December 2024, we announced that we had reached full planned enrollment of at least 5,000 subjects across clinical trial sites in the United States and the United Kingdom. Topline data is expected in the third quarter of 2025. Given the severity of the 2024-25 flu season, we may consider a potential early analysis of efficacy data from the ongoing CD388 Phase 2b NAVIGATE study in the first half of 2025. If an analysis of the CD388 Phase 2b NAVIGATE study is completed in the first half of 2025, such results will be disclosed and we may consider initiating a Phase 3 study during the 2025-26 Northern Hemisphere influenza season. Refer to other risks described in Item 1A. “Risk Factors” of this Annual Report on Form 10-K.

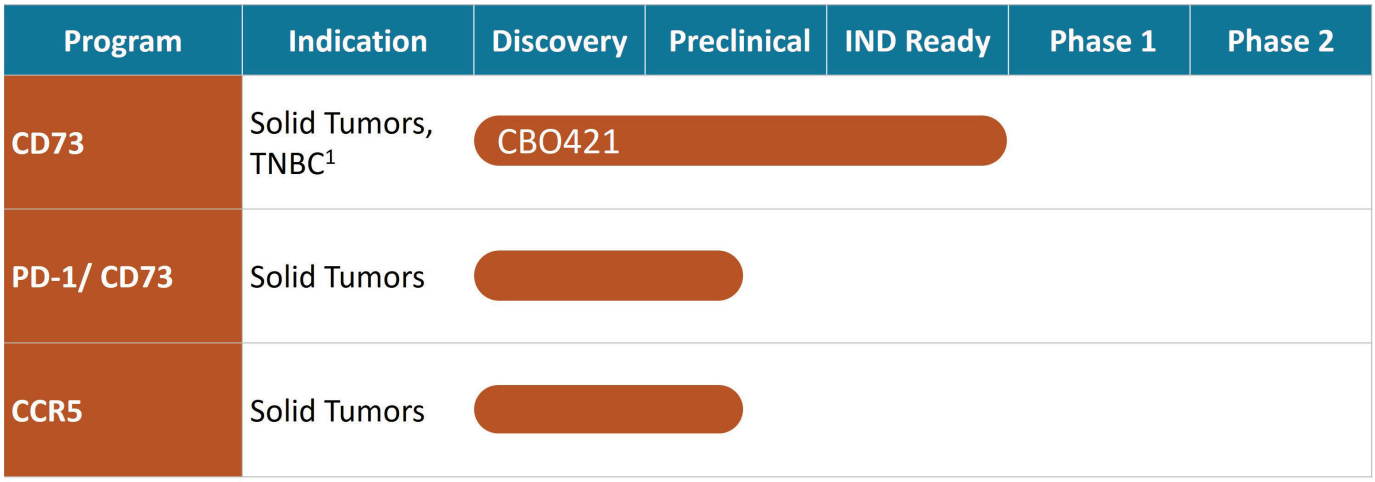
Cloudbreak Oncology Programs

We have expanded the Cloudbreak platform beyond infectious diseases, to discover and develop highly potent DFCs that can target single or multiple immune checkpoint pathways for the treatment of solid tumors.

Immune checkpoint antagonists have generated durable responses in cancers with improved side effect profiles compared to conventional chemotherapy. However, improved outcomes from existing therapies have been limited to a small subset of patients. To broaden the response rate to more patients, targeting additional mechanisms of tumor immune evasion will be critical.

Using Cloudbreak, we seek to develop a new generation of immunotherapies targeting the tumor microenvironment. Our lead oncology DFC candidate, CBO421, is a highly differentiated 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 triple negative breast cancer, or TNBC, and other solid tumors. As a monotherapy and in combination with PD-1 inhibitors, CBO421 has demonstrated activity and formation of immunologic memory in multiple murine tumor models, along with differentiated activity in T-cell reactivation assays and tumor penetration compared with the most advanced CD73 antibody therapeutics in clinical development. CBO421 received IND clearance in July 2024.

Cloudbreak Oncology Pipeline:



1. TNBC = Triple Negative Breast Cancer

We do not plan to initiate clinical trials for any oncology product candidates at this time but continue business development discussions for our oncology DFC programs, including CBO421.

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 and commercialize our lead clinical-stage asset CD388, a DFC intended for influenza prophylaxis.** On September 23, 2024, we announced the first subjects dosed in the CD388 Phase 2b NAVIGATE study to evaluate the efficacy and safety of CD388 for the pre-exposure prophylaxis of influenza during the 2024-25 flu season and on December 4, 2024, announced that the study had reached its full planned enrollment of at least 5,000 subjects. Topline data is expected in the third quarter of 2025. Given the severity of the 2024-25 flu season, we may consider a potential early analysis of efficacy data from the ongoing CD388 Phase 2b NAVIGATE study in the first half of 2025. If an analysis of the CD388 Phase 2b NAVIGATE study is completed in the first half of 2025, such results will be disclosed and we may consider initiating a Phase 3 study during the 2025-26 Northern Hemisphere influenza season. According to the U.S. Centers for Disease Control and Prevention, or CDC, preliminary cumulative estimated flu disease burden for the 2024-25 flu season observed as of January 18, 2025, the seasonal flu virus was circulating at high levels, causing many illnesses and possibly deaths and was continuing to rise.
- **Continue business development discussions for our oncology DFC programs, including CBO421.** Our lead oncology development candidate, CBO421, targets CD73 in the adenosine pathway. CBO421 received IND clearance in July 2024. We may fund these programs 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.

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.

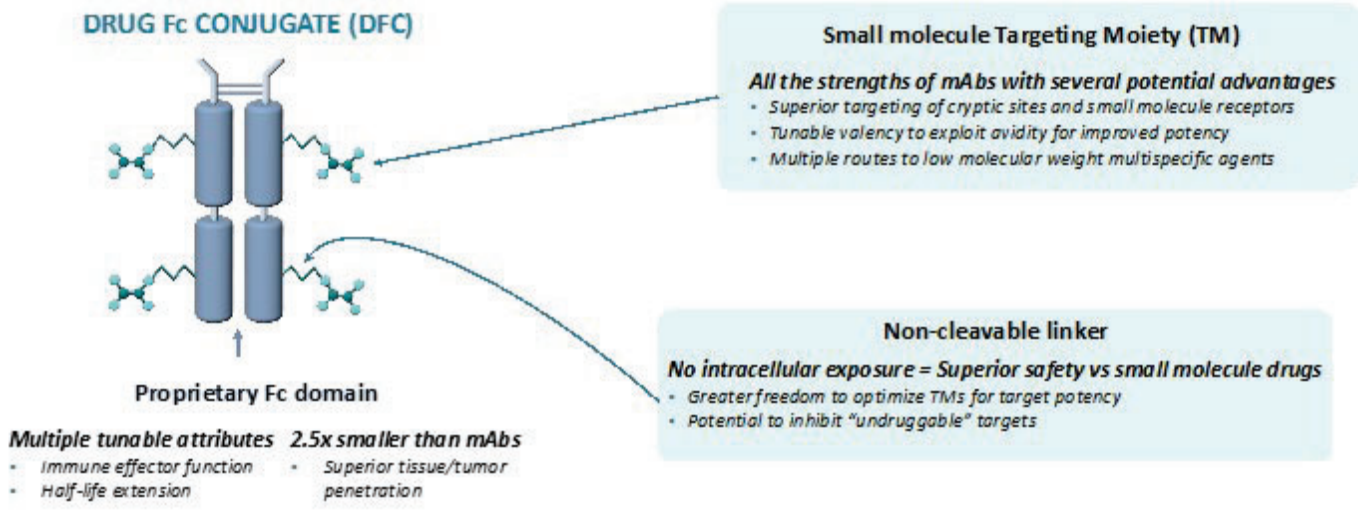
DFCs are fundamentally different from ADCs: DFCs are biologically stable drug-Fc conjugates designed to engage extracellular targets, while ADCs are designed to enter target cells to deliver and release cytotoxic small molecule drugs. In contrast to ADCs and monoclonal antibodies, DFCs are smaller, providing 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 cell surface.
- Long duration of action: Months of protection from disease with a single dose.
- Rapid onset: Rapid distribution to site of infection for treatment of disease.

Cloudbreak Influenza Program and Our 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 2018-19 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 broad panels of seasonal and pandemic Influenza A strains, including H1N1 pandemic strains, H3N2, high pathogenicity H5N1 and H7N9 strains, 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 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.

In Vitro Studies Measuring CD388 Potency Against Historical and Circulating High-Pathogenicity Influenza Strains

In cell-based microneutralization assays against historical and currently circulating high pathogenicity influenza strains, including recently identified H5N1 strains, CD388 demonstrated potent activity, superior to oseltamivir (Tamiflu) and zanamivir (Relenza).

Cloudbreak Oncology Program and Our DFC Development Candidate CBO421

We have expanded the Cloudbreak platform beyond infectious diseases, to discover and develop highly potent DFCs that can target single or multiple immune checkpoint pathways for the treatment of solid tumors.

Immune checkpoint antagonists have generated durable responses in cancers with improved side effect profiles compared to conventional chemotherapy. However, improved outcomes from existing therapies have been limited to a small subset of patients. To broaden the response rate to more patients, targeting additional mechanisms of tumor immune evasion will be critical.

Using Cloudbreak, we seek to develop a new generation of immunotherapies targeting the tumor microenvironment. Our lead oncology DFC candidate, CBO421, is a highly differentiated 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 triple negative breast cancer, or TNBC, and other solid tumors. As a monotherapy and in combination with PD-1 inhibitors, CBO421 has demonstrated activity and formation of immunologic memory in multiple murine tumor models, along with differentiated activity in T-cell reactivation assays and tumor penetration compared with the most advanced CD73 antibody therapeutics in clinical development. CBO421 received IND clearance in July 2024.

We do not plan to initiate clinical trials for any oncology product candidates at this time but continue business development discussions for our oncology DFC programs, including CBO421.

LICENSE AGREEMENTS

Janssen License Agreement

On April 23, 2024, we reacquired all rights to develop and commercialize CD388 when we entered into the Janssen License Agreement, which also effectively terminated the Janssen Collaboration Agreement, which we entered into in March 2021, including the license granted by us to Janssen.

Under the Janssen License Agreement, we assumed responsibility for further clinical development, manufacture, registration and commercialization of DFCs based on our Cloudbreak platform for the prevention and treatment of influenza, including CD388 and products or compounds containing CD388. Janssen granted us an exclusive, worldwide, fee-bearing royalty-free license for certain Janssen-controller technology to develop, manufacture, and commercialize compounds and products, including CD388. Janssen agreed to (i) transfer and disclose to us certain Janssen-controlled know-how related to CD388, including manufacturing know-how, data and documentation, (ii) transfer all existing quantities of CD388 clinical materials, and (iii) transfer the cell banks used by or on behalf of Janssen for the production of CD388.

We paid Janssen an upfront payment of $85.0 million on April 24, 2024. We are also obligated to pay Janssen up to $150.0 million in development and regulatory milestone payments with respect to CD388 and up to $455.0 million in commercialization milestone payments with respect to CD388. We have no obligation to pay any royalties to Janssen for future sales of any commercialized CD388 product.

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 CD388, any other Cloudbreak development candidates, and any future product candidates. Our third-party contract manufacturers are currently producing, and will produce in the future, our product candidates for use in our preclinical studies and clinical trials and ultimately for commercial supply utilizing reliable and reproducible processes and common manufacturing techniques.

INTELLECTUAL PROPERTY

The proprietary nature of, and protection for, 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 CD388, CBO421, and other product candidates and technology in the U.S. and abroad. As of March 6, 2025, our patent portfolio included eight families of patents and patent applications related to various aspects of CD388, and four families of patent applications related to various aspects of CBO421.

With respect to CD388, we received the first U.S. patent in December 2022. The patent is projected to expire in 2039 plus any available patent term extension. The latest of the issued patents and any patents that result from our currently pending applications would be expected to expire in 2044, 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 2045, 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.

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 CD388 and any other Cloudbreak development candidates we pursue in the future, combined 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.

For certain patient populations and approved indications, we expect that CD388 will be used in conjunction with approved vaccines for influenza in order to provide additional protection. For other patient populations and approved indications, we expect that CD388 may compete with 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 would compete against approved anticancer therapeutics as well as investigational CD73-targeting small molecule drugs, including quemliclustat being developed by Arcus Biosciences, Inc. and 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 biologics under the Public Health Service, or PHS, Act 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 a Biologics License Application, or BLA;
- 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 BLA.

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 a BLA requesting approval to market the product for one or more indications. Under federal law, the submission of most BLAs and clinical BLA supplements are additionally subject to a substantial application fee, and the sponsor of an approved BLA is also subject to annual program fees, which are typically increased annually.

The FDA conducts a preliminary review of all BLAs 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 a BLA 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 BLAs. Under these goals, the FDA has committed to review most such applications for non-priority products within ten 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 BLA 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 BLA. 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 BLA 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 BLA 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.

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. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

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

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

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

Additional Health Care Laws

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

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

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

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

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information.

Additionally, the federal Physician Payments Sunshine Act, created under the Affordable Care Act, and its implementing regulations, require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually information related to certain payments or other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.

The majority of states also have statutes or regulations similar to the aforementioned federal fraud and abuse laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in

several states, apply regardless of the payor. Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments or other transfers of value provided to physicians and other health care providers and entities, marketing expenditures, or drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives.

If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to potentially significant criminal, civil and administrative penalties, damages, fines, disgorgement, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, exclusion from participation in government healthcare programs, as well as contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage and Reimbursement

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients and providers are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of therapies in which our products are used.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the U.S., for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. In the U.S., no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for each of our product candidates will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage, and adequate reimbursement, for the product. 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 amendments to and executive judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed 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 second Trump 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, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, effective January 1, 2024.

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. The IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least seven years covered under Medicare, or the Medicare Drug Price Negotiation Program, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first 10 drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected 15 additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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, or 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 February 27, 2025, we had 38 total employees, 8 of whom hold Ph.D. or M.D. degrees, 20 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

Due to the delayed filing with the SEC of our Annual Report on Form 10-K for the year ended December 31, 2023, we are not currently eligible to use a registration statement on Form S-3 to register the offer and sale or resale of securities, which may adversely affect our ability to raise future capital.

As a result of the late filing with the SEC of our Annual Report on Form 10-K for the year ended December 31, 2023, we will not be eligible to register the offer and sale of our securities using a registration statement on Form S-3 until we have timely filed all periodic reports required under the Securities Exchange Act of 1934, as amended, or the Exchange Act, for at least 12 calendar months (or through May 1, 2025), and there can be no assurance that we will be able to file all such reports in a timely manner in the future. Should we wish to register the offer and sale of additional securities to the public, our transaction costs and the amount of time required to complete the transaction could increase, making it more difficult to execute any such transaction successfully and potentially harming our business, strategic plan and financial condition.

We need substantial additional funding to advance CD388 beyond Phase 2b, and to advance CBO421 and our other Cloudbreak programs.

Our ability to advance CD388 beyond Phase 2b, and to advance CBO421 and other product candidates from our other Cloudbreak programs is dependent 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 CD388 trials through to Phase 2b;
- the costs, timing and outcome of any regulatory review of 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 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 will need substantial additional funding in connection with our continuing operations and to achieve our goals. As of December 31, 2024, we had cash, cash equivalents and restricted cash of $196.2 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, cash equivalents and restricted cash due to market conditions such as 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 or one or more of our other Cloudbreak DFC programs, or any 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, as well as potentially entering into 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 controlled equity offering sales agreement with Cantor Fitzgerald & Co., or the Sales Agreement. We will not be able to sell any additional shares of our common stock under the Sales Agreement until at least May 1, 2025, due to the loss of our Form S-3 eligibility for primary and secondary offerings.

In April 2024, we entered into a securities purchase agreement with certain institutional and other accredited investors, pursuant to which we issued and sold, in a private placement, or the April 2024 Private Placement, 240,000 shares of Series A Convertible Voting Preferred Stock, for which we received total gross proceeds of $240.0 million. The proceeds from the April 2024 Private Placement were used to fund the upfront payment of $85.0 million under a license and technology transfer agreement with J&J Innovative Medicine, previously Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, or Janssen, and the remainder of the gross proceeds of $155.0 million are being utilized to develop CD388 as a universal preventative against seasonal and pandemic influenza A and B, beginning with the current CD388 Phase 2b NAVIGATE study that we initiated in September 2024. On July 19, 2024, we issued 2,469,250 shares of common stock upon the automatic conversion of 35,275 shares of such Series A Convertible Voting Preferred Stock.

In November 2024, we entered into a securities purchase agreement with certain institutional accredited investors, pursuant to which we issued and sold, in a private placement, or the November 2024 Private Placement, (i) an aggregate of 3,892,274 shares of our common stock, and (ii) in lieu of shares of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of common stock, for which we received total gross proceeds of $105.0 million.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, like our sale of Series A Convertible Voting Preferred Stock in the April 2024 Private Placement and our sale of common stock and pre-funded warrants in the November 2024 Private Placement, 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. We may need to enter into agreements with third parties for the development and commercialization of DFCs identified from our Cloudbreak program which may require that 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 advancement of 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 incurred a net loss of $169.8 million and $22.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $611.3 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 our prior collaborations. We have completed Phase 1 and Phase 2a studies of CD388. 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 CD388 through clinical development;
- resume the preclinical development of CBO421 and other DFCs from our Cloudbreak platform or otherwise, and advance one or more of such product candidates into clinical trials;
- seek marketing approvals for 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, or R&D, 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 active conflicts in the Middle East 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 Belarus, as well as Belarusian and Russian interests, and threatened additional sanctions and controls. The impact of these measures, as well as potential responses to them by Russia or Belarus, 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.

Risks Related to Drug Discovery, Development and Commercialization

We depend heavily on the success of CD388, which has completed 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 received IND clearance for CD388, our DFC for prevention and treatment of influenza, from the FDA in March 2022 and have completed a Phase 1 clinical trial and a Phase 2a clinical trial of CD388 to evaluate the pre-exposure prophylactic activity of CD388 against influenza virus as well as a separate Phase 1 Japanese bridging study. In September 2024, we initiated the CD388 Phase 2b NAVIGATE trial to be conducted during the Northern Hemisphere influenza season and on December 4, 2024 we announced that enrollment in the trial was complete. We received IND clearance for CBO421 in July 2024. Our assumptions about why CD388 is worthy of continued development, as well as our assumptions about the market for CD388 or any other potential products from our Cloudbreak program, are based on data primarily collected by other companies. The timing and costs of our preclinical and clinical development programs, the likelihood of 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 CD388 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 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 ongoing CD388 Phase 2b NAVIGATE trial or enroll a sufficient number of eligible subjects into one or more Phase 3 trials to support regulatory approval of CD388, 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 CD388 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, we 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.

In addition, some of our competitors may have ongoing or new clinical trials for product candidates that would treat the same indication as CD388, 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 CD388;
- 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 CD388 addresses.

Our inability to enroll and retain a sufficient number of patients into Phase 3 clinical trials in a reasonable timeframe may require us to abandon the entire CD388 clinical development program. Any enrollment delays would result in increased development costs, which could cause the value of our company to decline and could limit our ability to obtain necessary additional financing.

If clinical trials for CD388 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.

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 antivirals 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 clinical 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 CD388, 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 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 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 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.

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;
- 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.

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 CD388 will compete against approved and investigational agents for the treatment or prevention of viral influenza infections, including influenza vaccines, monoclonal antibodies targeting hemagglutinin, and small molecule 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 tumors and viral infections. We are aware of a large number of approved and investigational therapies in these areas also.

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 R&D, 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 CD388 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. We do not plan to initiate clinical trials for any oncology product candidates at this time but continue business development discussions for our oncology DFC programs, including CBO421. 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 influenza and immuno-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. 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 may seek to selectively establish collaborations and, if we are unable to establish them on commercially reasonable terms or at all, we may have to alter our research, clinical development and commercialization plans.

We may seek to collaborate with pharmaceutical and biotechnology companies to advance the Cloudbreak program for DFCs. We may also seek funding from government grants or contracts to advance the Cloudbreak program for DFCs. 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 R&D, such as only after Phase 1 clinical trials have been completed. In order to advance the Cloudbreak program for DFCs, we will need to obtain significant funding to complete 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 R&D 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 R&D 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. Furthermore, some materials for our product candidates may be sourced from a single-source supplier, and we may be unable to identify an alternative supplier in the event any such single-source supplier is unable to perform.

Any performance failure on the part of our existing or future manufacturers or suppliers, 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 House of Representatives of the prior Congress (the 118th Congress) passed the BIOSECURE Act which proposed targeting U.S. government contracts, grants and loans for entities that use biotechnology equipment or services from certain named Chinese biotechnology companies and potentially other biotechnology companies designated in the future. The language of the proposed BIOSECURE Act would, among other things, prohibit U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a “biotechnology company of concern” to perform that contract. The version of the bill passed by the prior House of Representatives included a “grandfathering” provision which provided that the BIOSECURE Act’s prohibitions would not apply to pre-existing contracts and agreements entered into prior to the legislation’s effective date until January 1, 2032. The BIOSECURE Act did not become law in the 118th Congress. It is unclear whether the current Congress (the 119th Congress) will introduce the BIOSECURE Act or similar legislation in this current congressional session and, if so, how the scope, prohibitions, or designated biotechnology companies of concern may differ from the version of the BIOSECURE Act passed by the House in the prior 118th Congress. 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 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 ownership and investment interests, held by physicians and their immediate family members; 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 with whom we work, 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 with whom we work, 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 with whom we work 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 with whom we work. 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 with whom we work 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 with whom we work are subject to a variety of evolving threats, including but not limited to, social-engineering attacks (including through deep fakes, which are 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.

It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and systems.

Remote work 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 parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third parties 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 parties 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 the third parties with whom we work experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if the third parties with whom we work 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 that of the third parties with whom we work have not been compromised.

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 with whom we work). We have not and may not in the future, however, detect and remediate all such vulnerabilities including on a timely basis. Further, we have (and may in the future) experienced delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.

Certain of the previously identified or similar threats have in the past and may in the future 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 with whom we work. For example, in November 2020, Covington & Burling LLP, a law firm that has represented us, was the target of a cyberattack in which a sophisticated actor exploited a software vulnerability to access the firm's network, including confidential client materials. Our files were not impacted by this data breach. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) 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 have required us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents, or take other action, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

If we (or a third party with whom we work) experience a security incident or are perceived to have experienced a security incident, we may experience material 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 material 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, our sensitive data 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 and the third parties with whom we work 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 (or such failure by the third parties with whom we work) 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.

Numerous 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, or 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 for intentional violations 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. The CCPA and certain other comprehensive U.S. state privacy laws exempt some data processed in the context of clinical trials, but these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. 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.

Outside the U.S., an increasing number of laws, regulations, and industry standards 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.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the U.S. or other countries due to data localization requirements or limitations on cross-border data flows. Europe 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. Other jurisdictions may or have already adopted similarly stringent 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. Regulators in the United States are also increasingly scrutinizing certain personal data transfers and have proposed and may enact certain personal data transfer and localization requirements.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and we are or may become in the future subject to such obligations. 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 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 statements related to compliance with certain certifications or self-regulatory principles, concerning data privacy and security. Regulators in the U.S. are increasingly scrutinizing these statements, and if these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, 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 with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work 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 or restrictions 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. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. 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.

We are also subject to export control and import laws and regulations. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions.

There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors or collaborators, or those of our affiliates, will comply with all applicable anti-corruption, export and import control, and sanctions laws and regulations. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

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 are not conducting any clinical trials in China nor licensing any products in China but we may do so in the near future in respect of our development of CD388. 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 any clinical 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 any trial 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 any 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, the Affordable Care Act was signed into law, 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, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, effective 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 amendments to and executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed 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 second Trump 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.

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.

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. The IRA, among other things, (1) directs the Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs that have been on the market for at least seven years covered under Medicare, or the Medicare Drug Price Negotiation Program, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first 10 drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected 15 additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act was announced. 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, or 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, particularly in light of the 2024 U.S. Presidential and Congressional elections, 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 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 CD388 and CBO421 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 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 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 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 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 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 unable to resume our preclinical Cloudbreak programs.

We have suspended research and development activities for our preclinical Cloudbreak programs. In order to resume work on our Cloudbreak programs for DFCs, 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 oncology products. If we cannot obtain or maintain government or other funding for our Cloudbreak programs for DFCs we may be forced to discontinue those programs.

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

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

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

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

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

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

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

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

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 influenza 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 active conflicts in the Middle East 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 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.

Our principal stockholders and management own a significant percentage of our stock and are able to exert significant influence 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 significantly influence us through this ownership position. These stockholders may be able to significantly influence all matters requiring stockholder approval, including 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.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Based on our evaluation of the

effectiveness of our internal control over financial reporting as of September 30, 2024, we determined that we had a material weakness as of September 30, 2024 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 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 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.

During 2024, as part of the remediation process, we implemented various controls to address our exposure to indirect taxes, which included additional training to existing staff, enhanced use of indirect tax consultants and experts, review and analysis of our new contracts for possible indirect tax exposures, quarterly calculations of the legal liability for indirect taxes for all shipments during the preceding quarter, and quarterly reconciliation of our legal liability account including assessment of any additional interest due or possible reversals based on compliance remediation. Based on these additional procedures and control, our management has concluded this material weakness has been remediated as of December 31, 2024. The remediation actions are also being monitored by the Audit Committee of our Board of Directors. However, we cannot assure you that we will be able to maintain effective controls and procedures. If we are unable to successfully 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 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.

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 Exchange Act, 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 10,946,635 shares of common stock outstanding as of December 31, 2024. 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, warrants or pre-funded 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 of 1933 as amended, or 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, through the conversion of our Series A Convertible Voting Preferred Stock and Series X Convertible Preferred Stock, or through exercise of warrants and pre-funded warrants, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Significant additional capital will be needed to continue our operations as currently planned, including conducting clinical trials, commercialization efforts, expanded R&D 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.

As of December 31, 2024, there were (i) 2,104,472 shares of Series X Convertible Preferred Stock outstanding, which are convertible into an aggregate of 1,052,236 shares of common stock, subject to the limitations on conversion set forth in the Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock, and (ii) 204,725 shares of Series A Convertible Voting Preferred Stock outstanding, which are convertible into an aggregate of 14,330,750 shares of common stock, subject to the limitations on conversion set forth in the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock. Additionally, as of December 31, 2024, there were (i) warrants to purchase up to an aggregate of 866 shares of common stock outstanding, each at an exercise price of $230.95 per share and (ii) pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of common stock outstanding, each at an exercise price of $0.0001 per pre-funded warrant share.

Pursuant to our 2024 Equity Incentive Plan, our management is authorized to grant equity awards to our employees, directors and consultants. Further, we may grant awards under our 2020 Inducement Incentive Plan, as amended, to certain eligible employees. Additionally, we may grant or provide for the grant of rights to purchase shares of our common stock pursuant to our 2015 Employee Stock Purchase Plan. Any future grants of equity awards, warrants, pre-funded warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

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 R&D 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.

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 loss carryforwards in a taxable year is limited to 80% of taxable income in such year. In addition, under Sections 382 and 383 of the IRC, 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 loss 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, 2024, we had U.S. federal net operating loss carryforwards of approximately $202.8 million, portions of which will begin to expire in 2035, and which could be limited by reason of one or more ownership changes. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2023 and before 2027. 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.

The Tax Act eliminated the option to deduct R&D 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, 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 global pandemics, 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 our 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 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 February 27, 2025, there were 18 holders of record for our common stock, which does not include beneficial owners of our common stock whose shares are held in the name of various dealers, clearing agencies, banks, brokers and other fiduciaries.

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

Except as previously reported in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the Securities and Exchange Commission during the year ended December 31, 2024, there were no unregistered sales of equity securities by us during the year ended December 31, 2024.

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 using our proprietary Cloudbreak® platform to develop drug-Fc conjugate, or DFC, immunotherapies designed to save lives and improve the standard of care for patients facing serious diseases.

Our lead clinical-stage asset is CD388, a DFC intended for influenza prophylaxis, which we discovered and advanced to the clinic under a partnership with J&J Innovative Medicine, previously Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, or Janssen. To date, we have completed two Phase 1 studies and one Phase 2a study of CD388 under our prior license and collaboration agreement that we entered into with Janssen in March 2021, or the Janssen Collaboration Agreement. In 2023, as part of a prioritization of its research and development, or R&D, business, Janssen disclosed its intention to discontinue internal development of multiple product candidates in its infectious disease pipeline, including CD388. Through a competitive process, we reacquired all rights to develop and commercialize CD388 by executing a license and technology transfer agreement with Janssen, or the Janssen License Agreement, in April 2024. Under the terms of the Janssen License Agreement, we received an exclusive, worldwide, fee-bearing but royalty-free license under certain Janssen-controlled technology to develop, manufacture and commercialize compounds, including CD388.

Concurrent with the CD388 reacquisition, we completed a private placement pursuant to which we sold an aggregate of 240,000 shares of our Series A Convertible Voting Preferred Stock to certain institutional and other accredited investors, or the April 2024 Private Placement, which was led by RA Capital Management, with significant participation from Bain Capital Life Sciences, Biotech Value Fund, or BVF, and Canaan Partners. The April 2024 Private Placement provided $240.0 million in gross proceeds, of which we used $85.0 million to fund the upfront payment under the Janssen License Agreement. The remainder of the gross proceeds of $155.0 million are being utilized to develop CD388 as a universal preventative against seasonal and pandemic influenza A and B, beginning with the current CD388 Phase 2b NAVIGATE study that we initiated in September 2024. We believe the reacquisition of CD388 is transformational for Cidara and potentially for those who could benefit from a long-acting, universal preventative against known forms of influenza.

In addition, in April 2024 we simultaneously divested rezafungin, our sole non-Cloudbreak asset, to enable us to focus our resources on the development of CD388. We entered into an Asset Purchase Agreement, or Napp Purchase Agreement, with Napp Pharmaceutical Group Limited, or Napp, an affiliate of Mundipharma Medical Company, or Mundipharma, our licensee for the asset in all territories other than the U.S. and Japan, pursuant to which we sold to Napp all of our rezafungin assets, including our right to receive future milestones and royalties under the License Agreement between us and Melinta Therapeutics, LLC, or Melinta (our U.S. licensee), or the Melinta License Agreement, and the License and Collaboration Agreement between us and Mundipharma, or the Mundipharma Collaboration Agreement.

Following these transactions, our sole R&D focus has now shifted to our proprietary Cloudbreak platform, which enables the development of novel DFCs that inhibit specific disease targets while simultaneously engaging the immune system. With the reacquisition of CD388, it is now our most advanced DFC program. CD388 is a highly potent antiviral designed to deliver universal prevention and treatment of seasonal and pandemic influenza.

In November 2024, we completed a private placement pursuant to which we sold an aggregate of 3,892,274 shares of our common stock and pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of common stock to certain institutional and other accredited investors, or the November 2024 Private Placement. The November 2024 Private Placement provided $105.0 million in gross proceeds.

Cloudbreak Platform

We believe our Cloudbreak platform has the potential to offer a fundamentally new approach to treat and prevent serious diseases such as viral infections and solid tumors, 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 multi-specific 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 targeting 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 highly potent antiviral designed to deliver universal prevention and treatment of seasonal and pandemic influenza. Our lead oncology DFC is CBO421, a development candidate targeting CD73 for the treatment of solid tumors, which received investigational new drug application, or IND, clearance in July 2024. We do not plan to initiate clinical trials for any oncology product candidates at this time but continue business development discussions for our oncology DFC programs, including CBO421.

Cloudbreak Influenza Program (CD388)

We have completed two Phase 1 studies and one Phase 2a study of CD388, our influenza DFC:

- A randomized, double-blind, dose-escalation Phase 1 study to determine the safety, tolerability and pharmacokinetics of intramuscular and subcutaneous administration of CD388 in healthy subjects (NCT05285137);
- A separate Phase 1 Japanese bridging study (NCT05619536); and
- A Phase 2a study (NCT05523089) to evaluate the pre-exposure prophylactic activity of CD388 against influenza.

We initiated the CD388 Phase 2b NAVIGATE study in September 2024.

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 1 and Phase 2a Results

On September 21, 2023, we announced efficacy and safety data from our Phase 1 and Phase 2a studies 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 (maximum dose tested):

In total, 108 subjects were dosed in our Phase 1 and Phase 2a studies, 84 of which were dosed subcutaneously, or SQ, and 24 were dosed intramuscularly, or IM.

Percent of SQ CD388 or Placebo Treatment Related Adverse Events in Phase 1 and Phase 2a studies

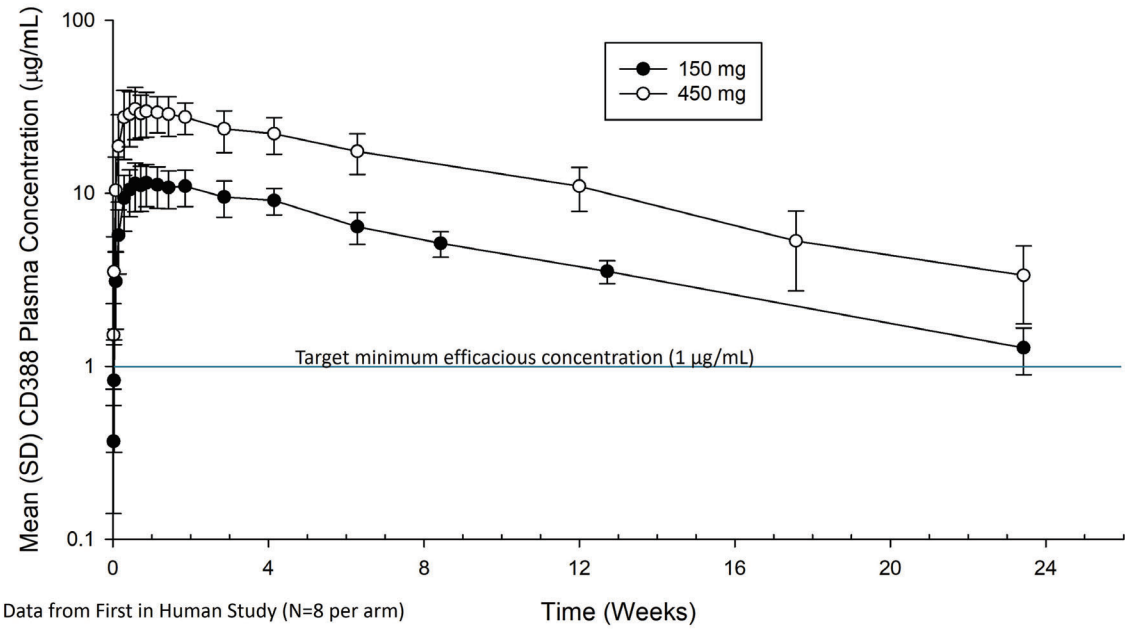
	First in Human Study (Phase 1)	Japanese Bridging Study (Phase 1)	Human Challenge Study (Phase 2a)
Dose	**CD388 N=8/dose; Placebo N=12**	**CD388 N=7*/dose; Placebo N=6**	**50mg N=2; 150mg N=28; Placebo N=29**
Placebo	33.3	16.7	—
50 mg	62.5	28.6	—
150 mg	12.5	12.5	—
450 mg	—	—	N/A
900 mg	25.0	N/A	N/A

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, IM, route mainly), Grade 1, all resolved spontaneously.
- No clinically relevant electrocardiogram, or ECG, vital signs or physical exam abnormalities.

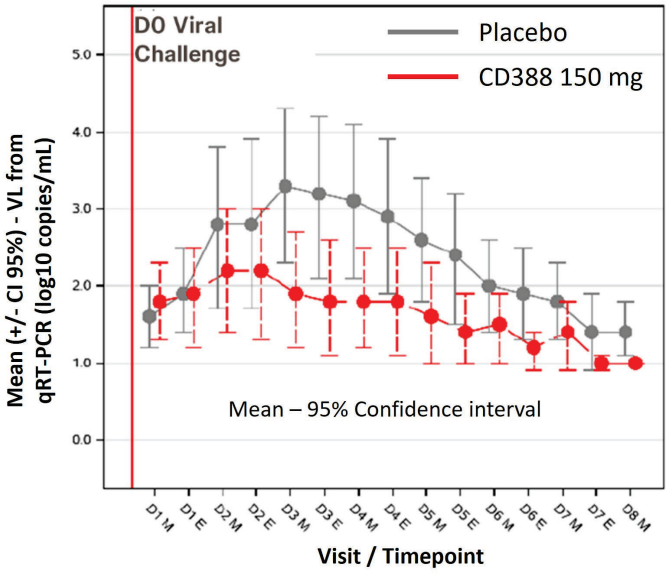
* 150mg N=8

First in Human - single CD388 dose of 150 mg to 450 mg potentially provides seasonal coverage:

Differentiation between doses expected near the end of the flu season



CD388 demonstrated protection in Phase 2a Human Challenge Model:



Primary endpoint: AUC viral load-time_ qRT-PCR

One sided p-value Wilcoxon rank sum test: 0.0390

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
Quantitative reverse transcriptase polymerase chain reaction, or qRT-PCR, confirmed influenza infection *	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

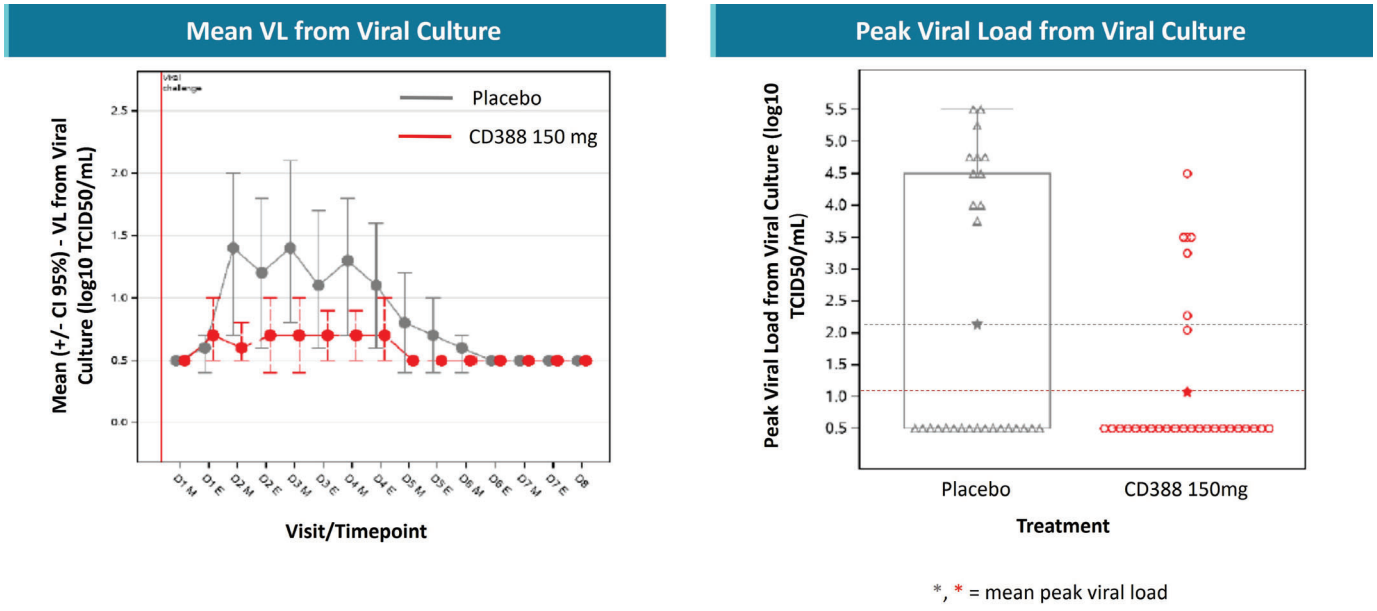
*RT-PCR-confirmed influenza infection: two quantifiable (≥ lower limit of quantification, or LLOQ) qRT-PCR measurements (reported on two or more independent samples over two days), from Day 1 (pm) up to Day 8 (am).

**RT-PCR-confirmed symptomatic influenza infection: RT-PCR-confirmed influenza infection (two quantifiable (≥LLOQ) qRT-PCR measurements (reported on two or more independent samples over two days)), from Day 1 (pm) up to Day 8 (am), and symptoms ≥2 at a single time point.

***RT-PCR-confirmed moderate to severe symptomatic influenza infection: RT-PCR confirmed influenza infection (two quantifiable (≥LLOQ) qRT-PCR measurements (reported on two or more independent samples over two days)), from Day 1 (pm) up to Day 8 (am), and any symptoms of grade ≥2 at a single time point.

As shown above, despite the small sample size in this analysis, a decrease in viral replication in the upper respiratory tract and influenza infection was observed in participants receiving a single dose of CD388 when compared to placebo. No treatment emergent adverse events leading to study discontinuation or 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 from Phase 2a Human Challenge Study confirmed efficacy seen in early analyses:



CD388 Phase 2a and Phase 1 Data Presentations at 34th European Society of Clinical Microbiology and Infectious Diseases (ESCMID) conference:

In April 2024, we presented data from the Phase 2a study of CD388 in various poster presentations at the 34th ESCMID conference. The first presentation showed CD388 was well-tolerated and demonstrated statistically significant antiviral effects when administered as a single subcutaneous dose in healthy volunteers challenged with influenza. The second presentation highlighted data from a Phase 1 single ascending dose study of CD388 which showed the drug has an extended half-life of 6-8 weeks. These data underscore the potential of CD388 to provide patients with seasonal influenza prevention.

CD388 Phase 2a and Phase 1 Data Presentations at the Options XII conference:

In October 2024, we presented data from the Phase 2a study and the two Phase 1 studies. The first presentation was an oral presentation and showed the comprehensive safety data from all completed studies in the CD388 development program, demonstrating that CD388 appears to be well-tolerated at single doses up to 900 mg and repeat doses up to 450 mg. The second presentation was a poster presentation of the Phase 1 Japanese Bridging study that demonstrated that the pharmacokinetics of CD388 were similar between Japanese and Western participants and required no dose changes.

CD388 Phase 2a and Phase 1 Data Presentations at the ID Week conference:

In October 2024, we presented additional data from the Phase 2a study and the Phase 1 First-in-Human study. The first presentation was an oral presentation that showed that among those participants who had serology confirmation of influenza infection in the Phase 2a study the rates of symptomatic clinical influenza and viral load AUC were significantly lower for CD388 participants versus placebo participants. The second presentation was a poster presentation that showed comprehensive safety and pharmacokinetic data from the First-in-Human Phase 1 study. This poster demonstrated that a single dose of CD388 should be sufficient to last through an entire influenza season and the lack of hypersensitivity or anti-drug antibodies with repeat dosing of CD388.

Peer-reviewed Manuscript on CD388 Preclinical Data Accepted for Publication:

A peer-reviewed manuscript describing the design and preclinical characterization of CD388 has been accepted for publication and is expected to appear in print in the first half of 2025. The manuscript highlights the potent, universal antiviral activity of CD388 in cell-based assays and lethal mouse infection models, and low potential for resistance development.

CD388 Phase 2b NAVIGATE Study Timeline

We initiated the CD388 Phase 2b NAVIGATE study during the 2024-25 Northern Hemisphere influenza season, with dosing of the first subjects on September 20, 2024. The CD388 Phase 2b NAVIGATE study is a randomized, double-blinded, controlled trial with single doses of CD388 or placebo administered at the beginning of the influenza season with subjects followed for the influenza season to monitor for breakthrough cases of influenza. The primary endpoint of this study will compare the rates of laboratory-confirmed clinical influenza between different single dose levels of CD388 and placebo over an influenza season. The patient population in this study will be healthy adults who have not received an influenza vaccination for the upcoming season. In December 2024, we announced that we had reached full planned enrollment of at least 5,000 subjects across clinical trial sites in the United States and the United Kingdom. Topline data is expected in the third quarter of 2025. Given the severity of the 2024-25 flu season, we may consider a potential early analysis of efficacy data from the ongoing CD388 Phase 2b NAVIGATE study in the first half of 2025. If an analysis of the CD388 Phase 2b NAVIGATE study is completed in the first half of 2025, such results will be disclosed and we may consider initiating a Phase 3 study during the 2025-26 Northern Hemisphere influenza season. Refer to other risks described in Item 1A. “Risk Factors” of this Annual Report on Form 10-K.

Cloudbreak Oncology Programs

We have expanded the Cloudbreak platform beyond infectious diseases, to discover and develop highly potent DFCs that can target single or multiple immune checkpoint pathways for the treatment of solid tumors.

Immune checkpoint antagonists have generated durable responses in cancers with improved side effect profiles compared to conventional chemotherapy. However, improved outcomes from existing therapies have been limited to a small subset of patients. To broaden the response rate to more patients, targeting additional mechanisms of tumor immune evasion will be critical.

Using Cloudbreak, we seek to develop a new generation of immunotherapies targeting the tumor microenvironment. Our lead oncology DFC candidate, CBO421, is a highly differentiated 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 triple negative breast cancer, or TNBC, and other solid tumors. As a monotherapy and in combination with PD-1 inhibitors, CBO421 has demonstrated activity and formation of immunologic memory in multiple murine tumor models, along with differentiated activity in T-cell reactivation assays and tumor penetration compared with the most advanced CD73 antibody therapeutics in clinical development. CBO421 received IND clearance in July 2024.

Cloudbreak Oncology Pipeline:

Program	Indication	Discovery	Preclinical	IND Ready	Phase 1	Phase 2
CD73	Solid Tumors, TNBC[1]	CBO421				
PD-1/ CD73	Solid Tumors					
CCR5	Solid Tumors					

1. TNBC = Triple Negative Breast Cancer

We do not plan to initiate clinical trials for any oncology product candidates at this time but continue business development discussions for our oncology DFC programs, including CBO421.

Compliance with Nasdaq Listing Requirements and Reverse Stock Split

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 us until November 9, 2023 pursuant to the February 9, 2023 Hearings Decision of the Panel, we were not eligible for a compliance period and the Staff notified us that this matter served as a basis for delisting our 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.

At our special meeting of stockholders held on April 4, 2024, our stockholders approved a proposal to (i) amend our Amended and Restated Certificate of Incorporation to effect a reverse stock split of our 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 our board of directors and with such reverse stock split to be effected at such time and date, if at all, as determined by our board of directors in its sole discretion.

On April 12, 2024, our board of directors approved a reverse stock split of all outstanding shares of our common stock at a ratio of 1-for-20, or the Reverse Stock Split. Our 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, we filed with the Secretary of State of the State of Delaware a Certificate of Amendment of our Amended and Restated Certificate of Incorporation, or the Charter Amendment, to effect the Reverse Stock Split. The Charter Amendment became effective at 5:00 p.m. Eastern Time on April 23, 2024. Our common stock began trading on The Nasdaq Capital Market on a split-adjusted basis when the market opened on April 24, 2024 under a new CUSIP number (171757206).

On May 14, 2024, we received a letter from the Staff notifying us that we had regained compliance with Nasdaq's requirements for continued listing. In addition, the Panel imposed a discretionary Panel monitor until May 14, 2025, such that if we fail to maintain compliance with any continued listing requirement during such period, the Staff will issue a delist determination letter and we will promptly schedule a new hearing before the Panel to address such noncompliance.

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, inflation, bank failures, labor shortages, supply chain disruptions, recession risks, the recent presidential election in the U.S., potential tariffs and potential disruptions from the ongoing Russia-Ukraine conflict and related sanctions and the active conflicts in the Middle East. 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.

Common Stock Equivalents Outstanding

As of December 31, 2024, we had 10,946,635 shares of common stock outstanding, 204,725 shares of Series A Convertible Voting Preferred Stock outstanding, which are convertible into 14,330,750 shares of common stock, 2,104,472 shares of Series X Convertible Preferred Stock outstanding, which are convertible into 1,052,236 shares of common stock, warrants to purchase up to 866 shares of our common stock outstanding, pre-funded warrants to purchase up to 3,149,035 shares of our common stock outstanding, and outstanding stock options and restricted stock units covering 2,481,011 shares of our common stock for a total of 31,960,533 shares of common stock equivalents outstanding.

Liquidity Overview

We have a limited operating history and the sales and income potential of our business and market are unproven. We have experienced net losses and negative cash flows from operating activities since our inception. As of December 31, 2024, we had an accumulated deficit of $611.3 million. We expect 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 our cost structure.

At December 31, 2024, we had cash, cash equivalents and restricted cash of $196.2 million, which we expect will provide sufficient liquidity for a period of at least one year following the date that our consolidated financial statements are issued as part of this Annual Report on Form 10-K.

Our ability to execute our current business plan depends on our ability to obtain additional funding through equity offerings, debt financings, other third-party funding, or potential licensing or 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 our business plan.

We plan to continue to fund our losses from operations through cash, cash equivalents and restricted cash on hand, as well as through future equity offerings, debt financings, other third-party funding, or 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.

FINANCIAL OPERATIONS OVERVIEW

Revenues

We have generated all of our revenues from our strategic partnership with Janssen. In the future, we may generate revenue from a combination of license fees and other upfront payments, other funded R&D 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.

Acquired In-process Research and Development Expenses

Acquired in-process research and development, or IPR&D, expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones.

We evaluate license agreements for IPR&D projects to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the license agreement for IPR&D does not meet the definition of a business and the assets have not reached technological feasibility and have no alternative future use, we expense payments made under such license agreements as acquired IPR&D expense in our consolidated statements of operations and comprehensive loss. In those cases, payments for milestones achieved and payments for a product license prior to regulatory approval of the product are expensed in the period incurred. Payments made in connection with regulatory and sales-based milestones will be capitalized and amortized to cost of revenue.

Research and development expenses

Our R&D expenses have related primarily to nonclinical and clinical development of our Cloudbreak platform. R&D expenses consist of wages, benefits and stock-based compensation for R&D 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, and nonclinical and clinical trial costs. We accrue clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies or other activities within studies and other events.

R&D 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.

R&D 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:

- 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.

R&D expenses by major program or category for the years ended December 31, 2024, and 2023, were as follows (in thousands):

	Year ended December 31,	
	2024	2023
Cloudbreak platform	56,454	25,936
Personnel costs	13,039	8,568
Other research and development expenses	2,386	2,259
Total research and development expenses	$ 71,879	$ 36,763

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

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

General and administrative expenses

General and administrative, or G&A, expenses relate to finance, human resources, legal and other administrative activities. G&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 G&A expenses include facility and overhead costs not otherwise included in R&D expenses, consultant expenses, travel expenses, professional fees for auditing, tax, legal, and other services.

Other income, net

Other income, net consists primarily of interest income and expense, and various income or expense items of a non-recurring nature. We earn interest income from interest-bearing accounts and money market accounts for cash, cash equivalents and restricted cash. Interest expense represents interest on finance lease liabilities.

Discontinued Operations

On April 24, 2024, we entered into the Napp Purchase Agreement with Napp, pursuant to which we sold to Napp all of our rezafungin assets and related contracts. We completed all conditions of the sale on April 24, 2024. We determined that the sale of rezafungin represented a strategic shift that will have a major effect on our operations and financial results. Accordingly, the sale of rezafungin is classified as discontinued operations.

We present discontinued operations when there is a disposal of a component or a group of components that represents a strategic shift that will have a major effect on operations and financial results. The results from discontinued operations of the rezafungin assets prior and subsequent to its sale are presented as net income from discontinued operations, net of income taxes, in the consolidated statements of operations and comprehensive loss for all periods presented, including the loss on disposal of discontinued operations recognized during the second quarter of 2024. The assets and liabilities for the rezafungin operations related activities prior and subsequent to its sale have been classified as discontinued operations and segregated for all periods presented in the consolidated balance sheets. See Note 10 to the consolidated financial statements for additional information.

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 contained 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.

See Note 7 and Note 10 to the consolidated 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 R&D 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, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and 2023 (in thousands):

	Year ended December 31,		
	2024	2023	Change
Collaboration revenue	$ 1,275	$ 23,283	$ (22,008)
Acquired in-process research and development	84,883	—	$ 84,883
Research and development	71,879	36,763	35,116
General and administrative	20,615	13,580	7,035
Other income, net	5,811	1,995	3,816
Income tax expense	—	(15)	15
Income from discontinued operations, net of income taxes	464	2,149	(1,685)

Collaboration revenue

Collaboration revenue was $1.3 million and $23.3 million for the years ended December 31, 2024 and 2023, respectively, and related to the achievement of milestones and ongoing R&D and clinical supply services provided to Janssen under the Janssen Collaboration Agreement. The Janssen Collaboration Agreement was terminated upon the effectiveness of the Janssen License Agreement on April 24, 2024.

Acquired in-process research and development expenses

Acquired IPR&D expenses were $84.9 million for the year ended December 31, 2024 and related to an upfront payment of $85.0 million paid to Janssen under the Janssen License Agreement, on April 24, 2024, plus $0.4 million in direct transaction costs, offset by a settlement gain of $0.5 million to settle the preexisting Janssen Collaboration Agreement relationship.

Research and development expenses

R&D expenses were $71.9 million for the year ended December 31, 2024 compared to $36.8 million for the year ended December 31, 2023. The increase in R&D expenses is primarily due to higher expenses associated with our CD388 Phase 2b NAVIGATE study and higher personnel costs, including $1.2 million for severance and employee benefits incurred related to a reduction in force, offset by lower nonclinical expenses associated with our Cloudbreak platform.

General and administrative expenses

G&A expenses were $20.6 million for the year ended December 31, 2024 compared to $13.6 million for the year ended December 31, 2023. The increase in G&A expenses is primarily due to higher audit fees, legal costs, and personnel costs.

Other income, net

Other income, net during the years ended December 31, 2024 and 2023 related primarily to interest income generated from cash held in interest-bearing accounts, offset by interest expense on finance lease liabilities.

Income tax expense

Income tax expense for the year ended December 31, 2023 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. For the year ended December 31, 2023 the tax provision for income taxes from continuing operations consisted primarily of state minimum taxes.

Income from discontinued operations

On April 24, 2024, we entered into the Napp Purchase Agreement with Napp, pursuant to which we sold to Napp all of our rezafungin assets and related contracts. We completed all conditions of the sale on April 24, 2024. We determined that the sale of rezafungin represented a strategic shift that will have a major effect on our operations and financial results. Accordingly, the sale of rezafungin is classified as discontinued operations.

Income from discontinued operations was $0.5 million for the year ended December 31, 2024 and primarily consisted of revenue of $29.3 million related to sale of rezafungin assets, including sale of IP and inventory, product revenue related to shipments of REZZAYO naked vials to Mundipharma, as well as R&D and clinical supply services provided to Mundipharma and Melinta, offset by (i) cost of product revenue of $9.0 million, (ii) R&D expenses of $10.5 million associated with the rezafungin clinical trial and development costs, (iii) selling, general and administrative, or SG&A, expenses of $7.5 million primarily associated with rezafungin-related patent costs, accrued interest and penalties for indirect taxes for rezafungin-related shipments and accrued indirect tax penalties on disposal of rezafungin, and (iv) loss on disposal of discontinued operations of $1.8 million.

Income from discontinued operations was $2.1 million for the year ended December 31, 2023 and primarily consisted of revenue of $40.6 million related to the achievement of milestones and R&D and clinical supply services provided to Mundipharma and Melinta, as well as product revenue related to shipments of REZZAYO naked vials to Mundipharma and Melinta, offset by (i) cost of product revenue of $1.5 million, (ii) R&D expenses of $31.8 million associated with the rezafungin clinical trial and development costs, (iii) SG&A expenses of $4.8 million primarily associated with amortization of contract costs related to obtaining the Melinta License Agreement, rezafungin-related patent costs and accrued interest and penalties for indirect taxes for rezafungin-related shipments, and (iv) income tax expense of $0.4 million.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of liquidity are our cash, cash equivalents and restricted cash, as well as equity financings. We have devoted our resources to funding R&D 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, potentially entering into 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 disruptions to, and volatility in, financial markets in the U.S. and worldwide from geopolitical and macroeconomic events, including global pandemics, the recent presidential election in the U.S., the ongoing Russia-Ukraine conflict and related sanctions, the active conflicts in the Middle East, and bank failures. As a result of our failure to timely file our Annual Report on Form 10-K for the year ended December 31, 2023, we lost our Form S-3 eligibility for primary and secondary offerings for at least 12 calendar months following the date our Annual Report on Form 10-K filing was first delinquent, or through May 1, 2025.

On April 23, 2024, we entered into a securities purchase agreement with certain institutional and other accredited investors named therein in connection with the April 2024 Private Placement, pursuant to which we issued and sold 240,000 shares of Series A Convertible Voting Preferred Stock at a purchase price of $1,000 per share. The closing of the April 2024 Private Placement took place on April 24, 2024, and we received total gross proceeds of $240.0 million. As a condition to the effectiveness of the Janssen License Agreement, we paid Janssen an upfront payment of $85.0 million on April 24, 2024.

On September 9, 2024, our management, as authorized by our board of directors, approved a reduction in our workforce of 20 employees, which represented approximately 30% of our workforce, or the Reduction. The Reduction was substantially completed by November 1, 2024 and has and is expected to continue to substantially reduce our capital needs related to recurring personnel costs going forward. As a result of the Reduction, we incurred charges of approximately $1.2 million for severance payments and employee benefits included in R&D expenses in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. We do not expect to incur additional charges related to the Reduction. As of December 31, 2024, approximately $0.1 million of these charges were unpaid and included in accrued compensation and benefits in the consolidated balance sheets. We expect these charges to be paid during the first quarter of 2025.

On November 20, 2024, we entered into a securities purchase agreement with certain institutional and other accredited investors named therein, or the November 2024 Purchasers, in connection with the November 2024 Private Placement, pursuant to which we issued and sold (i) an aggregate of 3,892,274 shares of our common stock at a purchase price of $14.912 per share, and (ii) in lieu of shares of common stock to certain November 2024 Purchasers, pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of common stock at a purchase price of $14.9119 per pre-funded warrant (representing the $14.912 per share purchase price less the exercise price of $0.0001 per pre-funded warrant share). The pre-funded warrants are exercisable at any time after their original issuance and will not expire. The closing of the November 2024 Private Placement took place on November 26, 2024, and we received total gross proceeds of $105.0 million.

On December 11, 2024, we established a standby letter of credit with our banking institution, Wells Fargo, for $6.0 million for the benefit of our indirect tax service provider, as it relates to indirect tax compliance services in various tax jurisdictions outside of the U.S. in connection with the rezafungin supply chain activities and commercial sales of REZZAYO. The letter of credit expires on November 30, 2025 and is automatically extended without amendment for an additional one-year period from the current expiration date, unless notified by us to terminate prior to 90 days from any

expiration date. The cash held as collateral for this standby letter of credit is recorded as restricted cash and is held in an interest-bearing account.

As of December 31, 2024 we have no outstanding loan balances.

Our finance lease for lab equipment expires in January 2027. Total undiscounted finance lease payments are $0.6 million as of December 31, 2024.

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 us. As of December 31, 2024, we were not reasonably certain that we 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 were $3.4 million as of December 31, 2024.

We are mindful that conditions in the current macroeconomic environment could affect our ability to achieve our goals. 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 R&D 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 conduct R&D activities associated with our Cloudbreak platform, as well as personnel and G&A support costs.

Comparison of cash flows for the years ended December 31, 2024 and 2023

The following table shows a summary of our cash flows for the years ended December 31, 2024 and 2023 (in thousands):

	Year ended December 31,	
	2024	**2023**
Net cash (used in) provided by:		
Operating activities	$ (176,533)	$ (22,432)
Investing activities	(129)	(505)
Financing activities	337,061	25,984
Net increase in cash, cash equivalents and restricted cash	160,399	3,047
Cash, cash equivalents and restricted cash at beginning of year	35,778	32,731
Cash, cash equivalents and restricted cash at end of year	$ 196,177	$ 35,778

Operating activities

Net cash used in operating activities was $176.5 million for the year ended December 31, 2024, compared to $22.4 million for the year ended December 31, 2023. Cash used in operating activities for the year ended December 31, 2024 was primarily attributable to (i) a net loss of $169.8 million which included an upfront payment of $85.0 million paid to Janssen under the Janssen License Agreement on April 24, 2024, plus $0.4 million in direct transaction costs, (ii) a $10.9 million increase in prepaid expenses, other current assets, and other assets primarily associated with deposits paid to a contract research organization at the start of our CD388 Phase 2b NAVIGATE study, (iii) a $14.3 million decrease in accounts receivable, primarily associated with the collection of an $11.1 million milestone payment from Mundipharma under the Mundipharma Collaboration Agreement before execution of the Napp Purchase Agreement, and (iv) a $29.3 million decrease in contract liabilities primarily associated with the recognition of collaboration revenue on the consolidated statements of operations and comprehensive loss.

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.

For all periods presented, the primary use of cash was to fund R&D 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, 2024 and 2023 consisted of purchases of property and equipment.

Financing activities

Net cash provided by financing activities of $337.1 million during the year ended December 31, 2024 consisted primarily of (i) net proceeds of $239.1 million, from the sale of 240,000 shares of Series A Convertible Voting Preferred Stock pursuant to the April 2024 Private Placement, and (ii) net proceeds of $98.2 million from the sale of 3,892,274 shares of common stock and pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of common stock pursuant to the November 2024 Private Placement, offset by payment of finance lease liabilities of $0.3 million.

Net cash provided by financing activities of $26.0 million during the year ended December 31, 2023 consisted primarily of (i) net proceeds of $17.3 million from the sale of 554,300 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 311,583 shares of common stock under our controlled equity sales agreement with Cantor Fitzgerald & Co., after deducting placement agent fees.

Discontinued Operations

The cash flows related to discontinued operations have not been segregated and are included in the consolidated statements of cash flows. The total net cash used in operating activities from discontinued operations was $18.0 million and $10.5 million for the years ended December 31, 2024 and 2023, respectively. There were no investing or financing activities from discontinued operations for the years ended December 31, 2024 and 2023.

The increase in cash used in operating activities from discontinued operations primarily related to lower milestone payments received offset by decreased clinical, development, and manufacturing activities related to the rezafungin program during the year ended December 31, 2024 as compared to the year ended December 31, 2023.

The absence of cash outflows from discontinued operations is expected to reduce our operating cash outflows from continuing operations given that we no longer have any future obligations related to rezafungin. The expected cash outflows for these obligations to complete the ongoing clinical trials, development activities, and manufacturing activities would have been offset by any near-term future milestones and royalties.

Operating Capital Requirements

Our ability to execute our operating plan depends on our ability to obtain additional funding through equity offerings, debt financings, other third-party funding, or potential licensing or collaboration arrangements. We plan to continue to fund our losses from operations through cash, cash equivalents and restricted cash on hand, as well as through future equity offerings, debt financings, other third party funding, or 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, 2024 and 2023, 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, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

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.

Preclinical and Clinical Trial Accruals

Description of the Matter

As of December 31, 2024, the Company accrued $10.3 million for clinical trial accruals included in accrued liabilities. As described in Note 2 of the consolidated financial statements, 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 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. The Company accrues the expenses as goods or services are used or rendered. Clinical trial site costs are accrued as patients enter and progress through the trial.

Auditing management's accounting for clinical trial accruals is especially challenging as evaluating the progress or stage of completion of the activities under the Company's clinical agreements is dependent upon a high volume of data from third-party service providers and internal clinical personnel, which is tracked in spreadsheets and other end user computing programs.

How We Addressed the Matter in Our Audit

To test the completeness of the Company's clinical trial accruals, among other procedures, we obtained supporting evidence of the research and development activities performed for significant clinical trials. We corroborated the status of significant research and development activities through meetings with accounting and clinical project managers. To verify the appropriate measurement of clinical trial accruals, we compared the costs for a sample of transactions against the related invoices and contracts, and confirmed amounts incurred to-date with third-party service providers. We also examined a sample of subsequent payments to evaluate the completeness of the clinical trial accruals.

Accrued Indirect Tax Liabilities

Description of the Matter

As discussed in Note 2 to the consolidated financial statements, prior to the sale of rezafungin, the Company's purchases of clinical drug supplies and raw materials, inventory transfers, and sales of commercial drug product were subject to 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 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. As of December 31, 2024, the Company recorded $26.0 million of accrued indirect tax liabilities.

Auditing the Company's accrued indirect tax liabilities is challenging because the indirect tax liabilities are 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

March 6, 2025

CIDARA THERAPEUTICS, INC.

Consolidated Balance Sheets

(In thousands, except share and per share data)	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 189,825	$ 35,778
Restricted cash	6,352	—
Accounts receivable	1,694	14,075
Prepaid expenses and other current assets	12,866	1,712
Current assets from discontinued operations	—	9,290
Total current assets	210,737	60,855
Property and equipment, net	521	557
Finance lease right-of-use asset, net	703	782
Operating lease right-of-use asset	2,739	3,788
Other assets	96	114
Noncurrent assets from discontinued operations	—	934
Total assets	$ 214,796	$ 67,030
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 3,608	$ 3,772
Accrued liabilities	13,348	14,177
Accrued indirect tax liabilities	26,045	18,040
Accrued compensation and benefits	4,911	5,034
Current contract liabilities	—	430
Current portion of finance lease liability	264	218
Current portion of operating lease liability	1,378	1,082
Current liabilities from discontinued operations	—	24,665
Total current liabilities	49,554	67,418
Long-term finance lease liability	310	575
Long-term operating lease liability	1,624	3,002
Noncurrent liabilities from discontinued operations	—	4,245
Total liabilities	51,488	75,240
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2024 and 2023:		
Series A Convertible Voting Preferred Stock, $0.0001 par value; 204,725 shares authorized at December 31, 2024; 240,000 shares issued and 204,725 shares outstanding at December 31, 2024; no shares authorized, issued and outstanding at December 31, 2023	—	—
Series X Convertible Preferred Stock, $0.0001 par value; 4,947,759 shares authorized at December 31, 2024 and 2023; 2,156,713 shares issued and 2,104,472 shares outstanding at December 31, 2024 and 2,156,713 shares issued and 2,104,472 shares outstanding at December 31, 2023	—	—
Common stock, $0.0001 par value; 50,000,000 shares authorized at December 31, 2024 and 20,000,000 shares authorized at December 31, 2023; 10,946,635 shares issued and outstanding at December 31, 2024; 4,530,113 shares issued and outstanding at December 31, 2023	1	1
Additional paid-in capital	774,565	433,220
Accumulated deficit	(611,258)	(441,431)
Total stockholders' equity (deficit)	163,308	(8,210)
Total liabilities and stockholders' equity (deficit)	$ 214,796	$ 67,030

See accompanying notes.

CIDARA THERAPEUTICS, INC.

Consolidated Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)	Years ended December 31, 2024	2023
Revenues:		
Collaboration revenue	$ 1,275	$ 23,283
Total revenues	1,275	23,283
Operating expenses:		
Acquired in-process research and development	84,883	—
Research and development	71,879	36,763
General and administrative	20,615	13,580
Total operating expenses	177,377	50,343
Loss from operations	(176,102)	(27,060)
Other income, net:		
Interest income, net	5,811	1,995
Total other income, net	5,811	1,995
Net loss from continuing operations before income tax expense	(170,291)	(25,065)
Income tax expense	—	(15)
Net loss from continuing operations	(170,291)	(25,080)
Income from discontinued operations (including loss on disposal of discontinued operations of $1,799 and zero during the years ended December 31, 2024 and 2023, respectively), net of income taxes	464	2,149
Net loss and comprehensive loss	$ (169,827)	$ (22,931)
Basic and diluted net loss per common share from continuing operations	$ (26.82)	$ (5.74)
Basic and diluted net earnings per common share from discontinued operations	0.07	0.49
Basic and diluted net loss per common share	$ (26.75)	$ (5.25)
Shares used to compute basic and diluted net earnings (loss) per common share	6,349,631	4,371,375

See accompanying notes.

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

(In thousands, except share data)	Series A Convertible Voting Preferred Stock		Series X Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance, December 31, 2022	—	$ —	1,818,472	$ —	3,623,591	$ 1	$ 404,061	$ (418,500)	$ (14,438)
Underwritten public offering, net of issuance costs	—	—	286,000	—	554,300	—	17,256	—	17,256
Public offering of common stock, net of issuance costs	—	—	—	—	310,983	—	8,699	—	8,699
Issuance of common stock upon exercise of stock options	—	—	—	—	1,287	—	21	—	21
Issuance of common stock for restricted share units vested	—	—	—	—	24,487	—	—	—	—
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	15,465	—	122	—	122
Stock-based compensation	—	—	—	—	—	—	3,061	—	3,061
Net loss	—	—	—	—	—	—	—	(22,931)	(22,931)
Balance, December 31, 2023	—	—	2,104,472	—	4,530,113	1	433,220	(441,431)	(8,210)
Private placements, net of issuance costs	240,000	—	—	—	3,892,274	—	337,330	—	337,330
Issuance of common stock upon conversion of Series A Convertible Voting Preferred Stock	(35,275)	—	—	—	2,469,250	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	4,144	—	60	—	60
Issuance of common stock for restricted share units vested	—	—	—	—	40,346	—	—	—	—
Value of shares withheld to fund payroll taxes	—	—	—	—	—	—	(39)	—	(39)
Issuance of common stock under Employee Stock Purchase Plan	—	—	—	—	10,508	—	87	—	87
Stock-based compensation	—	—	—	—	—	—	3,907	—	3,907
Net loss	—	—	—	—	—	—	—	(169,827)	(169,827)
Balance, December 31, 2024	204,725	$ —	2,104,472	$ —	10,946,635	$ 1	$ 774,565	$ (611,258)	$ 163,308

See accompanying notes.

CIDARA THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(In thousands)	Years ended December 31, 2024	2023
Operating activities:		
Net loss	$ (169,827)	$ (22,931)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of discontinued operations	1,799	—
Stock-based compensation	3,907	3,061
Non-cash operating lease expense	1,048	1,158
Depreciation and amortization	154	112
Amortization of costs to obtain a contract with a customer	184	77
Amortization of finance lease right-of-use asset	79	6
Non-cash interest expense	56	5
Changes in assets and liabilities:		
Accounts receivable	14,275	(10,413)
Inventory	6,097	(6,097)
Prepaid expenses, other current assets, and other assets	(10,851)	3,735
Accounts payable and accrued liabilities	(1,001)	8,886
Accrued indirect tax liabilities	8,005	6,506
Accrued compensation and benefits	(36)	235
Contract liabilities	(29,340)	(5,799)
Operating lease liabilities	(1,082)	(973)
Net cash used in operating activities	(176,533)	(22,432)
Investing activities:		
Purchases of property and equipment	(129)	(505)
Net cash used in investing activities	(129)	(505)
Financing activities:		
Proceeds from private placements, net of issuance costs	337,330	—
Proceeds from underwritten public offering, net of issuance costs	—	17,256
Proceeds from public offering of common stock, net of issuance costs	—	8,707
Proceeds from exercise of stock options	46	21
Payment of finance lease liabilities	(276)	—
Payment for shares withheld to fund payroll taxes	(39)	—
Net cash provided by financing activities	337,061	25,984
Net increase in cash, cash equivalents and restricted cash	160,399	3,047
Cash, cash equivalents and restricted cash at beginning of year	35,778	32,731
Cash, cash equivalents and restricted cash at end of year	$ 196,177	$ 35,778
Supplemental disclosure of cash flows:		
Income taxes paid	$ 95	$ 797
Non-cash investing activities:		
Purchases of property and equipment, included in accounts payable and accrued liabilities	$ —	$ 11
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	$ 87	$ 122
Proceeds from exercise of stock options included in prepaid expenses, other current assets, and other assets	$ 14	$ —

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 using its proprietary Cloudbreak® platform to develop drug-Fc conjugate, or DFC, immunotherapies designed to save lives and improve the standard of care for patients facing serious diseases. The Company's proprietary Cloudbreak platform enables development of novel 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 has completed Phase 1 and Phase 2a clinical trials under a partnership with J&J Innovative Medicine, previously Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, or Janssen. On April 23, 2024, the Company and Janssen entered into a license and technology transfer agreement, or the Janssen License Agreement, under which the Company reacquired all rights for CD388 from Janssen to develop and commercialize CD388.

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.

Sale of Rezafungin

The Company's first commercially approved product in the United States, or U.S., was 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 April 24, 2024, the Company and Napp Pharmaceutical Group Limited, or Napp, an affiliate of Mundipharma Medical Company, or Mundipharma, entered into an Asset Purchase Agreement, or the Napp Purchase Agreement, pursuant to which the Company sold to Napp all of the Company's rezafungin assets and related contracts. The Company completed all conditions of the sale on April 24, 2024. The Company determined that the sale of rezafungin represented a strategic shift that will have a major effect on the Company's operations and financial results. Accordingly, the sale of rezafungin is classified as discontinued operations.

The results from discontinued operations of the rezafungin assets prior and subsequent to its sale are presented as income from discontinued operations in the consolidated statements of operations and comprehensive loss for all periods presented, including any gain or loss recognized on closing. The assets and liabilities for the rezafungin operations related activities prior and subsequent to its sale have been classified as discontinued operations and segregated for all periods presented in the consolidated balance sheets. See Note 10 for additional information.

Reverse Stock Split

On April 23, 2024, the Company effected the approved 1-for-20 reverse stock split of its shares of common stock, or the Reverse Stock Split. All references in this Annual Report on Form 10-K to the number of common shares, price per share and weighted average number of shares outstanding have been adjusted to reflect the Reverse Stock Split on a retroactive basis. As a result of the Reverse Stock Split, an immaterial amount was reclassified from common stock to additional paid-in capital.

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, 2024, the Company had an accumulated deficit of $611.3 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, 2024, the Company had cash, cash equivalents and restricted cash of $196.2 million, which the Company expects will provide sufficient liquidity to support its planned operations for a period of at least one year following the date that these consolidated financial statements are issued as part of this Annual Report on Form 10-K.

The Company's ability to execute its current business plan beyond this date depends on its ability to obtain additional funding through equity offerings, debt financings, other third-party funding, or potential licensing or collaboration arrangements. The Company may not be able to raise additional funding on terms acceptable to the Company, or at all, and any failure to raise funds as and when needed will compromise the Company's ability to execute on its business plan.

The Company plans to continue to fund its losses from operations through cash, cash equivalents and restricted cash on hand, as well as through future equity offerings, debt financings, other third-party funding, or 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, the Company 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, license, and purchase 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, or CODM, which is the Chief Executive Officer of the Company. The Company views its operations and manages its business as a single reportable segment with a single operating segment as further described in the "Description of Business" in Note 1.

The Company manages research and development, or R&D, activities on a consolidated basis. The Company expects to generate future revenue from a combination of license fees and other upfront payments, funded R&D agreements, milestone payments, product sales, government and other third-party funding, and royalties, which depend on the results, regulatory approval, and timing of the successful commercialization of its product candidates.

Comprehensive loss is the measure of segment profit or loss used by CODM in making decisions regarding resource allocation and assessing performance, which is also reported on the consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the consolidated balance sheets as total assets.

The CODM uses comprehensive loss in making decisions regarding resource allocation and evaluating financial performance.

The following table represents the results of the Company's reportable segment for the years ended December 31, 2024 and 2023:

	Years ended December 31,	
(In thousands)	**2024**	**2023**
Revenues generated in U.S.	$ 1,275	$ 23,283
Less:		
Acquired in-process research and development	(84,883)	—
Research and development - Cloudbreak platform	(56,454)	(25,936)
Personnel costs	(21,901)	(15,360)
General and administrative	(11,753)	(6,788)
Research and development - Non-program	(2,386)	(2,259)
Other segment items:		
Interest income, net	5,811	1,995
Income from discontinued operations, net of income taxes	464	2,149
Income tax expense	—	(15)
Segment net loss and comprehensive loss	$ (169,827)	$ (22,931)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further analysis is required to determine whether the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

Discontinued Operations

The Company presents discontinued operations when there is a disposal of a component or a group of components that represents a strategic shift that will have a major effect on operations and financial results. The results from discontinued operations of the rezafungin assets prior and subsequent to its sale are presented as net income from discontinued operations in the consolidated statements of operations and comprehensive loss for all periods presented, including any gain or loss recognized on closing. The assets and liabilities for the rezafungin operations related activities prior and subsequent to its sale have been classified as discontinued operations and segregated for all periods presented in the consolidated balance sheets. See Note 10 for additional information.

Cash, Cash Equivalents and Restricted Cash

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

Restricted cash consists of cash held as collateral to secure a standby letter of credit as required by certain contracts.

The following table provides a reconciliation of cash, cash equivalents and restricted cash in the consolidated balance sheets to the total amount shown at the end of the applicable period in the consolidated statements of cash flows:

	December 31, 2024	December 31, 2023
(In thousands)		
Cash and cash equivalents	$ 189,825	$ 35,778
Restricted cash	6,352	—
Total cash, cash equivalents and restricted cash shown in the consolidated statements of cash flows	$ 196,177	$ 35,778

Accounts Receivable

Accounts receivable is stated at the original invoice amount and consists of amounts due from customers related to milestones achieved, certain R&D and clinical supply costs subject to reimbursements under the collaboration and license agreements, royalties earned, product sales, and the associated indirect taxes collectible from customers. The Company records accounts receivable 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 is 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, 2024 or 2023.

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, cash equivalents and restricted cash. The Company maintains deposits in government insured financial institutions in excess of government insured limits. The Company invests its cash balances in financial institutions that it believes have high credit quality, has not experienced any losses on such accounts and does not believe it is exposed to significant credit risk.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative, or G&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 R&D expenses within discontinued operations, and the related interest and penalties are included in selling, general and administrative, or SG&A, expenses within discontinued operations. Subsequent to the sale of rezafungin, the Company retained the liability as part of its continuing operations and continued interest expense is included in G&A expenses in continuing operations. 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 as part of continuing operations at that time. Indirect tax amounts on commercial sales (product revenue) and asset disposals 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 in inventory within discontinued operations.

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 recognizes 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.

See Note 7 and Note 10 for additional information.

Acquired In-process Research and Development Expenses

Acquired in-process research and development, or IPR&D, expenses include consideration for the purchase of IPR&D through asset acquisitions and license agreements as well as payments made in connection with asset acquisitions and license agreements upon the achievement of development milestones.

The Company evaluates license agreements for IPR&D projects to determine if it meets the definition of a business and thus should be accounted for as a business combination. If the license agreement for IPR&D does not meet the definition of a business and the assets have no alternative future use, the Company expenses payments made under such license agreements as acquired IPR&D expense in its consolidated statements of operations and comprehensive loss. In those cases, payments for milestones achieved and payments for a product license prior to regulatory approval of the product are expensed in the period incurred. Payments made in connection with regulatory and sales-based milestones will be capitalized and amortized to cost of revenue.

Research and Development Costs

R&D expenses consist of wages, benefits and stock-based compensation charges for R&D 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 R&D expense if the technology has not been conclusively proven to be feasible and has no alternative future use.

General and Administrative Expenses

G&A expenses relate to finance, human resources, legal and other administrative activities. G&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 G&A expenses include facility and overhead costs not otherwise included in R&D expenses, consultant expenses, travel expenses, professional fees for auditing, tax, legal, and other services, 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 R&D 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 2015 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 Earnings (Loss) Per Share

The Company follows the guidance in ASC 260, *Earnings Per Share*, or ASC 260, which establishes standards regarding the computation of earnings per share, or EPS, by companies that have issued securities other than common stock that contractually entitle the holder to participate in dividends and earnings of a company. The guidance requires earnings to be hypothetically allocated between the common, preferred, and other participating stockholders based on their respective rights to receive non-forfeitable dividends, whether or not declared. Participating securities include Series A Convertible Voting Preferred Stock, or Series A Convertible Preferred Stock, Series X Convertible Preferred Stock, and pre-funded warrants, see Note 5 for additional information. Basic net EPS is then calculated by dividing the net income attributable to common stockholders (after the reduction for any preferred stock and assuming current income for the period had been distributed) by the weighted-average number of common shares outstanding for the period. The Company calculates diluted net EPS by using the more dilutive of the (1) treasury stock method, reverse treasury stock method or if-converted method, as applicable, or (2) the two-class method. Dilutive common stock equivalents are comprised of warrants (excluding pre-funded warrants), Series A Convertible Preferred Stock, Series X Convertible Preferred Stock, RSUs, PRSUs and options outstanding under the Company's stock option plans and ESPP, on an as converted basis.

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 A Convertible Preferred Stock or the Series X Convertible Preferred Stock as the preferred stockholders do not have a contractual obligation to share in the Company's losses. In loss periods, basic and diluted net loss per share are identical because the otherwise dilutive potential common shares become anti-dilutive and are therefore excluded.

In accordance with ASC 260, if a company had a discontinued operation, the Company uses income (loss) from continuing operations as its control number to determine whether potential common shares are dilutive or anti-dilutive for purposes of reporting basic and diluted net earnings (loss) per common share from discontinued operations.

As discussed in Note 5, as part of its November 2024 Private Placement (as defined below), the Company issued and sold pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of common stock at a purchase price of $14.9119 per pre-funded warrant (representing the $14.912 per share purchase price less the exercise price of $0.0001 per pre-funded warrant share). Since the $0.0001 exercise price per pre-funded warrant share represents little consideration and is non-substantive in relation to the purchase price of $14.9119 per pre-funded warrant, and as the pre-funded warrants are exercisable at any time after their original issuance with no further vesting conditions or contingencies associated with them, the shares underlying the pre-funded warrants are therefore included in the calculation of basic net loss per common share.

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,	
	2024	2023
Common stock warrants	866	866
Series A Convertible Preferred Stock	14,330,750	—
Series X Convertible Preferred Stock	1,052,236	1,052,236
Common stock options, RSUs and PRSUs issued and outstanding	2,481,011	638,037
Total	17,864,863	1,691,139

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, restricted cash, accounts receivable, prepaid expenses and other current assets, 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 November 2023, the FASB issued Accounting Standards Update, or ASU, 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which is intended to improve reportable segment disclosure requirements, primarily through additional disclosures about significant segment expenses. The standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company adopted ASU 2023-07 effective January 1, 2024, and included additional disclosures in Note 1. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In December 2023, the FASB issued ASU 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.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*. This ASU requires public business entities to disclose, for interim and annual reporting periods, additional information about certain income

statement expense categories. The requirements are effective for fiscal years beginning after December 15, 2026, and for interim periods beginning after December 15, 2027. Entities are permitted to apply either the prospective or retrospective transition methods. The Company is currently evaluating the impact that the adoption of this ASU will have on its consolidated financial statements.

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, 2024				
Assets:				
Cash and money market accounts	$ 189,825	$ 189,825	$ —	$ —
Restricted cash and money market accounts	6,352	6,352	—	—
Total assets at fair value	$ 196,177	$ 196,177	$ —	$ —
December 31, 2023				
Assets:				
Cash and money market accounts	$ 35,778	$ 35,778	$ —	$ —
Total assets at fair value	$ 35,778	$ 35,778	$ —	$ —

4. PROPERTY AND EQUIPMENT

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

	December 31, 2024	December 31, 2023
Laboratory equipment	$ 2,935	$ 2,817
Leasehold improvements	425	425
Computer hardware and software	327	327
Office equipment	36	36
Furniture and fixtures	142	142
	3,865	3,747
Less accumulated depreciation and amortization	(3,344)	(3,190)
Total	$ 521	$ 557

Depreciation and amortization of property and equipment of $0.2 million and $0.1 million were recorded for the years ended December 31, 2024 and 2023, respectively.

5. STOCKHOLDERS' EQUITY

Reverse Stock Split

On April 23, 2024, the Company effected the Reverse Stock Split of its shares of common stock and decreased its authorized number of shares of common stock from 200,000,000 shares to 20,000,000 shares.

All references in this Annual Report on Form 10-K to the number of common shares, price per share and weighted average number of shares outstanding have been adjusted to reflect the Reverse Stock Split on a retroactive basis.

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 year ended December 31, 2023, the Company sold 310,983 shares of common stock under the Sales Agreement for net proceeds of approximately $8.7 million after deducting placement agent fees. The Company has not sold any shares of its common stock under the Sales Agreement since July 2023. The Company will not be able to sell shares of its common stock under the Sales Agreement until at least May 1, 2025, due to the loss of its Form S-3 eligibility for primary and secondary offerings.

2023 Underwritten Public Offering

On March 7, 2023, the Company completed concurrent but separate underwritten public offerings with Cantor, the underwriter, and issued and sold 554,300 shares of its common stock, including the exercise in full by Cantor of their option to purchase an additional 72,300 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 $25.34 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.

April 2024 Private Placement

On April 23, 2024, the Company entered into a securities purchase agreement with certain institutional and other accredited investors, pursuant to which the Company issued and sold, in a private placement, or the April 2024 Private Placement, 240,000 shares of Series A Convertible Preferred Stock at a purchase price of $1,000 per share. The closing of the April 2024 Private Placement took place on April 24, 2024, and the Company received total gross proceeds of $240.0 million. The Company received total net proceeds of approximately $239.1 million, after deducting issuance costs payable by the Company.

November 2024 Private Placement

On November 20, 2024, the Company entered into a securities purchase agreement with certain institutional accredited investors, pursuant to which the Company issued and sold, in a private placement, or the November 2024 Private Placement, (i) an aggregate of 3,892,274 shares of the Company's common stock at a purchase price of $14.912 per share, and (ii) in lieu of shares of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of common stock at a purchase price of $14.9119 per pre-funded warrant (representing the $14.912 per share purchase price less the exercise price of $0.0001 per pre-funded warrant share). The pre-funded warrants are exercisable at any time after their original issuance and will not expire. The closing of the November 2024 Private Placement took place on November 26, 2024, and the Company received total gross proceeds of $105.0 million. The Company received total net proceeds of approximately $98.2 million, after deducting issuance costs payable by the Company.

Preferred Stock

Under the Company's amended and restated certificate of incorporation, as amended, 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, 2024.

Series A Convertible Preferred Stock

In April 2024, the Company designated 240,000 shares of preferred stock as Series A Convertible Preferred Stock with a par value of $0.0001 per share.

On July 18, 2024, the Company's stockholders approved, for purposes of Nasdaq Listing Rule 5635(b), the issuance of up to 16,800,000 shares of common stock upon conversion of 240,000 shares of Series A Convertible Preferred Stock issued in the April 2024 Private Placement.

On July 19, 2024, the Company issued 2,469,250 shares of common stock upon the automatic conversion of 35,275 shares of Series A Convertible Preferred Stock, subject to the terms and limitations contained in the Certificate of Designation of Preferences, Rights and Limitations of the Series A Convertible Voting Preferred Stock, including that shares of Series A Convertible Preferred Stock shall not be convertible if the conversion would result in a holder beneficially owning more than 9.99% of the Company's outstanding shares of common stock as of the applicable conversion date. After conversion, the converted shares of Series A Convertible Preferred Stock resumed the status of authorized but unissued shares of preferred stock and are no longer designated as Series A Convertible Preferred Stock. As of December 31, 2024, shares of preferred stock designated as Series A Convertible Preferred Stock totaled 204,725.

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

Conversion: Each share of Series A Convertible Preferred Stock is convertible at the option of the holder into 70 shares of common stock. Holders are not permitted to convert Series A 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 Securities Exchange Act of 1934, as amended, or 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 A 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 A Convertible Preferred Stock are entitled to participate in such dividends on an as-if-converted basis.

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

Voting: Holders of the Series A Convertible Preferred Stock are entitled to vote together with the holders of common stock on an as-if-converted basis on all matters submitted to a vote of stockholders; provided that holders of Series A Convertible Preferred Stock are not permitted to vote with respect to matters submitted to a vote of stockholders, to the extent that after giving effect to such action, such 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 action.

The Company evaluated the Series A Convertible Preferred Stock for liability or equity classification under ASC 480, *Distinguishing Liabilities from Equity*, and determined that equity treatment is appropriate as it does not meet the criteria for liability accounting. Additionally, the Series A 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 A Convertible Preferred Stock is recorded as permanent equity.

Series X Convertible Preferred Stock

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 26,120 shares of the Company's common stock. After conversion, the converted shares of Series X Convertible Preferred Stock resumed the status of authorized but unissued shares of preferred stock and are no longer designated as Series X Convertible Preferred Stock. As of December 31, 2024 and 2023, 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 0.5 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

On July 18, 2024, the Company's stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation, as amended, to increase the authorized number of shares of common stock from 20,000,000 shares to 50,000,000 shares, which amendment was filed by the Company with the Secretary of State of the State of Delaware on July 18, 2024 and was effective as of such date.

The Company had 50,000,000 shares of common stock authorized as of December 31, 2024. 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, 2024, (i) warrants to purchase up to an aggregate of 866 shares of the Company's common stock were outstanding, each with an exercise price of $230.95 per share and (ii) pre-funded warrants to purchase up to an aggregate of 3,149,035 shares of the Company's common stock were outstanding, each with an exercise price of $0.0001 per share.

As of December 31, 2023, warrants to purchase up to an aggregate of 866 shares of the Company's common stock were outstanding, each with an exercise price of $230.95 per share. During the year ended December 31, 2023, 624,993 common stock warrants expired unexercised.

The warrants had no intrinsic value as of December 31, 2024 and 2023 and the pre-funded warrants had a total aggregate intrinsic value of $84.6 million as of December 31, 2024. 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,	
	2024	2023
Common stock warrants, including pre-funded warrants	3,149,901	866
Series A Convertible Preferred Stock	14,330,750	—
Series X Convertible Preferred Stock	1,052,236	1,052,236
Common stock options, RSUs and PRSUs issued and outstanding	2,481,011	638,037
Authorized for future stock awards	1,021,947	170,783
Awards available under the ESPP	63,631	49,623
Total	22,099,476	1,911,545

6. EQUITY INCENTIVE PLANS

2024 Equity Incentive Plan, 2020 Inducement Incentive Plan and 2015 Equity Incentive Plan

In May 2024, the Company's board of directors approved and adopted the Company's 2024 Equity Incentive Plan, or 2024 EIP. In July 2024, the Company's stockholders approved the adoption of the 2024 EIP. The 2024 EIP is the successor to and continuation of the Company's 2015 Equity Incentive Plan, or 2015 EIP, previously approved and adopted in March 2015 by the Company's board of directors and stockholders. The 2024 EIP became effective on July 18, 2024. Upon the effectiveness of the 2024 EIP, no additional awards were or will be granted under the 2015 EIP, although all outstanding stock awards granted under the 2015 EIP continue to be governed by the terms of the 2015 EIP. Under the 2024 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.

In December 2020, the Company's board of directors approved and adopted the 2020 Inducement Incentive Plan, which was most recently amended in February 2025, 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.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors (or the compensation and human capital committee thereof), subject to the provisions of the 2024 EIP, 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 2024 EIP, 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 ESPP.

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, 2024 and 2023, 10,508 shares and 15,465 shares, respectively, were issued pursuant to the ESPP. As of December 31, 2024, total unrecognized compensation expense related to the ESPP was $0.1 million and is expected to be recognized over approximately 0.6 years.

Restricted Stock Units

The following table summarizes RSU and PRSU activity during the year ended December 31, 2024:

	Number of RSUs and PRSUs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2023	104,886	$ 22.83
RSUs granted	153,012	12.30
RSUs vested	(43,179)	24.31
RSUs and PRSUs canceled	(37,446)	19.59
Outstanding at December 31, 2024	177,273	$ 14.06

The weighted-average grant date fair value of RSUs granted by the Company during the year ended December 31, 2023 was $20.04 per share. The total fair value of RSUs vested during the years ended December 31, 2024 and 2023 was approximately $1.0 million and $0.7 million, respectively.

At December 31, 2024, estimated unrecognized compensation expense related to RSUs granted was approximately $1.9 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 2.3 years.

Stock Options

The following table summarizes stock option activity during the year ended December 31, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Total Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	533,151	$ 44.61	6.72	$ 57
Options granted	1,891,401	11.73		
Options exercised	(4,144)	14.59		
Options canceled	(116,670)	28.13		
Outstanding at December 31, 2024	2,303,738	$ 18.50	8.84	$ 29,729
Vested and expected to vest at December 31, 2024	2,303,738	$ 18.50	8.84	$ 29,729
Exercisable at December 31, 2024	558,680	$ 38.59	6.40	$ 3,792

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, 2024 and 2023 was $8.47 and $14.45, respectively, per share.

As of December 31, 2024, total unrecognized share-based compensation expense related to unvested stock options was approximately $15.0 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 2.7 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 2024 EIP, 2020 IIP and 2015 EIP and the shares purchasable under the 2015 ESPP during the periods presented:

	For the years ended December 31,	
	2024	2023
2024 EIP, 2020 IIP and 2015 EIP		
Risk-free interest rate	3.63% - 4.68%	3.58% - 4.61%
Expected dividend yield	0%	0%
Expected volatility	82% - 87%	82% - 83%
Expected term (years)	5.23 - 6.08	5.50 - 6.08
2015 ESPP		
Risk-free interest rate	4.34% - 5.42%	4.29% - 5.43%
Expected dividend yield	0%	0%
Expected volatility	60% - 109%	64% - 147%
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,	
	2024	2023
Stock compensation expense:		
Research and development	$ 1,426	$ 839
General and administrative	2,250	1,469
Stock compensation expense recorded in continuing operations	3,676	2,308
Stock compensation expense recorded in discontinued operations	231	753
Total stock compensation expense	$ 3,907	$ 3,061

7. SIGNIFICANT AGREEMENTS AND CONTRACTS

Janssen License Agreement

On April 23, 2024, the Company reacquired all rights to develop and commercialize CD388 when the Company and Janssen entered into a license and technology transfer agreement, or the Janssen License Agreement, which also effectively terminated the Janssen Collaboration Agreement (as defined below), including the license granted by the Company to Janssen.

Under the Janssen License Agreement, the Company assumed responsibility for further clinical development, manufacture, registration and commercialization of DFCs based on the Company's Cloudbreak platform for the prevention and treatment of influenza, including CD388 and products or compounds containing CD388. Janssen granted the Company an exclusive, worldwide, fee-bearing royalty-free license for certain Janssen-controller technology to develop, manufacture, and commercialize compounds and products, including CD388. Janssen agreed to (i) transfer and disclose to the Company certain Janssen-controlled know-how related to CD388, including manufacturing know-how, data and documentation, (ii) transfer all existing quantities of CD388 clinical materials, and (iii) transfer the cell banks used by or on behalf of Janssen for the production of CD388.

The Company paid Janssen an upfront payment of $85.0 million on April 24, 2024. The Company is also obligated to pay Janssen up to $150.0 million in development and regulatory milestone payments with respect to CD388 and up to $455.0 million in commercialization milestone payments with respect to CD388. The Company has no obligation to pay any royalties to Janssen for future sales of any commercialized CD388 product.

As the Company had an existing revenue contract with Janssen, or the Janssen Collaboration Agreement, the Company considered the contract modification and consideration payable to a customer guidance in ASC 606. The Company determined this bundled arrangement would be accounted for as a termination of the existing revenue contract and the creation of a new arrangement. No amounts paid or payable to Janssen were recorded against revenue as the consideration payable to Janssen does not exceed the fair value of the distinct assets acquired in the Janssen License Agreement.

In accordance with authoritative guidance, the Company was determined to be the accounting acquirer and substantially all of the fair value of the gross assets acquired is concentrated in the IPR&D of CD388. The reacquired license to develop, manufacture, and commercialize activities of CD388 is part of the acquired IPR&D. The transaction was accounted for as an asset acquisition. The acquired IPR&D did not have an alternative future use as of the acquisition date. Therefore the initial purchase price of $85.4 million, inclusive of $0.4 million in direct transaction costs, was expensed as of the acquisition date as acquired IPR&D in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024.

Prior to the acquisition, the Company had $0.5 million in contract liabilities related to deferred revenue balances and unearned cancelled performance obligations associated with the Janssen Collaboration Agreement. The settlement of the preexisting contract liabilities was recorded as an offset to the Janssen License Agreement's initial purchase price resulting in $84.9 million expensed as acquired IPR&D in the consolidated statements of operations and comprehensive loss.

The Company's contingent future obligation to pay Janssen up to $150.0 million in development and regulatory milestone payments with respect to CD388 and up to $455.0 million in commercialization milestone payments with respect to CD388 will be recognized if and when the contingency is resolved and the consideration is paid or becomes payable.

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 collaborated 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 R&D 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 was 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 was the IND holder for the Research Plan clinical trials. Both parties were responsible for conducting certain specified chemistry, manufacturing and controls, or CMC, development activities under the Research Plan. Janssen was solely responsible, and reimbursed 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 assumed the future development, manufacturing and commercialization activities of CD388 under the Janssen Collaboration Agreement. The Company continued to work in collaboration with Janssen to complete the Phase 1 and Phase 2a clinical trials and was reimbursed for all ongoing development activities by Janssen as per the Janssen Collaboration Agreement.

Following Janssen's Election to Proceed Notice, Janssen, was 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 R&D 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 covenanted 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 does 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 R&D costs incurred in conducting Research Plan activities. The Company was 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. The Janssen Collaboration Agreement was terminated upon the effectiveness of the Janssen License Agreement on April 24, 2024, and all potential future milestone payments and royalties were forfeited by the Company.

Revenue Recognition

Prior to the Janssen Collaboration Agreement termination on April 24, 2024, the Company determined the transaction price is equal to the up-front fee of $27.0 million, plus the R&D funding of $47.8 million, plus milestones achieved of $10.0 million. The transaction price included the total estimated costs related to R&D and clinical supply services. 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 R&D 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, was as follows:

Licenses of Intellectual Property. The license to the Company's intellectual property, bundled with the associated know-how, represented 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 in May 2021 as collaboration revenue in its consolidated statements of operations and comprehensive loss.

Research and Development Services. The R&D services performed represented a distinct performance obligation. The Company recognized 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 recognized revenue based on actual amounts incurred as the underlying services were 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 deemed 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 was recognized based on the progress of these performance obligations, the unrecognized portion was recorded as contract liabilities at the reporting period end and was expected to 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.

Royalties. As the license was deemed to be the predominant item to which sales-based royalties related, the Company recognized royalty revenue when the related sales occurred. No royalty revenue was recognized during the years ended December 31, 2024 and 2023.

Contract Liabilities

The following table presents a summary of the activity in the Company's contract liabilities pertaining to the Janssen Collaboration Agreement during the year ended December 31, 2024 (in thousands):

Opening balance, December 31, 2023	$ 430
Revenue from performance obligations satisfied during reporting period	(370)
Gain on settlement of unsatisfied performance obligations	(60)
Closing balance, December 31, 2024	$ —

As of December 31, 2024, the aggregate transaction price allocated to performance obligations that are unsatisfied is zero under the Janssen Collaboration Agreement.

As of December 31, 2024, the Company recorded no accounts receivable associated with the Janssen Collaboration Agreement. As of December 31, 2023, the Company recorded $1.9 million in accounts receivable associated with the Janssen Collaboration Agreement.

The following table presents collaboration revenue under the Janssen Collaboration Agreement (in thousands):

	Year Ended December 31, 2024	Year Ended December 31, 2023
Revenue from Janssen Collaboration Agreement:		
Point in Time:		
License of Intellectual Property - upon milestones achieved	$ —	$ 2,347
Over Time:		
Research and Development Services	1,273	19,011
Clinical Supply Services	2	1,925
Total Revenue from Janssen Collaboration Agreement	$ 1,275	$ 23,283

8. INCOME TAXES

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

	December 31, 2024	December 31, 2023
Current tax (benefit) provision:		
Federal	$ —	$ (1)
State	—	16
Total current tax provision	—	15
Deferred tax provision:		
Federal	—	—
State	—	—
Total deferred tax provision	—	—
Total tax provision	$ —	$ 15

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 from continuing operations computed at the federal statutory rate and the provision for income taxes (in thousands):

	Years Ended December 31,	
	2024	2023
Federal income taxes at 21% for 2024 and 2023	$ (35,761)	$ (5,264)
State income tax, net of federal benefit	(1,730)	(241)
Nondeductible expenses	478	234
Tax credits	(4,683)	(1,096)
Rate change	108	(54)
Change in valuation allowance	39,911	5,861
Reserve for uncertain tax positions	1,171	273
162m deferred tax asset limitation	195	128
Expired stock awards	227	174
Other	84	—
Income tax expense	$ —	$ 15

Prior year tax expense is primarily the result of capitalized Internal Revenue Code, or IRC, Section 174 R&D 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.

The income tax expense from discontinued operations for the year ended December 31, 2023 of $0.4 million is not included in the above income tax provision from continuing operations.

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

	December 31,	
	2024	2023
Deferred tax assets:		
Net operating losses	$ 46,721	$ 35,506
Tax credits	13,775	9,747
Intangibles	17,946	136
Capitalized R&D	37,218	25,871
Stock compensation	1,411	1,424
Lease liabilities	660	1,112
Contract liabilities	—	5,951
Accrued indirect tax liabilities	3,109	4,114
Other	840	725
Total deferred tax assets	121,680	84,586
Less valuation allowance	(120,898)	(83,086)
Deferred tax assets, net of valuation allowance	782	1,500
Deferred tax liabilities:		
Prepaid expenses	(180)	(214)
Capitalized inventory costs	—	(244)
Right-of-use assets	(602)	(1,042)
Total deferred tax liabilities	(782)	(1,500)
Net deferred tax assets	$ —	$ —

The deferred income tax assets and liabilities associated with discontinued operations remain in the Company's consolidated balance sheets rather than being included in the assets and liabilities for discontinued operations, as the sale of rezafungin is structured as a sale of assets. Certain deferred income tax assets and liabilities associated with discontinued operations were realized upon the sale of rezafungin assets in April 2024.

At December 31, 2024, the Company had federal and state tax net operating loss carryforwards of approximately $202.8 million and $145.2 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 R&D credit and orphan drug credit carryforwards totaling $14.1 million and state R&D credit carryforwards totaling $6.2 million. The federal R&D credit and orphan drug credit carryforwards begin to expire in 2038, unless previously utilized. The state R&D credit carryforwards have no expiration date, with the exception of an immaterial amount that will begin to expire in 2029.

At December 31, 2024, management assessed the realizability of the Company's deferred tax assets by considering whether it is more likely than not some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considered the scheduled reversal of deferred tax liabilities, tax planning strategies and projected future taxable income in making this assessment. Due to cumulative operating losses for the three years ended December 31, 2024, the Company recorded a full valuation allowance against its U.S. federal and state deferred tax assets of $120.9 million and $83.1 million, respectively, as management has determined that it is more likely than not that the tax benefits will not be realized in the future. The valuation allowance increased by $37.8 million and $6.4 million in 2024 and 2023, respectively.

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 R&D 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, 2024 and 2023, the unrecognized tax benefits recorded were approximately $12.9 million and $11.5 million, respectively. Approximately $11.0 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 primarily related to federal and state R&D credits generated during 2024. 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 2024 and 2023 is as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Balance as of the beginning of the year	$ 11,520	$ 11,015
Increases related to current year tax positions	1,386	552
Decreases related to prior year tax positions	—	(47)
Balance as of the end of the year	$ 12,906	$ 11,520

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 2012 are subject to examination by the federal and state tax authorities due to the carryforward of unutilized net operating losses and R&D 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.

9. 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, 2024 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, 2024, 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 and timing of cash flows arising from the Company's finance lease as of December 31, 2024 (in thousands):

2025	$	300
2026		300
2027		25
Total undiscounted finance lease payments		625
Less: Imputed interest		(51)
Present value of finance lease payments	$	574

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		(85)
Net finance lease right-of-use asset	$	703
Current portion of finance lease liability	$	264
Long-term finance lease liability		310
Total finance lease liabilities	$	574

As of December 31, 2024, the weighted average remaining finance lease term was 2.1 years.

Cash paid for amounts included in the measurement of finance lease liabilities was $0.3 million and zero for the years ended December 31, 2024 and 2023, respectively.

Finance lease costs were $0.1 million and immaterial for the years ended December 31, 2024 and 2023, respectively.

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 increased 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, 2024, 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 and timing of cash flows arising from the Company's operating lease as of December 31, 2024 (in thousands):

2025	$	1,665
2026		1,731
Total undiscounted operating lease payments		3,396
Less: Imputed interest		(394)
Present value of operating lease payments	$	3,002

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

Balance Sheet Classification:		
Operating lease right-of-use asset	$	2,739
Current portion of operating lease liability	$	1,378
Long-term operating lease liability		1,624
Total operating lease liabilities	$	3,002

As of December 31, 2024, the weighted average remaining operating lease term was 2 years.

Cash paid for amounts included in the measurement of operating lease liabilities was $1.6 million and $1.3 million for the years ended December 31, 2024 and 2023, respectively.

Operating lease costs were $1.7 million and $1.6 million for the years ended December 31, 2024 and 2023, 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 R&D activities, manufacturing, and professional services. These contracts generally provide for termination either on notice or after a notice period.

Reduction in Force

On September 9, 2024, management of the Company, as authorized by the board of directors of the Company, approved a reduction in the Company's workforce (the "Reduction") of 20 employees, which represented approximately 30% of the Company's workforce. The Reduction reflects the Company's focus on the clinical development of CD388, its influenza product candidate. The Reduction was substantially completed by November 1, 2024.

As a result of the Reduction, the Company incurred charges of approximately $1.2 million for severance payments and employee benefits included in R&D expenses in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. The Company does not expect to incur additional charges related to the Reduction. As of December 31, 2024, approximately $0.1 million of these charges were unpaid and included in accrued compensation and benefits in the consolidated balance sheets. The Company expects these charges to be paid during the first quarter of 2025.

Standby Letter of Credit

On December 11, 2024, the Company established a standby letter of credit with its banking institution, Wells Fargo, for $6.0 million for the benefit of its indirect tax service provider, as it relates to indirect tax compliance services in various tax jurisdictions outside of the U.S. in connection with the rezafungin supply chain activities and commercial sales of REZZAYO. The letter of credit expires on November 30, 2025 and is automatically extended without amendment for an additional one-year period from the current expiration date, unless notified by the Company to terminate prior to 90 days from any expiration date. The cash held as collateral for this standby letter of credit is recorded as restricted cash and is held in an interest-bearing account.

10. DISCONTINUED OPERATIONS

On April 24, 2024, the Company and Napp, entered into the Napp Purchase Agreement, pursuant to which the Company sold to Napp, effective as of April 24, 2024, the following:

- all of the Company's rezafungin assets, including all of the Company's right to receive future milestones and royalties under the Melinta License Agreement and the Mundipharma Collaboration Agreement,
- all rezafungin intellectual property rights, including patents and know-how, all product data, regulatory approvals and documentation,
- rezafungin and comparator inventory,
- specified prepaid assets and specified contracts, in exchange for Napp's assumption of certain liabilities of the rezafungin business, including the ongoing costs of the ReSPECT Phase 3 clinical trial and the ReSTORE Phase 3 clinical trial in China and the Company's obligations from and after closing under the Melinta License Agreement,

- the Commercial Supply Agreement dated January 23, 2023 between the Company and Melinta, and
- the Commercial Supply Agreement, dated December 12, 2022 between the Company and Mundipharma, or the Mundipharma Commercial Supply Agreement.

No Company employees were transferred to Napp.

The Company, Napp and Mundipharma also entered into an Assignment and Novation Agreement to transfer the Mundipharma Collaboration Agreement and Mundipharma Commercial Supply Agreement from the Company to Napp, or the Novation Agreement. In the Novation Agreement, Mundipharma agreed to forgive the Company's obligation to refund a $11.1 million development milestone advance due as of December 31, 2024, net of royalties, to Mundipharma under the Mundipharma Collaboration Agreement, provided that (a) the Company performed its obligation to provide carryover services under a Transition Services Agreement with Napp, or the TSA, for a period of 45 days following the closing, (b) the Company delivered all of the purchased assets, including product know-how and product-data, in accordance with the Napp Purchase Agreement and a know-how transfer plan delivered in connection with the Napp Purchase Agreement and (c) the Company performed its obligation to provide other services in accordance with the TSA for 75 days following the closing. If such conditions were not met, the Company was obligated to refund the development milestone advance, net of royalties, within 10 business days of the date on which it was determined that the conditions for forgiveness were not satisfied. On July 18, 2024, the Company received a notice of satisfaction from Mundipharma that it had completed the required performance obligations under the TSA and, accordingly, the $11.1 million development milestone advance previously made to the Company, and reimbursable to Mundipharma, was forgiven by Mundipharma.

In connection with the Napp Purchase Agreement and as a condition to entering into the Napp Purchase Agreement, the Company entered into an amendment, dated April 23, 2024, to the Melinta License Agreement that, among other changes, modified the future regulatory milestones payable upon receipt of marketing approval of the current rezafungin acetate product. The Melinta License Agreement, as amended, was assigned and novated to Napp at the closing of the asset sale.

The action to divest rezafungin was taken because of the Company's strategy to streamline its portfolio and focus on the Cloudbreak platform and other financial considerations.

The Company has determined that the sale of rezafungin represents a strategic shift that had a major effect on its result of operations. Rezafungin met the criteria to be reported as discontinued operations at the time of the sale. The Company has separately reported the financial results of rezafungin as discontinued operations in the consolidated statements of operations and comprehensive loss for all periods presented.

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 R&D expense in the period incurred.

Inventory is comprised of raw materials and work-in-process, 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 within discontinued operations in the consolidated statements of operations and comprehensive loss. As a result of the sale of rezafungin, all inventory has been reclassified to discontinued operations.

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 R&D expense in the period incurred.

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 R&D 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.

Product Revenue

In December 2022 and January 2023, the Company entered into separate Commercial Supply Agreements with Mundipharma and Melinta Therapeutics, LLC, or Melinta, for the batch supply of REZZAYO naked vials for commercial use. Under the Commercial Supply Agreements, Mundipharma and Melinta were 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 represented a distinct performance obligation. The Commercial Supply Agreements were terminated upon the effectiveness of the assignment to Napp on April 24, 2024.

The transaction price recognized as revenue for each performance obligation under the Commercial Supply Agreements consisted of variable consideration which was determined based on the estimated per vial costs, plus the contractually stated margin rate. The amounts recognized as revenue were adjusted, as needed, each reporting period based on actual costs incurred for each batch. Variable consideration was included in the transaction price only to the extent that it was considered probable that a significant reversal in the amount of cumulative revenue recognized would not occur when the uncertainty associated with the variable consideration was 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 were recorded as indirect tax liabilities. The transaction price was fully allocated to the single performance obligation.

The Company concluded that the performance obligation was satisfied and product revenue was recognized when the customer obtained control of the product, which occurred 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 were performed after a customer obtained control of the product were treated as activities to fulfill the promise to a customer and any amounts billed to a customer represented revenues for the product provided. Costs related to such shipping and handling were classified as cost of product revenue.

There were no assets and liabilities related to discontinued operations as of December 31, 2024, as all balances were recognized in income from discontinued operations at the completion of the transaction. Assets and liabilities classified as discontinued operations in the consolidated balance sheets as of December 31, 2023 consisted of the following:

	December 31, 2023
(In thousands)	
Carrying amount of major assets included as part of discontinued operations:	
Current assets:	
Accounts receivable	$ 2,171
Inventory	6,097
Prepaid expenses and other current assets	1,022
Current assets from discontinued operations	9,290
Noncurrent assets:	
Other assets	934
Noncurrent assets from discontinued operations	934
Total assets from discontinued operations	$ 10,224
Carrying amount of major liabilities included as part of discontinued operations:	
Current liabilities:	
Current contract liabilities	$ 24,665
Current liabilities from discontinued operations	24,665
Noncurrent liabilities:	
Long-term contract liabilities	4,245
Noncurrent liabilities from discontinued operations	4,245
Total liabilities from discontinued operations	$ 28,910

Inventory consisted of the following (in thousands):

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

The Company's capitalized inventory consisted 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 R&D expense in the period incurred. There were no inventory write downs during the years ended December 31, 2024 and 2023.

The results of operations from discontinued operations during the years ended December 31, 2024 and 2023 have been reflected as income from discontinued operations, net of income taxes in the consolidated statements of operations and comprehensive loss and consisted of the following:

	Years ended December 31,	
(In thousands)	**2024**	**2023**
Major line items constituting pretax income from discontinued operations		
Revenues:		
Total revenues	$ 29,263	$ 40,622
Operating expenses:		
Cost of product revenue	9,030	1,523
Research and development	10,507	31,769
Selling, general and administrative	7,463	4,753
Total operating expenses	27,000	38,045
Income from operations	2,263	2,577
Other expense, net:		
Loss on disposal of discontinued operations	(1,799)	—
Total other expense, net	(1,799)	—
Income from discontinued operations before income tax expense	464	2,577
Income tax expense	—	(428)
Income from discontinued operations, net of income taxes	$ 464	$ 2,149

The cash flows related to discontinued operations have not been segregated and are included in the consolidated statements of cash flows. The total net cash used in operating activities from discontinued operations was $18.0 million and $10.5 million for the years ended December 31, 2024 and 2023, respectively. There were no investing or financing activities from discontinued operations for the years ended December 31, 2024 and 2023.

Napp Purchase Agreement

In connection with the execution of the Napp Purchase Agreement, the Company modified its existing collaboration and license arrangements and Commercial Supply Agreements with Mundipharma and Melinta. As a result of the modified revenue contracts and the termination of these revenue arrangements, the Company concluded the Napp Purchase Agreement and the other aforementioned arrangements represented a bundled arrangement with a single commercial objective that required assessment under the guidance for revenue recognition. As a result, the Company identified the distinct performance obligations within the arrangements (including whether the distinct performance obligations were within the scope of ASC 606), determined the transaction price and the standalone selling prices of the distinct performance obligations, and allocated the transaction price using the relative standalone selling price method to the distinct performance obligations.

Revenue Recognition

On April 24, 2024, as of the execution date of the Napp Purchase Agreement (and all other bundled arrangements), the Company determined the transaction price is equal to $21.2 million for the sale of all rezafungin assets, including the Company's right to receive future milestones and royalties from Mundipharma and Melinta, all rezafungin intellectual property rights, including patents and know-how, rezafungin and comparator inventory, specified prepaid assets, the Commercial Supply Agreements with Melinta and Mundipharma, and certain transition services. The transaction price includes the forgiveness of $25.3 million in contract liabilities (inclusive of the $11.1 million development milestone advance) and $0.6 million for the transition services agreement. The Company paid $2.1 million to Napp and forgave $2.6 million in accounts receivable, both of which are included as a reduction to the transaction price.

The $21.2 million transaction price was allocated to the distinct performance obligations on the basis of their respective relative standalone selling prices.

All Rezafungin assets. The Company transferred all rezafungin assets, including all rezafungin intellectual property rights, including patents and know-how, rezafungin and comparator inventory in April 2024 at a point in time. Therefore, the Company recognized the revenue related to this bundled performance obligations in the amount of $20.8 million as revenue in the results from operations from discontinued operations.

Specified Prepaid Assets and Contracts. The Company transferred specified prepaid and contracts in April 2024 at a point in time. The nature of the assets transferred were determined to be outside the scope of ASC 606 and therefore, the $0.3 million was recorded as part of the loss on disposal of discontinued operations.

Transition Services. The Company performed its services under the TSA over the initial 76-day period subsequent to the effective date of the Napp Purchase Agreement. In connection with the carryover services provided after the sale of rezafungin, the Company recognized $0.1 million as revenue in the results of operations from discontinued operations during the year ended December 31, 2024. The Company's costs to provide the TSA services predominantly relate to employee labor costs which are reported within R&D and SG&A expenses within the results of operations from discontinued operations during the year ended December 31, 2024. The remaining unsatisfied performance obligation as of December 31, 2024 was zero.

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 was responsible for leading the conduct of an agreed global development plan, or the Global Development Plan, that included the 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 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 CMC development activities for the Mundipharma Licensed Product. Mundipharma was responsible for performing all development activities, other than Global Development Plan activities, that were 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 in Japan before the Mundipharma Collaboration Agreement was terminated.

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 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.

Financial Terms. As of the execution of the Mundipharma Collaboration Agreement, the parties 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 was $568.4 million, including an equity investment, an up-front payment, global development funding, and certain development, regulatory, and

commercial milestones. The Company was also eligible to receive double-digit royalties in the teens on tiers of annual net sales.

Termination. The Mundipharma Collaboration Agreement was terminated upon the effectiveness of the assignment to Napp on April 24, 2024.

Revenue Recognition

Prior to the Mundipharma Collaboration Agreement termination on April 24, 2024, the Company determined the transaction price was equal to the up-front fee of $30.0 million, plus the R&D funding of $31.2 million, plus milestones achieved of $27.9 million. The common stock issued pursuant to the Mundipharma Stock Purchase Agreement was determined to be issued at fair market value after applying a lack of marketability discount as Mundipharma received restricted shares. Therefore, no additional premium or discount was allocated to the transaction price of the Mundipharma Collaboration Agreement for the share issuance. The transaction price was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In estimating the stand-alone selling price for each performance obligation, the Company utilized discounted cash flows and developed assumptions that required judgment and included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success and costs for manufacturing clinical supplies. A description of the distinct performance obligations identified under the Mundipharma Collaboration Agreement, as well as the amount of revenue allocated to each distinct performance obligation, was as follows:

Licenses of Intellectual Property. The license to the Company's intellectual property, bundled with the associated know-how, represented 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 shared equally in the costs of ongoing rezafungin clinical development in the Mundipharma Territory up to the specified cap, which represented a distinct performance obligation. The Company recorded these cost-sharing payments due from Mundipharma as collaboration revenue. The Company concluded that progress towards completion of the performance obligation related to the R&D services was best measured in an amount proportional to the R&D expenses incurred and the total estimated R&D expenses.

Clinical Supply Services. The Company's initial obligation to supply rezafungin for ongoing clinical development in the Mundipharma Territory represented a distinct performance obligation. The Company concluded that progress towards completion of the performance obligations related to the clinical supply services was 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 was previously recorded as current contract liabilities as of December 31, 2024 because the rights to consideration were expected to be satisfied within one year. The Company received payment for this milestone in January 2021. Mundipharma was 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 had 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 would have been obligated to refund the uncredited portion of such milestone payment to Mundipharma on the earlier of such dates. The full amount was forgiven in July 2024 as part of the rezafungin asset sale and the Company included $11.1 million in the transaction price of the Napp Purchase Agreement. In December 2021, August 2022, December 2023, and January 2024, the Company achieved milestones of $2.8 million, $11.1 million, $11.1 million, and $2.8 million, respectively, under the Mundipharma Collaboration Agreement that the Company deemed 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 was recognized based on the progress of these performance obligations, the unrecognized portion was recorded as contract liabilities at the reporting period end and was recognized as revenue over the remaining progress of these performance obligations. The Company received payment for these milestones in January 2022, September 2022, February 2024, and April 2024, respectively.

Royalties. As the license was deemed to be the predominant item to which sales-based royalties related, the Company recognized royalty revenue when the related sales occurred. Royalty revenue recognized during the year ended December 31, 2024 was immaterial. No royalty revenue was recognized during the year ended December 31, 2023.

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 contained or incorporated 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 could, directly or indirectly, itself or in collaboration with any third party, developed, manufactured for development or commercialization, or commercialized 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 was solely responsible for the commercialization of rezafungin in the Melinta Territory, at its sole expense.

Continued Development and Regulatory Activities. The Company was responsible, at its sole expense, for conducting an agreed upon development plan, or the Melinta Development Plan, that included, among other activities, (a) completion of the 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 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 were 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 remained the holder of the rezafungin IND and new drug application, or NDA, before the Melinta License Agreement was assigned. Both regulatory applications were to 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 would have been responsible for performing all activities that may have been 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 assumed 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 was 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, supplied 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 was $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 was eligible to receive tiered royalties on U.S. sales in the low double digits to mid-teens.

Termination. The Melinta License Agreement was terminated upon the effectiveness of the assignment to Napp on April 24, 2024.

Revenue Recognition

Prior to the Melinta License Agreement termination on April 24, 2024, the Company determined the transaction price was 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 R&D 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, was as follows:

Licenses of Intellectual Property. The license to the Company's intellectual property, bundled with the associated know-how, represented 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 was required to provide R&D services, at its sole expense, as described under the Melinta Development Plan, which represented a distinct performance obligation. The Company concluded that progress towards completion of the performance obligation related to the R&D services was best measured in an amount proportional to the R&D expenses incurred and the total estimated R&D expenses.

Clinical Supply Services. The Company's obligation to supply rezafungin for ongoing clinical development in the Melinta Territory represented a distinct performance obligation. The Company concluded that progress towards completion of the performance obligations related to the clinical supply services was 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, 2024 was immaterial.

Milestone Payments. In March 2023, the Company achieved a $20.0 million milestone under the Melinta License Agreement that the Company deemed 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 was recognized based on the progress of these performance obligations, the unrecognized portion was recorded as contract liabilities at the reporting period end and was recognized as revenue over the remaining progress of these performance obligations. The Company received payment for this milestone in April 2023.

Royalties. As the license was deemed to be the predominant item to which sales-based royalties related, the Company recognized royalty revenue when the related sales occurred. The Company recognized $0.1 million and $0.2 million in royalty revenue during the years ended December 31, 2024 and 2023, respectively, following the commercial launch of REZZAYO by Melinta in the U.S. on July 31, 2023.

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 expense recognized during the years ended December 31, 2024 and 2023 of $0.2 million and $0.5 million, respectively, and is included within the results of operations from discontinued operations. As of December 31, 2024, there was no balance remaining of the asset recognized from costs to obtain the Melinta License Agreement.

Contract Liabilities

The following table presents a summary of the activity in the Company's contract liabilities pertaining to the Mundipharma Collaboration Agreement and Melinta License Agreement during the year ended December 31, 2024 (in thousands):

Opening balance, December 31, 2023	$ 28,910
Revenue from performance obligations satisfied during reporting period	(28,910)
Closing balance, December 31, 2024	$ —

As of December 31, 2024, the aggregate transaction price allocated to performance obligations that are unsatisfied is zero under both the Mundipharma Collaboration Agreement and the Melinta License Agreement.

As of December 31, 2024, the Company recorded no accounts receivable associated with the Mundipharma Collaboration Agreement and Melinta License Agreement. As of December 31, 2024, the Company recorded accounts receivable associated with the Napp Purchase Agreement of $1.7 million.

As of December 31, 2023, the Company recorded $13.9 million and $0.4 million in accounts receivable associated with the Mundipharma Collaboration Agreement and Melinta License Agreement, respectively. As of December 31, 2023, $1.7 million and $0.4 million of the accounts receivable associated with the Mundipharma Collaboration Agreement and Melinta License Agreement, respectively, were included in discontinued operations.

The following table presents collaboration revenue, included within discontinued operations, disaggregated by collaborator and timing of revenue recognition (in thousands):

	Year Ended December 31, 2024	
	Mundipharma	Melinta
Revenue from Collaboration, License and Purchase Agreements:		
Point in Time:		
Rezafungin Assets, including Sale of IP and Inventory	$ 20,833	$ —
License of Intellectual Property - upon milestones achieved	813	—
Product Revenue	2,826	—
Royalty Revenue	37	125
Over Time:		
Research and Development Services	3,895	457
Clinical Supply Services	175	—
Transition Services	102	—
Total Revenue from Collaboration, License and Purchase Agreements	$ 28,681	$ 582

	Year Ended December 31, 2023	
	Mundipharma	Melinta
Revenue from Collaboration and License Agreements:		
Point in Time:		
License of Intellectual Property - upon milestones achieved	$ 3,252	$ 17,257
Clinical Drug Supply	26	—
Product Revenue	2,867	1,468
Royalty Revenue	—	168
Over Time:		
Research and Development Services	12,303	2,441
Clinical Supply Services	840	—
Total Revenue from Collaboration and License Agreements	$ 19,288	$ 21,334

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, 2024, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2024.

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, 2024. 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, 2024, our internal control over financial reporting was effective.

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

Remediation of Previously Reported Material Weakness

We previously reported that our 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 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 was not detected and was restated in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

During 2024, as part of the remediation process, we implemented various controls to address our exposure to indirect taxes, which included additional training to existing staff, enhanced use of indirect tax consultants and experts, review and analysis of our new contracts for possible indirect tax exposures, quarterly calculations of the legal liability for indirect taxes for all shipments during the preceding quarter, and quarterly reconciliation of our legal liability account including assessment of any additional interest due or possible reversals upon settlement of our accrued indirect tax liabilities. Based on these additional procedures and control, our management has concluded this material weakness has been remediated as of December 31, 2024.

Changes in Internal Control over Financial Reporting

Except as discussed above, 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 implementation of our remediating plans for the material weakness, described above, resulted in changes in our internal control over financial reporting.

Item 9B. Other Information.

None.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below will be set forth in the sections headed “Election of Directors,” “Delinquent Section 16(A) Reports,” “Executive Officers” and “Information Regarding Committees of the Board of Directors” in our Proxy Statement for our 2025 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024, and is incorporated herein by reference.

We have adopted a written 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 Code of Business Conduct and Ethics 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 Code of Business Conduct and Ethics 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.

We have adopted insider trading policies and procedures governing the purchase, sale and/or other dispositions of our securities by our directors, officers and employees that are reasonably designed to promote compliance with insider trading laws, rules and regulations, and listing standards applicable to us. A copy of our insider trading policy is filed with this Annual Report on Form 10-K as Exhibit 19.1.

Item 11. Executive Compensation.

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

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

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

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

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

The information required by this item will be set forth in the sections headed “Certain Relationships and Related Party Transactions” and “Information Regarding the Board of Directors and Corporate Governance” in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be set forth in the section headed “Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

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

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

3. ***Exhibits***—For a list of exhibits filed with this Annual Report on Form 10-K, refer to the exhibit index below. The exhibits listed in the Exhibit Index are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Exhibit Index

Exhibit Number	Description
1.1	Controlled Equity 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).
2.1‡	Asset Purchase Agreement, by and between the Registrant and Napp Pharmaceutical Group Limited (Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K/A, filed on April 29, 2024).
2.2‡	Assignment and Novation Agreement, by and between the Registrant and Napp Pharmaceutical Group Limited (Incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K/A, filed on April 29, 2024).
2.3‡	First Amendment to Melinta License Agreement, dated April 23, 2024, by and between Melinta Therapeutics, LLC and the Registrant (Incorporated by reference to Exhibit 2.3 to the Registrant's Current Report on Form 8-K/A, filed on April 29, 2024).
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. (incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K, filed on April 22, 2024).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Cidara Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on July 18, 2024).
3.4	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).
3.5	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).
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Voting Preferred Stock (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on April 24, 2024).
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	Form of Pre-Funded Warrant to Purchase Common Stock for Private Placement (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on November 26, 2024).

4.5	Description of the Registrant's Securities.
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).
10.2+	2015 Equity Incentive Plan and Form of Grant Notice, Stock Option Agreement and Notice of Exercise thereunder (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-203434), filed on April 15, 2015).
10.3+	2015 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).
10.4+	2013 Stock Option and Grant Plan and Form of Stock Option Agreement, Notice of Exercise and Stock Option Grant Notice thereunder, as amended (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed on March 13, 2015).
10.5+	Non-Employee Director Compensation Policy, as amended.
10.6+	Form of Amended and Restated Employment Agreement by and between the Registrant and its executive officers (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on August 12, 2021).
10.7+	Cidara Therapeutics, Inc. 2020 Inducement Incentive Plan, as amended.
10.8+	Form of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Cidara Therapeutics, Inc. 2020 Inducement Incentive Plan, as amended (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, as amended (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	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).
10.19	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).
10.20+	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).
10.21+	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).
10.22+	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).
10.23	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).

10.24‡	Securities Purchase Agreement, by and among Cidara Therapeutics, Inc. and the purchasers named therein (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 24, 2024).
10.25	Form of Support Agreement (Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on April 24, 2024).
10.26+	2024 Equity Incentive Plan of the Registrant, Form of Grant Notice, Stock Option Agreement and Notice of Exercise, and Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement Thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 18, 2024).
10.27*	License and Technology Agreement, by and between the Registrant and Janssen Pharmaceuticals, Inc., dated April 23, 2024 (incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on August 13, 2024).
10.28	Securities Purchase Agreement, by and between the Registrant and the persons party thereto, dated November 20, 2024 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on November 26, 2024).
10.29	Registration Rights Agreement, by and between the Registrant and the persons party thereto, dated November 20, 2024 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on November 26, 2024).
10.30+	Employment offer letter between the Registrant and Frank Karbe, dated February 14, 2025.
10.31+	Separation Agreement by and between the Registrant and Taylor Sandison, dated January 7, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 7, 2025).
10.32+	Separation Agreement by and between the Registrant and Preetam Shah, dated February 14, 2025 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 18, 2025).
19.1	Insider Trading Policy of the Registrant.
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 (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K, filed on April 22, 2024).
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.
*	Certain portions of this exhibit have been omitted pursuant to Item 601 of Regulation S-K.
‡	Schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.
**	The certifications attached as Exhibits 32.1 and 32.2 accompany this Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary.

None.

SIGNATURES

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

Cidara Therapeutics, Inc.

Date: March 6, 2025

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

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

Name	Title	Date
/s/ Jeffrey Stein, Ph.D. **Jeffrey Stein, Ph.D.**	President, Chief Executive Officer and Member of the Board of Directors *(Principal Executive Officer)*	March 6, 2025
/s/ Frank Karbe **Frank Karbe**	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 6, 2025
/s/ Daniel D. Burgess **Daniel D. Burgess**	Chairman of the Board of Directors	March 6, 2025
/s/ Bonnie Bassler, Ph.D. **Bonnie Bassler, Ph.D.**	Member of the Board of Directors	March 6, 2025
/s/ Carin Canale-Theakston **Carin Canale-Theakston**	Member of the Board of Directors	March 6, 2025
/s/ James Merson, Ph.D. **James Merson, Ph.D.**	Member of the Board of Directors	March 6, 2025
/s/ Chrysa Mineo **Chrysa Mineo**	Member of the Board of Directors	March 6, 2025
/s/ Josh Resnick, M.D. **Josh Resnick, M.D.**	Member of the Board of Directors	March 6, 2025
/s/ Theodore R. Schroeder **Theodore R. Schroeder**	Member of the Board of Directors	March 6, 2025
/s/ Ryan Spencer **Ryan Spencer**	Member of the Board of Directors	March 6, 2025