UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2023

☐ 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, including Zip Code)	**(Registrant's Telephone Number, Including Area Code)**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $0.0001 Per Share	CDTX	The Nasdaq Stock Market LLC

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 X 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 X 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. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of May 8, 2023, the registrant had 90,025,187 shares of Common Stock ($0.0001 par value) outstanding.

CIDARA THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

CIDARA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)	March 31, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 47,976	$ 32,731
Accounts receivable	25,826	5,833
Prepaid expenses and other current assets	5,686	6,530
Total current assets	79,488	45,094
Property and equipment, net	270	222
Operating lease right-of-use asset	917	1,205
Other assets	1,061	1,072
Total assets	$ 81,736	$ 47,593
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,980	$ 1,447
Accrued liabilities	9,078	7,672
Accrued compensation and benefits	5,843	4,922
Current deferred revenue	15,761	14,614
Lease liability	1,001	1,317
Total current liabilities	35,663	29,972
Long-term deferred revenue	19,236	20,525
Total liabilities	54,899	50,497
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at March 31, 2023 and December 31, 2022:		
Series X Convertible Preferred Stock, $0.0001 par value; 4,947,759 shares authorized at March 31, 2023 and December 31, 2022; 2,156,713 shares issued and 2,104,472 shares outstanding at March 31, 2023; 1,870,713 shares issued and 1,818,472 shares outstanding and December 31, 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 90,024,562 shares issued and outstanding at March 31, 2023 and 72,470,440 shares issued and outstanding at December 31, 2022	9	7
Additional paid-in capital	430,585	404,055
Accumulated deficit	(403,757)	(406,966)
Total stockholders' equity (deficit)	26,837	(2,904)
Total liabilities and stockholders' equity (deficit)	$ 81,736	$ 47,593

See accompanying notes.

CIDARA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(unaudited)

(In thousands, except share and per share data)	Three Months Ended March 31, 2023	2022
Revenues:		
Collaboration revenue	$ 25,990	$ 7,109
Total revenues	25,990	7,109
Operating expenses:		
Research and development	18,715	20,166
General and administrative	4,298	5,204
Total operating expenses	23,013	25,370
Income (loss) from operations	2,977	(18,261)
Other income (expense):		
Interest income (expense), net	232	(20)
Total other income (expense), net	232	(20)
Net income (loss) and comprehensive income (loss)	3,209	(18,281)
Allocation of earnings to participating securities	(677)	—
Net income (loss) attributable to common stockholders	$ 2,532	$ (18,281)
Basic net earnings (loss) per common share	$ 0.03	$ (0.27)
Diluted net earnings (loss) per common share	$ 0.03	$ (0.27)
Shares used to compute basic net earnings (loss) per common share	78,640,086	68,138,116
Shares used to compute diluted net earnings (loss) per common share	101,189,396	68,138,116

See accompanying notes.

CIDARA THERAPEUTICS, INC.
Condensed Consolidated Statements of Cash Flows
(unaudited)

(In thousands)	Three Months Ended March 31, 2023	2022
Operating activities:		
Net income (loss)	$ 3,209	$ (18,281)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Stock-based compensation	640	1,338
Amortization of costs to obtain a contract with a customer	475	—
Amortization of operating lease right-of-use assets	288	258
Depreciation and amortization	32	39
Non-cash interest expense	—	1
Changes in assets and liabilities:		
Accounts receivable	(19,993)	(3,427)
Prepaid expenses, other current assets, and other assets	872	(1,120)
Accounts payable and accrued liabilities	3,116	657
Accrued compensation and benefits	921	(1,953)
Deferred revenue	(142)	(844)
Lease liabilities	(316)	(276)
Net cash used in operating activities	(10,898)	(23,608)
Investing activities:		
Purchases of property and equipment	(94)	(84)
Net cash used in investing activities	(94)	(84)
Financing activities:		
Proceeds from underwritten public offering, net of issuance costs	17,593	—
Proceeds from public offering of common stock, net of issuance costs	8,630	500
Proceeds from exercise of stock options	14	—
Principal repayments of Term Loan	—	(1,111)
Net cash provided by (used in) financing activities	26,237	(611)
Net increase (decrease) in cash and cash equivalents	15,245	(24,303)
Cash and cash equivalents at beginning of period	32,731	62,273
Cash and cash equivalents at end of period	$ 47,976	$ 37,970
Supplemental disclosure of cash flows:		
Interest paid	$ —	$ 25
Non-cash investing activities:		
Purchases of property and equipment, included in accounts payable and accrued liabilities	$ 55	$ 16
Non-cash financing activities:		
Issuance costs incurred but not yet paid, included in accounts payable and accrued liabilities	$ 337	$ —

See accompanying notes.

CIDARA THERAPEUTICS, INC.
Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)

Three Months Ended March 31, 2023

	Series X Convertible Preferred Stock		Common Stock				
(In thousands, except share data)	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2022	1,818,472	$ —	72,470,440	$ 7	$ 404,055	$ (406,966)	$ (2,904)
Underwritten public offering, net of issuance costs	286,000	—	11,086,000	1	17,255	—	17,256
Public offering of common stock, net of issuance costs	—	—	6,158,799	1	8,621	—	8,622
Issuance of common stock for exercise of options	—	—	16,250	—	14	—	14
Issuance of common stock for restricted share units vested	—	—	293,073	—	—	—	—
Stock-based compensation	—	—	—	—	640	—	640
Net income	—	—	—	—	—	3,209	3,209
Balance, March 31, 2023	2,104,472	$ —	90,024,562	$ 9	$ 430,585	$ (403,757)	$ 26,837

Three Months Ended March 31, 2022

	Series X Convertible Preferred Stock		Common Stock				
(In thousands, except share data)	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2021	1,818,472	$ —	67,863,674	$ 7	$ 398,733	$ (377,167)	$ 21,573
Public offering of common stock, net of issuance costs	—	—	644,265	—	500	—	500
Issuance of common stock for restricted share units vested	—	—	541,308	—	—	—	—
Stock-based compensation	—	—	—	—	1,165	—	1,165
Net loss	—	—	—	—	—	(18,281)	(18,281)
Balance, March 31, 2022	1,818,472	$ —	69,049,247	$ 7	$ 400,398	$ (395,448)	$ 4,957

See accompanying notes.

CIDARA THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. THE COMPANY AND BASIS OF PRESENTATION

Description of Business

Cidara Therapeutics, Inc., or the Company, was originally incorporated in Delaware in December 2012 as K2 Therapeutics, Inc., and its name was changed to Cidara Therapeutics, Inc. in July 2014. The Company is a biotechnology company focused on the discovery, development and commercialization of long-acting therapeutics designed to transform the standard of care for patients facing serious diseases. The Company is focused on infectious diseases and oncology. The Company's lead product candidate is rezafungin (trade name REZZAYO™), an intravenous formulation of a novel echinocandin antifungal. Rezafungin is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections. The Company's primary focus now is using its Cloudbreak® platform to develop a potential new class of drugs called drug-Fc conjugates, or DFCs, for the prevention and treatment of serious diseases. This technology couples potent inhibitors to a human antibody fragment to create long-acting DFCs designed to inhibit multiple disease targets. The Company's most advanced DFC program is CD388, a highly potent, long-acting antiviral designed to deliver universal prevention and treatment of seasonal and pandemic influenza, which is in Phase 1 and Phase 2a clinical trials. Additional programs are targeting multiple oncology and autoimmune indications.

The Company formed wholly-owned subsidiaries, Cidara Therapeutics UK Limited, in England, and Cidara Therapeutics (Ireland) Limited, in Ireland, in March 2016 and October 2018, respectively, for the purpose of developing its product candidates in Europe.

Basis of Presentation

The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. The Company has experienced net losses and negative cash flows from operating activities since its inception. At March 31, 2023, the Company had an accumulated deficit of $403.8 million. The Company expects to continue to incur net losses into the foreseeable future. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure.

At March 31, 2023, the Company had cash and cash equivalents of $48.0 million. Based on the Company's current business plan, management believes that existing cash and cash equivalents will not be sufficient to fund the Company's obligations for twelve months from the issuance of these financial statements. The Company's ability to execute its operating plan depends on its ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business. However, the Company's current working capital, anticipated operating expenses and net losses and the uncertainties surrounding its ability to raise additional capital as needed, as discussed below, raise substantial doubt about its ability to continue as a going concern for a period of one year following the date that these financial statements are issued. The condensed consolidated financial statements do not include any adjustments for the recovery and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

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

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

including actions taken to contain or treat COVID-19 and their effectiveness, as well as the economic impact on national and international markets.

Unaudited Interim Financial Data

The accompanying condensed consolidated financial statements are unaudited and have been prepared by the Company in accordance with U.S. generally accepted accounting principles, or GAAP, as found in the Accounting Standards Codification, or ASC, of the Financial Accounting Standards Board, or FASB. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim condensed consolidated financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended March 31, 2023 and 2022.

Basis of Consolidation

The condensed 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 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 condensed consolidated financial statements relate to estimated collaboration expenses related to the Company's collaboration and license agreements, certain accruals, including those related to nonclinical and clinical activities, and the stand-alone selling price of performance obligations associated with the Company's collaboration and license agreements. Although the estimates are based on the Company's knowledge of current events, comparable companies, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker, the Chief Executive Officer, in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents

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

Accounts Receivable

Accounts receivable is stated at the original invoice amount and consists of milestones achieved and certain research and development and clinical supply costs subject to reimbursement under the collaboration and license agreements. The Company records accounts receivables net of any allowances for doubtful accounts for potential credit losses. An allowance for doubtful accounts is determined based on the financial condition and creditworthiness of customers and the Company considers economic factors and events or trends expected to affect future collections experience. Any allowance would reduce the net receivables to the amount that is expected to be collected. The payment history of the Company's customers will be considered in future assessments of collectability as these patterns are established over a longer period of time. The Company did not record any credit losses as of March 31, 2023 or December 31, 2022.

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.

Income Taxes

The Company follows the FASB ASC 740, *Income Taxes*, or ASC 740, in reporting deferred income taxes. ASC 740 requires a company to recognize deferred tax assets and liabilities for expected future income tax consequences of events that have been recognized in the Company's condensed consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates in the years in which the temporary differences are expected to reverse. Valuation allowances are provided if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions pursuant to ASC 740, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes.

Revenue Recognition

The Company recognizes revenue is accordance with ASC Topic 606, *Revenue from Contracts with Customers*, or Topic 606, which applies to all contracts with customers, except for elements of certain contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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

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

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

period of adjustment. Revisions to the Company's estimate of the transaction price may also result in negative collaboration revenues and earnings in the period of adjustment.

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

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

In March 2021, the Company entered into an exclusive worldwide license and collaboration agreement, or the Janssen Collaboration Agreement, with Janssen Pharmaceuticals, Inc., or Janssen, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. The Company concluded that there were three performance obligations under the Janssen Collaboration Agreement: the license, the research and development services, and the clinical supply services, and that the obligations are distinct from each other. Revenue associated with the license was recognized upon delivery in May 2021.

In July 2022, the Company entered into a License Agreement, or the Melinta License Agreement, with Melinta Therapeutics, LLC, or Melinta. The Company concluded that there were three performance obligations under the Melinta License Agreement: the license, the research and development services, and the clinical supply services, and that the obligations are distinct from each other. Revenue associated with the license was recognized upon delivery in August 2022.

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

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

See Note 7 for additional information.

Research and Development Costs

Research and development expenses consist of wages, benefits and stock-based compensation charges for research and development employees, scientific consultant fees, facilities and overhead expenses, laboratory supplies, manufacturing expenses in preclinical development and certain manufacturing expenses before U.S. Food and Drug Administration, or FDA, approval, and nonclinical and clinical trial costs. The Company accrues nonclinical and clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies, and other events.

Costs incurred in purchasing technology assets and intellectual property are charged to research and development expense if the technology has not been conclusively proven to be feasible and has no alternative future use.

Preclinical and Clinical Trial Accruals

The Company makes estimates of its accrued expenses as of each balance sheet date in the financial statements based on the facts and circumstances known at that time. Accrued expenses for preclinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by contract research organizations, or CROs, clinical trial investigational sites and other clinical trial-related activities. Payments under certain contracts with

such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing for these services, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If possible, the Company obtains information regarding unbilled services directly from these service providers. However, the Company may be required to estimate these services based on other available information. If the Company underestimates or overestimates the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in accruals.

Stock-Based Compensation

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

The assumptions included in the Black-Scholes option pricing model include (a) the risk-free interest rate, (b) the expected volatility of the Company's stock, (c) the expected term of the award, and (d) the expected dividend yield. 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 do not intend to pay cash dividends in the foreseeable future.

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

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

Net Earnings (Loss) Per Share

The Company follows the guidance in FASB 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 X Convertible Preferred Stock (see Note 5). Basic net earnings per share 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 earnings per share 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, 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 if-converted method. 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.

The following table sets forth the computation of basic and diluted net earnings (loss) per common share (in thousands, except share and per share data):

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net income (loss)	$ 3,209	$ (18,281)
Allocation of earnings to participating securities	(677)	—
Numerator for basic net earnings (loss) per common share - net income (loss) attributable to common stockholders	$ 2,532	$ (18,281)
Effect of participating securities:		
Add back allocation of earnings to participating securities	677	—
Numerator for diluted net earnings (loss) per common share - net income (loss) attributable to common stockholders	$ 3,209	$ (18,281)
Denominator:		
Denominator for basic net earnings (loss) per common share - weighted average common shares outstanding	78,640,086	68,138,116
Effect of dilutive securities:		
Series X Convertible Preferred Stock, as converted	21,044,720	—
Common stock options, RSUs, PRSUs, and ESPP	1,504,590	—
Denominator for diluted net earnings (loss) per common share - adjusted weighted average common shares outstanding	101,189,396	68,138,116
Basic net earnings (loss) per common share	$ 0.03	$ (0.27)
Diluted net earnings (loss) per common share	$ 0.03	$ (0.27)

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

	Three Months Ended March 31,	
	2023	2022
Common stock warrants	12,517,328	12,517,328
Series X Convertible Preferred Stock	—	18,184,720
Common stock options, RSUs and PRSUs issued and outstanding	11,759,061	10,847,996
Total	24,276,389	41,550,044

Fair Value of Financial Instruments

The Company follows ASC 820-10 issued by the FASB with respect to fair value reporting for financial assets and liabilities. The guidance defines fair value, provides guidance for measuring fair value and requires certain disclosures. The guidance does not apply to measurements related to share-based payments. The guidance discusses valuation techniques such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The guidance establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels.

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

Recently Issued and Recently Adopted Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. The Company believes, based on its preliminary assessment, that the recently issued, but not yet adopted, accounting pronouncements will not have a material impact on the Company's condensed consolidated financial statements or related disclosures, or do not apply to the Company.

3. FAIR VALUE MEASUREMENTS

The Company follows ASC 820-10, Fair Value Measurements and Disclosures, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability.

As a basis for considering such assumptions, a three-tier fair value hierarchy has been established, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs for which there is little or no market data, which require the reporting entity to develop its own assumptions, which reflect those that a market participant would use.

The Company classifies investments in money market accounts within Level 1 as the prices are available from quoted prices in active markets.

None of the Company's non-financial assets or liabilities are recorded at fair value on a non-recurring basis. No transfers between levels have occurred during the periods presented.

The following tables summarize the Company's financial instruments measured at fair value on a recurring basis (in thousands):

	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
March 31, 2023				
Assets:				
Cash and money market accounts	$ 47,976	$ 47,976	$ —	$ —
Total assets at fair value	$ 47,976	$ 47,976	$ —	$ —
December 31, 2022				
Assets:				
Cash and money market accounts	$ 32,731	$ 32,731	$ —	$ —
Total assets at fair value	$ 32,731	$ 32,731	$ —	$ —

4. DEBT

Term Loan

On October 3, 2016, the Company entered into a loan and security agreement, or the Loan Agreement, with Pacific Western Bank, as the collateral agent and a lender, or the Lender, pursuant to which the Company has borrowed $10.0 million from the Lender, or the Term A Loan. The Term A Loan bore interest at a variable annual rate equal to the greater of (i) 4.5% or (ii) the Lender's prime interest rate plus 0.75%, and matured on July 3, 2022. The Term A Loan had an interest-only period through April 3, 2020, which was followed by equal monthly principal payments and was paid in full on July 5, 2022.

5. STOCKHOLDERS' EQUITY

Controlled Equity Sales Agreement

In September 2019, the Company began to sell shares of common stock under a controlled equity sales agreement, or the Sales Agreement, entered into on November 8, 2018 with Cantor Fitzgerald & Co, or Cantor. During the three months ended March 31, 2023, the Company sold 6,158,799 shares of common stock, at a weighted average price of $1.44 per share for gross proceeds of approximately $8.9 million, and for net proceeds of approximately $8.6 million after deducting placement agent fees. During the three months ended March 31, 2022, the Company sold 644,265 shares of common stock for net proceeds of approximately $0.5 million after deducting placement agent fees. As of March 31, 2023, the aggregate offering price remaining under the Sales Agreement is $37.2 million. The Company has not sold shares of common stock under the Sales Agreement from April 1, 2023 through the date of this filing.

2023 Public Offering

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

Preferred Stock

Under the amended and restated certificate of incorporation, the Company's board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding. The Company had 10,000,000 shares of preferred stock authorized at March 31, 2023.

In May 2018, the Company designated 5,000,000 shares of preferred stock as Series X Convertible Preferred Stock with a par value of $0.0001 per share.

On August 12, 2020, at the request of certain holders, 52,241 shares of the Company's Series X Convertible Preferred Stock were converted to an aggregate of 522,410 shares of the Company's common stock. As of March 31, 2023 and December 31, 2022, shares of preferred stock designated as Series X Convertible Preferred Stock totaled 4,947,759.

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

Conversion: Each share of Series X Convertible Preferred Stock is convertible at the option of the holder into 10 shares of common stock. Holders are not permitted to convert Series X Convertible Preferred Stock into common stock if, after conversion, the holder, its affiliates, and any other person whose beneficial ownership of common stock would be aggregated with the holder's for purposes of Section 13(d) or Section 16 of the Exchange Act, would beneficially own more than 9.99% of the number of shares of common stock outstanding immediately after the conversion.

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

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

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

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

Common Stock

The Company had 200,000,000 shares of common stock authorized as of March 31, 2023. Holders of outstanding shares of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the holders of common stock. Subject to the rights of the holders of any class of the Company's capital stock having any preference or priority over common stock, the holders of common stock are entitled to receive dividends that are declared by the Company's board of directors out of legally available funds. In the event of a liquidation, dissolution or winding-up, the holders of common stock are entitled to share ratably in the net assets remaining after payment of liabilities, subject to prior rights of preferred stock, if any, then outstanding. The common stock has no preemptive rights, conversion rights, redemption rights or sinking fund provisions, and there are no dividends in arrears or default. All shares of common stock have equal distribution, liquidation and voting rights, and have no preferences or exchange rights.

Common Stock Warrants

As of March 31, 2023 and December 31, 2022, warrants to purchase 12,517,328 shares of the Company's common stock were outstanding with a weighted average exercise price of $6.82 per share.

The warrants had no intrinsic value at March 31, 2023 and December 31, 2022. The intrinsic value of a common stock warrant is the difference between the market price of the common stock at the measurement date and the exercise price of the warrant.

Common Stock Reserved for Future Issuance

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

	March 31, 2023	December 31, 2022
Common stock warrants	12,517,328	12,517,328
Series X Convertible Preferred Stock	21,044,720	18,184,720
Common stock options, RSUs and PRSUs issued and outstanding	12,981,597	9,323,495
Authorized for future stock awards	3,400,881	4,469,969
Awards available under the ESPP	1,297,304	806,968
Total	51,241,830	45,302,480

6. EQUITY INCENTIVE PLANS

2020 Inducement Incentive Plan and 2015 Equity Incentive Plan

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

In March 2015, the Company's board of directors and stockholders approved and adopted the 2015 Equity Incentive Plan, or 2015 EIP. Under the 2015 EIP, the Company may grant stock options, stock appreciation rights, restricted stock, RSUs, and other awards to individuals who are employees, officers, directors or consultants of the Company. The number of shares of stock available for issuance under the 2015 EIP is automatically increased each January 1 by 4% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31 or such lesser number as determined by the Company's board of directors.

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2020 IIP and 2015 EIP. Stock options granted by the Company generally vest over a three- or four-year period. Certain stock options are subject to acceleration of vesting in the event of certain change of control transactions.

The stock options may be granted for a term of up to 10 years from the date of grant. The exercise price for stock options granted under the 2020 IIP and 2015 EIP must be at a price no less than 100% of the fair value of the shares on the date of grant, provided that for an incentive stock option granted to an employee who at the time of grant owns stock representing more than 10% of the voting power of all classes of stock of the Company, the exercise price shall be no less than 110% of the value on the date of grant.

2015 Employee Stock Purchase Plan

In March 2015, the Company's board of directors and stockholders approved and adopted the 2015 Employee Stock Purchase Plan, or the ESPP. The number of shares of stock available for issuance under the ESPP will be automatically increased each January 1 by the lesser of (i) 1% of the outstanding number of shares of the Company's common stock on the immediately preceding December 31, (ii) 490,336 shares, or (iii) such lesser number as determined by the Company's board of directors.

The ESPP allows substantially all employees to purchase the Company's common stock through a payroll deduction at a price equal to 85% of the lower of the fair market value of the stock as of the beginning or the end of each purchase period. An employee's payroll deductions under the ESPP are limited to 15% of the employee's eligible compensation.

During the three months ended March 31, 2023 and 2022, no shares were issued pursuant to the ESPP. As of March 31, 2023, total unrecognized compensation expense related to the ESPP was approximately $0.1 million. This unrecognized compensation cost is expected to be recognized over approximately 0.4 years.

Restricted Stock Units

The following table summarizes RSU and PRSU activity during the three months ended March 31, 2023:

	Number of RSUs and PRSUs	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2022	1,223,871	$ 1.47
RSUs and PRSUs granted	1,355,817	1.01
RSUs and PRSUs vested	(293,073)	1.08
RSUs and PRSUs canceled	(20,532)	1.67
Outstanding at March 31, 2023	2,266,083	$ 1.24

The weighted-average grant date fair value of RSUs and PRSUs granted by the Company during the three months ended March 31, 2022 was $0.83 per share. The total fair value of RSUs and PRSUs vested during the three months ended March 31, 2023 and 2022 was approximately $0.3 million and $1.0 million, respectively.

At March 31, 2023, estimated unrecognized compensation expense related to RSUs and PRSUs granted was approximately $2.6 million.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Total Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	8,099,624	$ 2.78	6.65	$ 48
Options granted	2,716,058	1.01		
Options exercised	(16,250)	0.83		
Options canceled	(83,918)	1.93		
Outstanding at March 31, 2023	10,715,514	$ 2.34	7.35	$ 1,512
Vested and expected to vest at March 31, 2023	10,715,514	$ 2.34	7.35	$ 1,512
Exercisable at March 31, 2023	5,875,683	$ 3.28	5.68	$ 217

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 three months ended March 31, 2023 and 2022 was $0.71 and $0.53 per share, respectively.

As of March 31, 2023, total unrecognized share-based compensation expense related to unvested stock options was approximately $3.7 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 2.3 years.

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

	Three Months Ended March 31,	
	2023	2022
Research and development	$ 367	$ 455
General and administrative	273	883
Total	$ 640	$ 1,338

7. SIGNIFICANT AGREEMENTS AND CONTRACTS

Mundipharma Collaboration Agreement

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

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

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

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

Until the seventh anniversary of the first commercial sale of the Mundipharma Licensed Product in the Mundipharma Territory, each party has granted the other party an exclusive, time-limited right of first negotiation to obtain a license to any anti-fungal product (other than Mundipharma Licensed Product, Subcutaneous Product and Other Products) that such party proposes to out-license in the other party's territory.

The Company's Retained Rights. As of March 31, 2023, the Company retained the exclusive right to develop, register and commercialize the Mundipharma Licensed Product, Subcutaneous Product and Other Products in Japan, or the Company Territory, and Mundipharma has granted the Company certain licenses under Mundipharma-controlled technology and jointly-developed technology to develop, register and commercialize Mundipharma Licensed Product, Subcutaneous Product and Other Products in the Company Territory and to manufacture such products and rezafungin worldwide.

Financial Terms. As of the execution of the Mundipharma Collaboration Agreement, the parties have agreed to share equally (50/50) the costs of Global Development Plan activities, or Global Development Costs, subject to a cap on Mundipharma's Global Development Cost share of $31.2 million. The total potential transaction value is $568.4 million, including an equity investment, an up-front payment, global development funding, and certain development, regulatory,

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

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

Revenue Recognition

As of March 31, 2023, the Company determined the transaction price is equal to the up-front fee of $30.0 million, plus the research and development funding of $31.2 million, plus milestones achieved of $13.9 million. The common stock issued pursuant to the Mundipharma Stock Purchase Agreement was determined to be issued at fair market value after applying a lack of marketability discount as Mundipharma received restricted shares. Therefore, no additional premium or discount was allocated to the transaction price of the Mundipharma Collaboration Agreement for the share issuance. The transaction price was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In estimating the stand-alone selling price for each performance obligation, the Company utilized discounted cash flows and developed assumptions that required judgment and included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success and costs for manufacturing clinical supplies. A description of the distinct performance obligations identified under the Mundipharma Collaboration Agreement, as well as the amount of revenue allocated to each distinct performance obligation, is as follows:

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

Research and Development Services. The Company and Mundipharma share equally in the costs of ongoing rezafungin clinical development in the Mundipharma Territory up to the specified cap, which represents a distinct performance obligation. The Company records these cost-sharing payments due from Mundipharma as collaboration revenue. The Company concluded that progress towards completion of the performance obligation related to the research and development services is best measured in an amount proportional to the research and development expenses incurred and the total estimated research and development expenses.

Clinical Supply Services. The Company's initial obligation to supply rezafungin for ongoing clinical development in the Mundipharma Territory represents a distinct performance obligation. The Company concluded that progress towards completion of the performance obligations related to the clinical supply services is best measured in an amount proportional to the clinical supply services expenses incurred and the total estimated clinical supply services.

Milestone Payments. In November 2020, the Company achieved a $11.1 million milestone under the Mundipharma Collaboration Agreement, which is recorded as long-term deferred revenue as of March 31, 2023 because the rights to consideration is not expected to be satisfied within one year. The Company received payment for this milestone in January 2021. Mundipharma is entitled to credit the full amount of this milestone payment toward future royalties payable to the Company, subject to a limit on the amount by which royalty payments to the Company may be reduced in any quarter. If Mundipharma has not fully credited the amount of such milestone payment toward royalties payable to the Company before the earlier of (i) December 31, 2024 and (ii) termination of the Mundipharma Collaboration Agreement by Mundipharma, the Company will be obligated to refund the uncredited portion of such milestone payment to Mundipharma on the earlier of such dates. In December 2021 and August 2022, the Company achieved milestones of $2.8 million and $11.1 million, respectively, under the Mundipharma Collaboration Agreement that the Company deems to be tied to all the performance obligations identified in the original agreement. Revenue associated with these milestones has been allocated proportionately to the original transaction price which was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In conjunction with the performance obligations already delivered, revenue is recognized based on the progress of these performance obligations, the unrecognized portion is recorded as deferred revenue at the reporting period end and will be recognized as revenue over the remaining progress of these performance obligations. The Company received payment for these milestones in January 2022 and September 2022, respectively. The Company determined that as of March 31, 2023, all remaining potential milestone payments are probable of significant revenue

reversal as their achievement is highly dependent on factors outside the Company's control or are otherwise constrained under the variable consideration guidance. Therefore, these milestone payments have been fully constrained and are not included in the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint.

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

Janssen Collaboration Agreement

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

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

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

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

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

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

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

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

Revenue Recognition

As of March 31, 2023, the Company determined the transaction price is equal to the up-front fee of $27.0 million, plus the research and development funding of $57.6 million, plus a milestone achieved of $3.0 million. The transaction price was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In estimating the stand-alone selling price for each performance obligation, the Company utilized discounted cash flows and developed assumptions that required judgment and included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success, costs to continue the research and development efforts and costs for manufacturing clinical supplies. A description of the distinct performance obligations identified under the Janssen Collaboration Agreement, as well as the amount of revenue allocated to each distinct performance obligation, is as follows:

Licenses of Intellectual Property. The license to the Company's intellectual property, bundled with the associated know-how, represents a distinct performance obligation. The license and associated know-how was transferred to Janssen in May 2021, therefore the Company recognized the revenue related to this performance obligation in the amount of $27.0 million in May 2021 as collaboration revenue in its condensed consolidated statements of operations and comprehensive income (loss).

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

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

Milestone Payments. In March 2022, the Company achieved a $3.0 million milestone under the Janssen Collaboration Agreement that the Company deems to be tied to all the performance obligations identified in the original agreement. Revenue associated with the milestone has been allocated proportionately to the original transaction price which was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In conjunction with the performance obligations already delivered, revenue is recognized based on the progress of these performance obligations, the unrecognized portion is recorded as deferred revenue at the reporting period end and will be recognized as revenue over the remaining progress of these performance obligations. The Company received payment for this milestone in May 2022. The Company determined that as of March 31, 2023, all remaining potential milestone payments are probable of significant revenue reversal as their achievement is highly dependent on factors outside the Company's control or are otherwise constrained under the variable consideration guidance. Therefore, these milestone payments have been fully constrained and are not included in the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint.

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

Melinta License Agreement

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

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

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

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

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

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

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

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

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

Termination. Either party may terminate the Melinta License Agreement for uncured material breach by the other party. After July 26, 2023, Melinta may terminate the Melinta License Agreement at will. The Company may terminate the Melinta License Agreement if Melinta or any of its affiliates or sublicensees, directly or indirectly through any third party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any of the patent rights licensed to Melinta by the Company.

Revenue Recognition

As of March 31, 2023, the Company determined the transaction price is equal to the up-front fee of $30.0 million, plus a milestone achieved of $20.0 million. The transaction price was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In estimating the stand-alone selling price for each performance obligation, the Company utilized discounted cash flows and developed assumptions that required judgment and included forecasted revenues, expected development timelines, discount rates, probabilities of technical and regulatory success, costs to continue the research and development efforts and costs for manufacturing clinical supplies. A description of the distinct performance obligations identified under the Melinta License Agreement, as well as the amount of revenue allocated to each distinct performance obligation, is as follows:

Licenses of Intellectual Property. The license to the Company's intellectual property, bundled with the associated know-how, represents a distinct performance obligation. The license and associated know-how was transferred to Melinta in August 2022, therefore the Company recognized the full revenue related to this performance obligation in the amount of $25.9 million in August 2022 as collaboration revenue in its condensed consolidated statements of operations and comprehensive income (loss).

Research and Development Services. The Company is required to provide research and development services, at its sole expense, as described under the Melinta Development Plan, which represents a distinct performance obligation. The Company concluded that progress towards completion of the performance obligation related to the research and development services is best measured in an amount proportional to the research and development expenses incurred and the total estimated research and development expenses.

Clinical Supply Services. The Company's obligation to supply rezafungin for ongoing clinical development in the Melinta Territory represents a distinct performance obligation. The Company concluded that progress towards completion of the performance obligations related to the clinical supply services is best measured in an amount proportional to the clinical supply services expenses incurred and the total estimated clinical supply services. Revenue related to the clinical supply services performance obligation recognized during the three months ended March 31, 2023 was immaterial.

Milestone Payments. In March 2023, the Company achieved a $20.0 million milestone under the Melinta License Agreement that the Company deems to be tied to all the performance obligations identified in the original agreement. Revenue associated with the milestone has been allocated proportionately to the original transaction price which was allocated to the performance obligations on the basis of the relative stand-alone selling price estimated for each performance obligation. In conjunction with the performance obligations already delivered, revenue is recognized based on the progress of these performance obligations, the unrecognized portion is recorded as deferred revenue at the reporting period end and will be recognized as revenue over the remaining progress of these performance obligations. The Company received payment for this milestone in April 2023. The Company determined that as of March 31, 2023, all remaining potential milestone payments are probable of significant revenue reversal as their achievement is highly dependent on factors outside the Company's control or are otherwise constrained under the variable consideration guidance. Therefore, these milestone payments have been fully constrained and are not included in the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint.

Royalties. As the license is deemed to be the predominant item to which sales-based royalties relate, the Company will recognize revenue when the related sales occur. No royalty revenue was recognized during the three months ended March 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. The Company incurred these costs in connection with all the performance obligations identified in the Melinta License Agreement and allocated the capitalized contract costs to performance obligations on a relative basis (i.e., in proportion to the transaction price allocated to each performance obligation) to determine the period of amortization. Amortization during the three months ended March 31, 2023 was $0.5 million and is included within general and administrative expenses in the Company's condensed consolidated statements of operations and comprehensive income (loss). As of March 31, 2023, the remaining balance of the asset recognized from costs to obtain the Melinta License Agreement was $0.2 million.

Contract Liabilities

The following table presents a summary of the activity in the Company's contract liabilities (recorded as deferred revenue on the balance sheet) pertaining to the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement during the three months ended March 31, 2023 (in thousands):

Opening balance, December 31, 2022	$ 35,139
Payments received in advance	38
Payments receivable	1,979
Revenue from performance obligations satisfied during reporting period	(2,159)
Closing balance, March 31, 2023	$ 34,997
Current portion of deferred revenue	$ 15,761
Long-term portion of deferred revenue	19,236
Total deferred revenue, March 31, 2023	$ 34,997

As of March 31, 2023, the aggregate transaction price allocated to performance obligations that are unsatisfied is $14.3 million, $22.0 million, and $4.9 million under the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement, respectively. These amounts are expected to be recognized over 2.0 years, 1.5 years, and 2.0 years which represent the remaining research periods under the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement, respectively.

As of March 31, 2023, the Company recorded $0.1 million, $5.7 million and $20.0 million in accounts receivable associated with the Mundipharma Collaboration Agreement, Janssen Collaboration Agreement, and Melinta License Agreement, respectively. As of December 31, 2022, the Company recorded $0.2 million and $5.6 million in accounts receivable associated with the Mundipharma Collaboration Agreement and Janssen Collaboration Agreement, respectively.

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

	Three Months Ended March 31, 2023		
	Mundipharma	**Janssen**	**Melinta**
Revenue from Collaboration and License Agreements:			
Point in Time:			
License of Intellectual Property	$ —	$ —	$ 17,257
Over Time:			
Research and Development Services	1,684	5,523	1,134
Clinical Supply Services	—	392	—
Total Revenue from Collaboration and License Agreements	$ 1,684	$ 5,915	$ 18,391

	Three Months Ended March 31, 2022		
	Mundipharma	**Janssen**	**Melinta**
Revenue from Collaboration and License Agreements:			
Point in Time:			
License of Intellectual Property	$ —	$ 816	$ —
Over Time:			
Research and Development Services	2,274	2,356	—
Clinical Supply Services	252	1,411	—
Total Revenue from Collaboration and License Agreements	$ 2,526	$ 4,583	$ —

8. COMMITMENTS AND CONTINGENCIES

Lease Obligations

On July 14, 2021, the Company entered into a sixth amendment to its lease with Nancy Ridge Technology Center, L.P. which extended the term of the lease by an additional 24 months and increases the base rent to $103,733 per month effective January 1, 2022, subject to 3% increases every January. The lease expires on December 31, 2023 with options for two individual two-year extensions, as described in the original lease agreement, which have not been exercised, and remain in effect and available to the Company. As of March 31, 2023, the Company was not reasonably certain that it would exercise the extension options, and therefore did not include these options in the determination of the total lease term for accounting purposes. The incremental borrowing rate used in measuring the Company's lease liability was 10.8%.

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

2023		1,046
Total undiscounted operating lease payments	$	1,046
Less: Imputed interest		(45)
Present value of lease payments	$	1,001

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

Balance Sheet Classification:		
Operating lease right-of-use asset	$	917
Lease liability	$	1,001

As of March 31, 2023, the weighted average remaining lease term was 0.8 years.

Cash paid for amounts included in the present value of operating lease liabilities was $0.3 million for the three months ended March 31, 2023 and 2022.

Operating lease costs were $0.3 million for the three months ended March 31, 2023 and 2022. These costs are primarily related to the Company's operating lease, but also include immaterial amounts for variable leases and short-term leases with terms greater than 30 days.

Contractual Obligations

The Company enters into contracts in the normal course of business with vendors for research and development activities, manufacturing, and professional services. These contracts generally provide for termination either on notice or after a notice period.

9. SUBSEQUENT EVENTS

On April 20, 2023, the Company entered into a Seventh Amendment to its lease, or the Amendment, which extended the term of the lease by an additional 36 months and increases the base rent to $133,371 per month effective January 1, 2024, subject to 4% increases every January. The 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.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report, and our Annual Report on Form 10-K, or our Annual Report, for the year ended December 31, 2022, filed with the Securities and Exchange Commission, or the SEC, on March 23, 2023.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, clinical and nonclinical data, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management and the impact of the COVID-19 pandemic on the foregoing. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. 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 Quarterly Report and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

OVERVIEW

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

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

Cloudbreak Platform

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

- Multivalent binding which has the potential to increase potency;
- Ability to engage different targets 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.

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

Our lead Cloudbreak candidate for the prevention of influenza is CD388, a DFC in a Phase 2a clinical trial. Our lead oncology DFC is CD421, a development candidate targeting CD73 for the treatment of solid tumors, which is in investigational new drug application, or IND, -enabling studies.

Cloudbreak Influenza Program

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

In September 2022, we initiated a Phase 2a trial (NCT05523089) to evaluate the pre-exposure prophylactic activity of CD388 against influenza virus. The Phase 2a trial, which dosed its first healthy volunteer in September 2022, is a single-center, randomized, double-blind, placebo-controlled, proof-of-concept study to assess the prophylactic antiviral activity, safety, tolerability and pharmacokinetics of CD388 against influenza via a human viral challenge (influenza) model. Multiple dose levels of CD388 will be evaluated in volunteers who will receive a single administration of CD388 or placebo prior to influenza viral challenge.

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

In December 2022, we received the first United States, or 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.

CD388 Phase 2a Interim Results

In March 2023, we announced efficacy and safety data from a planned interim analysis of our ongoing Phase 2a trial evaluating the pre-exposure prophylactic activity of CD388 against the H3N2 influenza A virus strain, as of a February 13, 2023 data cut-off. The interim analysis is based on 56 subjects enrolled in the trial, with 28 subjects receiving a single dose of CD388 (150 mg) and 28 subjects receiving a placebo.

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

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

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

Final results are expected later in 2023.

Cloudbreak Oncology Program

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

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

With our Cloudbreak oncology program we seek to develop a new generation of immunotherapies, and our lead oncology DFC candidate, CD421, is a potential first-in-class CD73 inhibitor that combines the strengths of small molecules and monoclonal antibodies targeting CD73. CD421 targets CD73 in the adenosine pathway, which contributes to immune evasion in solid cancers by flooding the tumor microenvironment with adenosine, a potent immune cell suppressor. CD73 is highly expressed on a variety of tumor and stromal cells as well as immunosuppressive cell populations, such as regulatory T cells and myeloid-derived suppressor cells. CD421 is designed to address the potency, efficacy, pharmacokinetic and safety limitations of small molecule and mAb candidates targeting CD73. We are currently advancing CD421 through IND-enabling studies and expect to file an IND in 2024.

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

Janssen Collaboration Agreement

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

Under the terms of the Janssen Collaboration Agreement, we are collaborating in the research, preclinical and early clinical development of CD388, under a mutually-agreed research plan with the objective of advancing development through Phase 1 clinical trials and the first Phase 2a clinical trial. We are responsible for performing all IND-enabling nonclinical studies and early-stage clinical trials under the research plan. Both parties are responsible for conducting certain specified chemistry, manufacturing and controls development activities under the research plan. Janssen is solely responsible, and reimburses us for internal personnel and out-of-pocket costs incurred in performing the research plan activities in accordance with an agreed budget. After completion of the research plan and upon its election to proceed with development, Janssen will be solely responsible for late-stage development, manufacturing, licensure and commercialization. Upon the effectiveness of the Janssen Collaboration Agreement, Janssen paid us an upfront payment of $27.0 million. As of the execution of the Janssen Collaboration Agreement, we are eligible for reimbursement by Janssen of up to $58.2 million in research and development costs incurred in conducting research plan activities. As of March 31, 2023, we have received the $27.0 million up-front payment, $30.7 million in research and development reimbursements, and $3.0 million in milestone payments.

We are eligible to receive up to an additional $237.0 million in development and regulatory milestone payments from Janssen for successful completion of certain activities over the next several years, including but not limited to Janssen's decision whether to proceed with clinical development and initiation of Phase 2b and Phase 3 trials. In addition, we may be eligible to receive approximately $455.0 million in commercial milestones as well as royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits.

Rezafungin

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

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

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

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

The European Medicines Agency, or EMA, accepted the marketing authorization application, or MAA, for rezafungin in August 2022 and it is currently under review. We expect an EMA approval decision by the end of 2023.

ReSPECT Phase 3 clinical trial

We are currently conducting the ReSPECT, single, global, randomized, double-blind, controlled Phase 3 pivotal clinical trial (NCT04368559) in patients undergoing allogeneic blood and marrow transplant to assess rezafungin in a 90-day prophylaxis regimen to prevent infections due to Candida, Aspergillus and Pneumocystis. Rezafungin, dosed at 400 mg for the first week followed by 200 mg once weekly out to 90 days, is being compared to a regimen containing two drugs (an azole and Bactrim) dosed once daily for 90 days. The primary efficacy outcome for this trial for the FDA and EMA is fungal-free survival at Day 90. We expect this trial to enroll approximately 462 patients, and over 50% of patients have been enrolled thus far. While the ReSPECT trial remains open for enrollment, we continue to monitor the near- and long-term impact of COVID-19 on the ability of our clinical investigators to recruit patients at each of our global clinical trial sites. The study is currently enrolling in the European Union, or EU, Canada and the U.S. and we expect the trial to be completed by the end of 2024.

Melinta License Agreement

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

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

The total potential transaction value of the Melinta License Agreement is $460.0 million, including a $30.0 million upfront payment and up to $430.0 million in regulatory and commercial milestones. In addition, we are eligible to receive tiered royalties on U.S. sales in the low double digits to mid-teens. As of March 31, 2023, we have received the $30.0 million up-front payment. In April 2023 we received a $20.0 million milestone payment.

Mundipharma Collaboration Agreement

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

As of March 31, 2023, we have received $9.0 million from the sale of our equity to Mundipharma, a $30.0 million up-front payment, $31.2 million in global development funding, and $25.1 million in milestone payments (including an $11.1 million milestone payment creditable against future royalties payable to us).

Compliance with Nasdaq Listing Requirements

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

Impact of the COVID-19 Pandemic and Other 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. The COVID-19 pandemic has delayed our conduct of clinical trials and other key activities and there is uncertainty regarding the emergence of potential new COVID-19 strains. Adopting a work-from-home policy during this pandemic has increased the complexity of our computer systems, making them inherently more vulnerable to service interruption or destruction, malicious intrusion and random attack. While we have not experienced significant disruptions to our manufacturing supply chain or distribution to date, we are unable to fully assess the potential impact that an extended duration of this pandemic may have on our manufacturing or distribution processes in the future. The extent of the impact of COVID-19 on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, all of which are uncertain and cannot be predicted. We continue to monitor the potential impact of the COVID-19 global pandemic on our business.

We may also be impacted by broader macroeconomic conditions, including high inflation, bank failures, labor shortages, supply chain disruptions, recession risks and potential disruptions from the ongoing Russia-Ukraine conflict and related sanctions. For example, the recent closures of Silicon Valley Bank, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. While we do not have deposits with these banks, if other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash and cash equivalents may be threatened, which could have a material adverse effect on our business and financial condition. The stock market, and in particular the market for pharmaceutical and biotechnology company stocks, has recently experienced significant decreases in value. This volatility and valuation decline have affected the market prices of securities issued by many companies, often for reasons unrelated to their operating performance.

Liquidity Overview

Since our inception, we have devoted substantially all of our financial resources and efforts to research and development and have incurred significant operating losses. As of March 31, 2023, we had an accumulated deficit of $403.8 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future.

In connection with the preparation of our financial statements for the three month period ended March 31, 2023, we performed an analysis of our ability to continue as a going concern. We believe, based on our current business plan, that our existing cash and cash equivalents will not be sufficient to fund our obligations for twelve months from the issuance of these financial statements, which raises substantial doubt about our ability to continue as a going concern. Our ability to execute our current business plan depends on our ability to obtain additional funding through equity offerings, debt financings or potential licensing and collaboration arrangements. We may not be able to raise additional funding on terms acceptable to us, or at all, and any failure to raise funds as and when needed will compromise our ability to execute on our business plan.

FINANCIAL OPERATIONS OVERVIEW

Revenues

To date, we have generated all of our revenues from our strategic partnerships with Mundipharma and Janssen, and our license agreement with Melinta. In the future, we may generate revenue from a combination of license fees and other upfront payments, other funded research and development agreements, milestone payments, product sales, government and other third-party funding and royalties in connection with strategic alliances. We expect that any revenue we generate will fluctuate from quarter-to-quarter as a result of the timing of our achievement of nonclinical, clinical, regulatory and commercialization milestones, the timing and amount of payments relating to such milestones and the extent to which any of our products are approved and successfully commercialized. If we are unable to fund our development costs or we are unable to develop product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenues and our results of operations and financial position would be adversely affected.

Research and development expenses

To date, our research and development expenses have related primarily to nonclinical development of our rezafungin acetate and our Cloudbreak platform, as well as clinical development of rezafungin acetate. Research and development expenses consist of wages, benefits and stock-based compensation for research and development employees, as well as the cost of scientific consultants, facilities and overhead expenses, laboratory supplies, manufacturing expenses 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.

Research and development costs are expensed as incurred and costs incurred by third parties are expensed as the contracted work is performed. We accrue for costs incurred as the services are being provided by monitoring the status of the study or project and the invoices received from our external service providers. We adjust our accruals as actual costs become known.

We may receive potential research and development funding through a partnership from the National Institute of Allergy and Infectious Diseases. We have evaluated the terms of the grants to assess our obligations and the classification of funding received. Amounts received for funded research and development are recognized in the condensed consolidated statements of operations and comprehensive income (loss) as a reduction to research and development expense over the grant period as the related costs are incurred to meet our obligations.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase over the next several years as we continue to conduct nonclinical and clinical studies, expand our research and development pipeline and progress our product candidates through clinical trials. However, it is difficult to determine with certainty the duration, costs and timing to complete our current or future nonclinical programs and clinical trials of our product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- the impact of the COVID-19 pandemic and other similar health crises;
- per patient trial costs;

- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory authorities;
- the duration of patient follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidates.

Research and development expenses by major program or category were as follows (in thousands):

	Three Months Ended March 31,	
	2023	2022
Rezafungin	$ 7,261	$ 12,121
Cloudbreak platform	6,655	2,758
Personnel costs	4,312	4,614
Other research and development expenses	487	673
Total research and development expenses	$ 18,715	$ 20,166

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

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

General and administrative expenses

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

Other income (expense), net

Other income and expense consist primarily of interest income and expense, and various income or expense items of a non-recurring nature.

We earn interest income from interest-bearing accounts and money market funds for cash and cash equivalents. Interest expense represents interest payable related to term loans and the amortization of debt issuance costs.

CRITICAL ACCOUNTING ESTIMATES

Our discussion and analysis of our financial condition and results of operations is based upon unaudited financial statements that we have prepared in accordance with accounting principles generally accepted in the U.S. The preparation of these unaudited 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 our Annual Report on Form 10-K, the significant accounting estimates that we believe are important to aid in fully understanding and evaluating our reported financial results include the following:

Revenue Recognition

We recognize revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, or Topic 606, which applies to all contracts with customers, except for elements of certain contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or service we transfer to a customer. At contract inception, once the contract is determined to be within the scope of Topic 606, we assess the goods or services promised within each contract and identify those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

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

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

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

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

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

In March 2021, we entered into the Janssen Collaboration Agreement with Janssen. We concluded that there were three performance obligations under the Janssen Collaboration Agreement: the license, the research and development services, and the clinical supply services, and that the obligations are distinct from each other. Revenue associated with the license was recognized upon delivery in May 2021.

In July 2022, we entered into the Melinta License Agreement with Melinta. We concluded that there were three performance obligations under the Melinta License Agreement: the license, the research and development services, and the clinical supply services, and that the obligations are distinct from each other. Revenue associated with the license was recognized upon delivery in August 2022.

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

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

See Note 7 to the financial statements for additional information.

Preclinical and Clinical Trial Accruals

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on the facts and circumstances known to us at that time. Our accrued expenses for preclinical studies and clinical trials are based on estimates of costs incurred and fees that may be associated with services provided by contract research organizations, or CROs, clinical trial investigational sites and other clinical trial-related activities. Payments under certain contracts with such parties depend on factors such as successful enrollment of patients, site initiation and the completion of clinical trial milestones. In accruing for these services, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If possible, we obtain information regarding unbilled services directly from these service providers. However, we may be required to estimate these services based on other information available to us. If we underestimate or overestimate the activities or fees associated with a study or service at a given point in time, adjustments to research and development expenses may be necessary in future periods. Historically, our estimated accrued liabilities have approximated actual expense incurred. Subsequent changes in estimates may result in a material change in our accruals.

RESULTS OF OPERATIONS

Comparison of the three months ended March 31, 2023 and 2022

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

	Three Months Ended March 31,		
	2023	2022	Change
Collaboration revenue	$ 25,990	$ 7,109	$ 18,881
Research and development expense	18,715	20,166	(1,451)
General and administrative expense	4,298	5,204	(906)
Other income (expense), net	232	(20)	252

Collaboration revenue

Collaboration revenue was $26.0 million for the three months ended March 31, 2023 and $7.1 million for the three months ended March 31, 2022. Revenue for the three months ended March 31, 2023 relates to the achievement of a milestone

and ongoing research and development and clinical supply services provided to Mundipharma, Janssen and Melinta of $1.7 million, $5.9 million and $18.4 million, respectively.

Revenue for the three months ended March 31, 2022 relates to the achievement of a milestone and ongoing research and development and clinical supply services provided to Mundipharma and Janssen of $2.5 million and $4.6 million, respectively.

Research and development expenses

Research and development expenses were $18.7 million for the three months ended March 31, 2023 and $20.2 million for the three months ended March 31, 2022. The decrease in research and development expenses is primarily due to lower clinical expenses associated with the rezafungin clinical trials and lower consulting and personnel costs, offset by higher clinical expenses associated with our Cloudbreak platform.

General and administrative expenses

General and administrative expenses were $4.3 million for the three months ended March 31, 2023 and $5.2 million for the three months ended March 31, 2022. The decrease in general and administrative expenses is primarily due to lower consulting, personnel and legal costs, offset by higher amortization of contract costs related to obtaining the Melinta License Agreement.

Other income (expense), net

Other income during the three months ended March 31, 2023 related primarily to interest income generated from cash held in interest-bearing accounts. Other expense during the three months ended March 31, 2022 related primarily to interest expense in connection with our loan from Pacific Western Bank, offset by interest income generated from cash held in interest-bearing accounts.

LIQUIDITY AND CAPITAL RESOURCES

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

Our ability to fund future operating needs will depend on a combination of equity, debt or other financing structures, receipt of payments under the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement, as well as potentially entering into other collaborations, strategic alliances or licensing arrangements with third parties or receiving government and/or charitable grants or contracts. Our ability to raise additional capital may also be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the U.S. and worldwide from geopolitical and macroeconomic events, including the COVID-19 pandemic, the ongoing Russia-Ukraine conflict and related sanctions, and bank failures.

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

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

We are eligible to receive up to $410.0 million in regulatory and commercial milestone payments from Melinta for successful completion of certain activities over the next several years, as well as tiered royalties on U.S. sales in the low double digits to mid-teens.

On November 8, 2018, we entered into the controlled equity offering sales agreement with Cantor Fitzgerald & Co., or the Sales Agreement, pursuant to which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to $50.0 million. As of March 31, 2023, the aggregate offering price remaining under the Sales Agreement was $37.2 million.

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

Our lease with Nancy Ridge Technology Center, L.P. expires on December 31, 2023 with options for two individual two-year extensions, which have not been exercised, and remain in effect and available to the Company. As of March 31, 2023, the Company was not reasonably certain that it would exercise the extension options, and therefore did not include these options in the determination of the total lease term for accounting purposes. Total undiscounted operating lease payments are $1.0 million as of March 31, 2023.

As discussed further below, we believe that our existing cash and cash equivalents will not be sufficient to fund our obligations for the next twelve months, or beyond. There are many factors that could impact our operating cash flow, most notably achievement of milestones under our Mundipharma Collaboration Agreement, Janssen Collaboration Agreement and Melinta License Agreement. Our current cash balance and eligibility to potentially receive non-dilutive capital of up to approximately $47.1 million in development and regulatory milestones from our existing partnerships, contingent on successful completion of activities planned over the next twelve months, has the potential to extend our cash runway in the near-term. There can be no assurance that we will be successful in completing all or part of the activities planned over the next twelve months which may adversely impact and reduce the amount of non-dilutive capital that we are eligible to receive from these activities.

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

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

As of March 31, 2023, we had $48.0 million in cash and cash equivalents. The following table shows a summary of our cash flows for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,	
	2023	2022
Net cash (used in) provided by:		
Operating activities	$ (10,898)	$ (23,608)
Investing activities	(94)	(84)
Financing activities	26,237	(611)
Net increase (decrease) in cash and cash equivalents	$ 15,245	$ (24,303)

Operating activities

Net cash used in operating activities was $10.9 million for the three months ended March 31, 2023, compared to net cash used in operating activities of $23.6 million for the three months ended March 31, 2022. Cash used in operating activities for the three months ended March 31, 2023 was primarily attributable to a net income of $3.2 million which included $20.0 million for a milestone achieved in March 2023 under the Melinta License Agreement, which was received in April 2023.

Cash used in operating activities for the three months ended March 31, 2022 was primarily attributable to a net loss of $18.3 million and included $2.8 million for a milestone achieved in December 2021 under the Mundipharma Collaboration Agreement, which was received in January 2022.

For all periods presented, the primary use of cash was to fund research and development activities for our product candidates, which activities and uses of cash we expect to continue to increase for the foreseeable future.

Investing activities

Our investing activities during the three months ended March 31, 2023 and 2022 consisted of purchases of property and equipment.

Financing activities

Net cash provided by financing activities during the three months ended March 31, 2023 primarily consisted of (i) net proceeds of $17.6 million from the sale of 11,086,000 shares of common stock and 286,000 shares of Series X

Convertible Preferred Stock pursuant to concurrent but separate underwritten public offerings and (ii) net proceeds of $8.6 million from the sale of 6,170,799 shares of common stock under the Sales Agreement, after deducting placement agent fees.

Net cash used in financing activities during the three months ended March 31, 2022 primarily consisted of net proceeds of $0.5 million from the sale of 644,265 shares of common stock under the Sales Agreement, after deducting placement agent fees, offset by principal payments of $1.1 million made in connection with our loan from Pacific Western Bank.

Operating Capital Requirements

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

ITEM 3. 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 4. CONTROLS AND PROCEDURES

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 March 31, 2023, we carried out an evaluation under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2023.

Changes in Internal Control over Financial Reporting

An evaluation was also performed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

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 and should be carefully considered.

- Our operations, business and financial results have been and could continue to be adversely impacted by the current public health pandemic related to COVID-19.
- We depend heavily on the success of rezafungin and CD388, which is currently in Phase 1 and Phase 2a clinical development, and we are very early in our efforts to develop other product candidates from our Cloudbreak program, none of which may be successful.
- If we experience delays or difficulties in enrolling patients in our clinical trials our receipt of necessary regulatory approvals could be delayed or prevented.
- If clinical trials for rezafungin, CD388, CD421 or any other product candidates are delayed, terminated or suspended, or fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, we may incur additional costs, or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If serious adverse reactions or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit our development of some or all of our product candidates.
- Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, formulary committees, third-party payors and others in the medical community necessary for commercial success.
- If, in the future, we are unable to establish sales and marketing capabilities or to selectively enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates, if and when they are approved. 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 face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We may not be successful in our efforts to identify, discover, and develop potential product candidates through our Cloudbreak platform or otherwise.
- We need substantial additional funding to complete the development of rezafungin and to advance CD388, CD421 and our Cloudbreak program.
- We are dependent on our collaboration partners to provide funding to continue the development of rezafungin and CD388; for the commercialization of rezafungin outside Japan; and for the late-stage development, manufacturing, registration and commercialization of CD388. If the collaborations are not successful, we may not be able to complete the development of rezafungin and CD388, or capitalize on the full market potential for rezafungin and CD388.
- We have no experience manufacturing product candidates on a clinical or commercial scale and will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be impaired.
- If we are unable to generate revenues from partnerships, government funding or other sources of funding, we may be forced to suspend or terminate one or more of our preclinical Cloudbreak programs.
- The price of our stock may be volatile, and you could lose all or part of your investment.

Risk Factors

You should carefully consider the following risk factors, as well as the other information in this Quarterly Report, 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, including our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations." The risk factors set forth below that are marked with an asterisk (*) contain changes to the similarly titled risk factors included in Item 1A of our Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to the COVID-19 Pandemic

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

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

Risks Related to Drug Discovery, Development and Commercialization

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

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

We received IND clearance for CD388, our DFC for prevention and treatment of influenza, from the FDA in March 2022 and subsequently initiated a Phase 1 clinical trial. In September 2022, we initiated a Phase 2a trial of CD388 to evaluate the pre-exposure prophylactic activity of CD388 against influenza virus and a separate Phase 1 Japanese bridging study has been initiated. We are also conducting in vitro and in vivo preclinical studies of other product candidates from our Cloudbreak program for viral infections and oncology indications. Our assumptions about why rezafungin and CD388 are worthy of continued development, as well as our assumptions about the markets for rezafungin, CD388 or any other potential products from our Cloudbreak program, are based on data primarily collected by other companies. The timing and costs of our preclinical and clinical development programs, the likelihood of marketing approval for rezafungin and CD388, and the regulatory paths for marketing approval for additional products from our Cloudbreak program remain uncertain. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend

heavily on the successful development and eventual commercialization of our product candidates. The success of rezafungin, CD388 and any other product candidates we may develop will depend on many factors, including the following:

- the impact of the COVID-19 pandemic on our operations;
- our ability to secure adequate additional funding;
- agreement with regulatory authorities on study designs and other requirements for study initiation;
- successful completion of preclinical studies;
- successful enrollment and completion of clinical trials;
- demonstration of safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- negotiation of favorable indications and other key elements of the product labeling;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and technologies;
- launching commercial sales of the product candidates if and when approved;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not timely enroll the ReSPECT Phase 3 clinical trial, or if we are unable to secure significant additional funding, we will not be able to complete the clinical development plans for the prophylaxis indication for rezafungin. If we do not accomplish one or more of any of the other goals in a timely manner, or at all, we could experience significant delays or an inability to successfully complete the development of and commercialize our product candidates, which would harm our business.

If we experience delays or difficulties in enrolling patients in our clinical trials our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to complete the ReSPECT clinical trial or the ongoing portion of the ReSTORE trial in China if we are unable to identify and enroll a sufficient number of eligible patients, as required by the FDA or similar regulatory authorities outside the U.S., or if we do not believe that the number of patients required by such regulatory authorities can be enrolled in a reasonable timeframe.

Our rezafungin Phase 3 clinical development program is a global program and, as such, our ability to timely enroll the clinical trials may be affected by many different factors specific to those global localities, such as, delays in our receipt of approval to commence trials in a particular country from applicable regulatory authorities and ethics committees, timely completion of clinical trial site initiation within each country, delays in local importation and receipt of necessary clinical trial supplies, and our ongoing compliance with local regulations, which may change during the course of the clinical trial.

In addition, the rezafungin clinical trials are heavily reliant on third-party contractors, including contractors that import clinical trial materials, and contract research organizations, or CROs, that conduct and monitor our clinical trials, and interact with regional or local regulators and ethics committees on our behalf. If we experience significant difficulties with any of our key contractors such that we determine it is in the best interests of the clinical trials to replace a key contractor, this could result in a significant delay in enrollment.

Additionally, timely enrollment in the ReSPECT trial is reliant on global clinical trial sites, most of which have been adversely affected by the COVID-19 global pandemic. For example, the COVID-19 global pandemic has significantly impacted our ability to activate sites and enroll patients in the ReSPECT trial in Europe and the U.S., resulting in substantial delays and increases in the cost of completing the trial. Our enrollment of patients in ReSTORE in China was

also delayed in part due to the pandemic. Some factors from the COVID-19 coronavirus outbreak that have adversely affected enrollment in our Phase 3 trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- the decision of some clinical trial sites to focus on the conduct of COVID-19 clinical trials;
- limitations imposed by hospitals serving as our clinical trial sites that prohibit entry on hospital premises by persons other than those supporting the hospital's COVID-19 efforts;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and
- employee quarantine or isolation days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

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

In addition, some of our competitors may have ongoing or new clinical trials for product candidates that would treat the same indications as rezafungin, or be used in the same patients and, therefore, patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Patient enrollment may also be affected by other factors, including:

- eligibility criteria, including regional or local practices that place additional limitations on patient eligibility;
- availability, safety and efficacy of approved medications or other investigational medications being studied clinically for the disease under investigation;
- perceived risks and benefits of rezafungin;
- efforts to facilitate timely enrollment in clinical trials;
- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- delays or failures in maintaining an adequate supply of quality drug product for use in clinical trials; and
- changing treatment patterns that may reduce the burden of disease which rezafungin addresses.

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

If clinical trials for rezafungin, CD388, CD421 or any other product candidates are delayed, terminated or suspended, or fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities, we may incur additional costs, or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A delay in starting or completing our clinical trials would materially impact our timelines and our ability to complete development of our product candidates in a timely manner or at all. For example, our entire rezafungin clinical development program has been severely impacted by the effects of the COVID-19 global pandemic. Additionally, our ability to complete our rezafungin Phase 3 development program is dependent on our ability to secure adequate additional funding.

A failure of one or more clinical trials could occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial.

Moreover, preclinical and clinical data are often susceptible to multiple interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. For example, the historically observed high rate of correlation for clinical efficacy for anti-infectives based on preclinical data may not apply for our current or future product candidates, and any of the potential benefits that we anticipate for human clinical use may not be realized.

We do not know whether either the ReSPECT trial or the Phase 1 or Phase 2a trials of CD388 will be completed on schedule. We have experienced significant delays in these trials arising from the COVID-19 global pandemic. We may experience numerous other unforeseen events that could delay or prevent our ability to commence or complete our clinical trials, which could then delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

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

If the FDA or similar regulatory authorities outside the U.S. do not agree with the design and implementation of our planned or ongoing clinical trials, including the safety database to support an NDA submission, or if we are unable to secure additional funding, we may not be able to complete the overall Phase 3 clinical development program for rezafungin as currently envisioned. For example, in response to feedback from the FDA, we considered supplementing the ReSTORE safety database with safety data from patients enrolled in the ReSPECT study who shared similar comorbidities and concomitant medications with patients in the ReSTORE study. This approach was ultimately unnecessary, but if we had implemented it, the timing of our NDA submission and the timing of completion of the ReSPECT study might have been impacted. If we do not accomplish one or more of any of the other goals in a timely manner, or at all, we could experience significant delays or an inability to successfully complete the development of and commercialize our product candidates, which would harm our business. If we are required to conduct additional clinical trials, or other tests of our product candidates beyond those that we currently contemplate, if we are unable to complete

clinical trials of our product candidates or other tests successfully or in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;
- be subject to significant restrictions on reimbursement from public and/or private payors; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or in receiving marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates, could allow our competitors to bring products to market before we do, could increase competition from generics of the same class, and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

If serious adverse reactions or unexpected characteristics of our product candidates are identified during development, we may need to abandon or limit our development of some or all of our product candidates.

Because it is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval, the risk of each of our programs is high. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. For example, the pharmacokinetic properties, such as a longer half-life or less frequent dosing regimen, that differentiate rezafungin from other echinocandins could have side effects that we have not anticipated and the consequences of such side effects could be more severe than have been seen with other echinocandins that have shorter half-lives or more frequent dosing regimens, or are dosed at lower concentrations than we expect for rezafungin.

Further, the treatment advantages that we are predicting for rezafungin, such as lower healthcare costs resulting from an ability to administer rezafungin once-weekly, which could allow earlier hospital discharge, or the predicted ability of rezafungin to be effective against resistant strains of fungal pathogens, may not be realized. For our DFCs, the bispecific mechanism of action, including the use of the immune system, may lead to side effects that are not anticipated based on the preclinical work we have conducted to date.

In the biotechnology industry, many agents that initially show promise in early stage testing may later be found to cause side effects that prevent further development of the agents. In addition, infections can occur in patients with co-morbidities and weakened immune systems, and there may be adverse events and deaths in our clinical trials that are attributable to factors other than investigational use of our product candidates.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential than opportunities we pursue. For example, we believe that an sNDA filing for rezafungin adding the prophylaxis indication can be supported by one Phase 3 trial in prophylaxis, however, financial constraints may require us to delay our prophylaxis program.

In support of the global effort to identify effective therapeutics to treat and prevent the COVID-19 coronavirus and stem the current global pandemic, we have expended financial resources to identify DFCs which may be effective in this area. In addition, we have recently expended financial resources on identification of DFCs targeting multiple potentially synergistic oncology targets. We have limited experience in identification and nonclinical and clinical testing of oncology therapeutics. Our resource allocation decisions may not result in us identifying valuable products or may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for a particular product candidate or opportunity,

we may relinquish valuable rights to that product candidate or opportunity through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or opportunity.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, formulary committees, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by hospitals and hospital pharmacies, physicians, patients, third-party payors and others in the medical community for us to achieve commercial success. If our product candidates do not achieve an adequate level of acceptance, we may not generate sufficient product revenue to become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and potential advantages compared to alternative therapies;
- the size of the markets in the countries in which approvals are obtained;
- terms, limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- our ability to offer any approved products for sale at competitive prices;
- convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies or dosing regimens;
- the willingness of physicians to prescribe these therapies and, in the case of rezafungin, transition to a once-weekly dosing regimen from traditional once-daily dosing;
- the strength of marketing and distribution support;
- the success of competing products and the marketing efforts of our competitors;
- sufficient third-party payor coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

If, in the future, we are unable to establish sales and marketing capabilities or to selectively enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates, if and when they are approved. In addition, if we enter into agreements with third parties to sell and market our product candidates, such third parties may not be successful in commercializing our products.*

We do not have a sales or marketing infrastructure. To achieve commercial success for any approved product, we must license the rights to third parties with such capabilities, develop a sales and marketing organization or outsource these functions to third parties.

There are risks involved both with establishing our own sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or to achieve adequate numbers of prescriptions for any future products; and
- costs and expenses associated with creating an independent sales and marketing organization.

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

the necessary resources and attention. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

If we do establish relationships with third parties to sell and market our product candidates, such third parties may not be successful in commercializing those products. For example, in the U.S. we are entirely dependent on Melinta to commercialize rezafungin. Melinta has no experience with commercialization of antifungal drugs and may be unable to hire individuals with the requisite expertise or develop and execute an appropriate commercialization plan.

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

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

We expect that rezafungin will primarily compete with certain antifungal classes of drugs, which include polyenes, azoles and echinocandins. Approved branded echinocandin antifungal therapies include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.), and Mycamine (micafungin, marketed by Astellas Pharma US, Inc.). We expect that there will be generics of all of the current echinocandins available at the time of rezafungin market approval, which will create added competition. In addition, there are other generic products approved for candidemia, marketed by companies such as Baxter Healthcare Corporation, Mylan Inc. and Glenmark Generics Inc., among others. In addition to approved therapies, we expect that rezafungin will compete with product candidates that we are aware of in clinical development by third parties, such as fosmanogepix (PF-07842805), which is being developed by Pfizer, Inc. and brexafungerp, which is approved for other indications and is being developed for invasive candidiasis by Scynexis, Inc.

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

Our competitors may develop products that are more effective, safer, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non-competitive. Our competitors may also obtain marketing approval from the FDA or other regulatory authorities for their products sooner than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of our competitors have significantly greater name recognition, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These same competitors may invent technology that competes with our rezafungin program, CD388, CD421, or our Cloudbreak platform.

These third parties may compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

From time to time, we publicly disclose interim, preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analysis of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

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

Even if we are able to commercialize any product candidates, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. In the U.S., new and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product-licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial marketing approval is granted. As a result, we might obtain marketing approval for a drug in a particular country but then be subject to price regulations that delay its commercial launch, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the drug in that country. Adverse pricing limitations may hinder our ability to commercialize and generate revenue from one or more product candidates, even if our product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health programs, private health insurers, integrated delivery networks and other third-party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels. A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient for commercial success. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the U.S. Moreover, eligibility for coverage and reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be

made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Commercial third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit the commercialization of any product candidates we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and we will face an even greater risk if we commercially sell any products that receive marketing approval. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs and distraction of management to defend any related litigation;
- the initiation of investigations by regulatory bodies;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- the inability to commercialize any products we may develop.

Although we have product liability insurance for our clinical trials, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue or expand our clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees in our workplace, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, chemical, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

We may not be successful in our efforts to identify, discover, and develop potential product candidates through our Cloudbreak platform or otherwise.*

Through our Cloudbreak platform, we are developing DFCs for the treatment and prevention of serious diseases, including influenza and various cancers. We have nominated the DFC CD388 as our lead development candidate for influenza, and we have nominated CD421 as our lead oncology DFC candidate. In applying our Cloudbreak platform, we may not be successful in identifying additional DFCs that could be developed as drug therapies. In addition, our Cloudbreak platform may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons. In particular, our research methodology used may not be successful in identifying compounds with sufficient potency, bioavailability or efficacy to be potential product candidates. In addition, our potential product candidates may, on further study, be shown to have harmful side effects or other negative characteristics.

Research programs to identify new product candidates require substantial technical expertise and human resources. For example, we have limited experience with the use of the Cloudbreak platform applied to viral pathogens and oncology targets. A failure to optimize our expertise using the Cloudbreak platform for the development of our Cloudbreak program may limit our ability to successfully advance this program and identify future product candidates. Research programs to identify new product candidates also require substantial financial resources. We may choose to expend our financial resources on potential product candidates that ultimately prove to be unsuccessful. For example, in response to the immediate global pandemic crisis, we have expended financial resources to identify therapeutics to treat or prevent the COVID-19 coronavirus, and we may be unsuccessful in identifying such a DFC. If we are unable to identify successful product candidates from our Cloudbreak platform for preclinical and clinical development, we will have spent financial resources on programs that did not yield viable products and therefore generate product revenue, which would harm our financial position and adversely impact our stock price.

Risks Related to Our Financial Position and Need for Additional Capital

We need substantial additional funding to complete the development of rezafungin and to advance CD388, CD421 and our Cloudbreak program.*

In connection with the preparation of our financial statements for the period ended March 31, 2023, we performed an analysis of our ability to continue as a going concern. We believe, based on our current business plan, that our existing cash and cash equivalents will not be sufficient to fund our obligations for the next twelve months, which raises substantial doubt about our ability to continue as a going concern. Our ability to continue to fund the development of rezafungin through completion of our planned Phase 3 trials depends on our ability to obtain additional funding. Our ability to advance CD388, CD421 and other product candidates from our Cloudbreak program is also dependent on our ability to obtain additional funding.

On September 3, 2019, we entered into the Mundipharma Collaboration Agreement, pursuant to which we granted Mundipharma exclusive commercialization rights to rezafungin outside the U.S. and Japan in exchange for a $30.0 million upfront payment, near-term funding to support the global Phase 3 ReSTORE and ReSPECT trials, and the potential to receive development, regulatory and commercial milestone payments and double-digit royalties in the teens on tiers of annual net sales. The Mundipharma Collaboration Agreement requires, among other things, that we complete the rezafungin development program. On March 31, 2021, we entered into the Janssen Collaboration Agreement, to develop and commercialize our Cloudbreak DFCs for the prevention and treatment of seasonal and pandemic influenza. Under the collaboration, we will be responsible for the development and manufacturing of the first influenza DFC, CD388, into the clinic and through Phase 2 clinical development, and Janssen will be responsible for late-stage development, manufacturing, registration and global commercialization. We received an upfront payment of $27.0 million. Janssen will fund all future research, development, manufacturing and commercialization for CD388, of which Janssen has funded $30.7 million as of March 31, 2023. On July 26, 2022, we entered into the Melinta License Agreement, pursuant to which we granted Melinta an exclusive license to develop, register and commercialize rezafungin in the U.S. in exchange for a $30.0 million upfront payment and the potential to receive regulatory and commercial milestone payments and tiered royalties on U.S. sales in the low double digits to mid-teens. The Melinta License Agreement requires, among other things, that we complete the rezafungin development program. Our ability to meet our development obligations under the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement depends on our ability to obtain additional funding.

There can be no assurance that additional funds will be available from any source or, if available, will be available on terms that are acceptable to us. There can also be no assurance that additional funds will be available to us without first obtaining the approval of our stockholders, which can be a difficult and lengthy process with an uncertain outcome.

Even if we raise additional capital, our expenses may increase in connection with our ongoing activities beyond what is currently expected. Our future capital requirements will depend on many factors, including:

- the ongoing effect of the COVID-19 global pandemic and the resulting impact on our rezafungin phase 3 clinical development program;
- the costs and timing to complete our Phase 3 ReSPECT trial, the remaining Chinese portion of the ReSTORE trial and the CD388 Phase 1 and Phase 2a trials;
- the costs, timing and outcome of any regulatory review of rezafungin, CD388, CD421 or future development candidates;
- our ability to establish and maintain collaborations, when and if necessary, on favorable terms, if at all;
- the costs and timing of commercialization activities, including manufacturing, marketing, sales and distribution, for rezafungin or any future product candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the scope, progress, results and costs of drug discovery, preclinical development, manufacturing development, laboratory testing and clinical trials for our product candidates, for the Cloudbreak platform; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential development candidates and conducting preclinical studies, manufacturing development and clinical trials are time consuming, expensive and uncertain processes that take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales for any of our current or future product candidates. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we need substantial additional funding in connection with our continuing operations and to achieve our goals. As of March 31, 2023, we had cash and cash equivalents of $48.0 million.

As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have recently experienced extreme volatility and disruptions, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate, it may make any additional debt or equity financing more difficult, more costly and more dilutive. In addition, we may not be able to access a portion of our existing cash and cash equivalents due to market conditions. For example, the recent closures of Silicon Valley Bank, Signature Bank and First Republic Bank have resulted in broader financial institution liquidity risk and concerns. While we do not have deposits with these banks, if other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash and cash equivalents may be threatened, which could have a material adverse effect on our business and financial condition. 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, CD421 or one or more of our other Cloudbreak DFC programs, be unable to continue the development of rezafungin, complete the ReSPECT Phase 3 clinical trial and meet our development obligations under the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement, or our other current and future license or collaboration agreements, and/or be forced to make reductions in spending, extend payment terms with suppliers, and/or liquidate or grant rights to assets where possible. Any of these actions could materially harm our business, results of operations and future prospects.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.*

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity, debt or other financing structures, receipt of payments under the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement, as well as potentially entering into other collaborations, strategic alliances or licensing arrangements with third parties or receiving government and/or charitable grants or contracts. In November 2018, we entered into a new controlled equity offering sales agreement with Cantor Fitzgerald & Co., or the Sales Agreement, which currently has an aggregate offering price of up to $50.0 million,

and, other than the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement, it is our only current external source of potential financing.

In September 2019, we issued $9.0 million of our common stock to Mundipharma in connection with entering into the Mundipharma Collaboration Agreement. In February 2020, we issued $30.0 million of our common stock and Series X Convertible Preferred Stock upon the closing of a rights offering. In October 2021, we issued $38.5 million of our common stock and Series X Convertible Preferred Stock upon the closing of concurrent but separate public offerings. In March 2023, we issued shares of our common stock and Series X Convertible Preferred Stock upon the closing of concurrent but separate public offerings, for gross proceeds of $19.5 million. As of March 31, 2023, we have issued 20,708,912 shares of common stock pursuant to the Sales Agreement with an aggregate offering price of approximately $41.0 million. To the extent that we raise additional capital through the sale of equity or convertible debt securities, like the sale of our common stock to Mundipharma, the sale of our common stock and Series X Convertible Preferred Stock issued in our rights offering, the sale of our common stock and Series X Convertible Preferred Stock in our concurrent public offerings or the sale of common stock under the Sales Agreement, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may be secured by all or a portion of our assets.

If we raise funds by entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. On September 3, 2019, we licensed all rights to rezafungin outside of the U.S. and Japan to Mundipharma in exchange for certain payments and double-digit royalties in the teens on tiers of annual net sales. In March 2021, we granted exclusive worldwide rights to CD388 and other influenza DFCs to Janssen in exchange for certain payments and royalties on tiers of annual net sales at rates from the mid-single digits to the high-single digits. In July 2022, we licensed all rights to rezafungin inside of the U.S. to Melinta in exchange for certain payments and tiered royalties on U.S. sales in the low double digits to mid-teens. We may need to enter into similar agreements with other third parties for the development and commercialization of rezafungin outside of the Mundipharma and Melinta territories, or for the development of DFCs identified from our Cloudbreak program outside the scope of the Janssen Collaboration Agreement, which may require we relinquish valuable rights to these products.

If we raise funds through government grants and contracts, we may be subject to restrictions on our operations or certain unfavorable terms. U.S. government grants and contracts, if available, typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. If we receive a U.S. government grant or contract, we would be required to comply with numerous laws and regulations relating to the formation, administration and performance of the grant or contract, which can make it more difficult for us to retain our rights under such grant or contract and result in increased costs.

If we are unable to raise additional funds through equity, debt or other financing structures, or through collaborations, strategic alliances or licensing arrangements with third parties, or through receiving government and/or charitable grants or contracts, we may be required to delay, reduce or terminate our rezafungin development program, including our ReSPECT Phase 3 clinical trial, be unable to meet our development obligations under the Mundipharma Collaboration Agreement and the Melinta License Agreement, and be unable to continue advancing the Cloudbreak program for non-influenza DFCs, or be forced to grant rights in the Cloudbreak program for non-influenza DFCs that we would otherwise prefer to retain for ourselves.

We have incurred significant operating losses since our inception, and we anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or maintain profitability.*

Since our inception, we have incurred significant operating losses. We had net income of $3.2 million and net loss of $18.3 million for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, we had an accumulated deficit of $403.8 million. To date, we have financed our operations primarily through sale of our stock in public offerings and private placements, through borrowings under loan facilities, and through payments received in connection with the Mundipharma Collaboration Agreement, the Janssen Collaboration Agreement and the Melinta License Agreement. We are currently conducting the ReSPECT and ReSTORE China Phase 3 clinical trials of rezafungin, Phase 1 and Phase 2a studies of CD388, and preclinical studies of our other DFCs, including CD421. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- submit INDs to the FDA and equivalent filings to other regulatory authorities, and seek approval of our clinical protocols by institutional review boards at clinical trial sites;
- continue to advance rezafungin and CD388 through clinical development;

- continue the preclinical development of our other DFCs from our Cloudbreak platform or otherwise, and advance one or more of such product candidates into clinical trials;
- seek marketing approvals for rezafungin, CD388, CD421 and other product candidates;
- establish or contract for a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;
- maintain, expand and enforce our intellectual property portfolio;
- hire additional manufacturing, clinical, regulatory, quality assurance and scientific personnel;
- add operational, financial and management systems and personnel, including personnel to support product development; and
- acquire or in-license other product candidates and technologies.

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

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

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

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

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

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

We have not yet demonstrated an ability to successfully complete large-scale, pivotal clinical trials required for regulatory approval of our product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes many years to develop one new product from the time it is discovered to when it is commercially available. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had product candidates in advanced clinical trials.

In addition we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors that may alter or delay our plans. We will need to continue to transition from a company with a research focus to a company capable of supporting late-stage development activities and, if a product candidate is approved, a company with commercial activities. We may not be successful in any step of such a transition.

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

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

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

Risks Related to Our Dependence on Third Parties

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

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

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

- have significant discretion in determining the efforts and resources they will apply to commercializing rezafungin in their respective territories, and may not commit sufficient resources to the marketing and distribution of rezafungin;
- may be unable to successfully commercialize rezafungin in one or more territories because, following regulatory approval, they may be unable to obtain formulary pricing approval, reimbursement approval, and/or formulary placement;
- have limited experience commercializing antifungal therapeutics and therefore may be unsuccessful in developing and implementing commercial launch plans for rezafungin;
- may terminate the Mundipharma Collaboration Agreement at will and may terminate the Melinta License Agreement at will after July 26, 2023;
- may be subject to changes in key personnel or strategic focus, have limited available funding or be subject to other external factors diverting resources or creates competing priorities, all of which could negatively impact the commercialization of rezafungin in their respective territories;
- may independently develop, or develop with third parties, products that compete directly or indirectly with rezafungin if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- may use our intellectual property or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential litigation;

- may not agree with certain development decisions resulting in the delay or termination of the programs, or that result in costly litigation or arbitration that diverts management attention and resources;
- could be involved in a business combination and the continued pursuit and emphasis on rezafungin could be delayed, diminished or terminated; and
- could be financially impacted by the COVID-19 pandemic, inflation or bank failures.

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

On March 31, 2021, we licensed the exclusive worldwide rights to CD388 and other influenza DFCs to Janssen. Our ability to complete the development of CD388 is dependent, on funds provided by Janssen. Under the Janssen Collaboration Agreement, following receipt of the Phase 2a Human Challenge Study data, Janssen must decide whether it will elect to proceed with further development of CD388. There can be no assurance that Janssen will elect to proceed despite the interim Phase 2a data that was announced in March 2023. If Janssen declines to proceed with development, no further milestones or royalties will be payable under the agreement.

Additionally, if Janssen elects to proceed with development, our ability to receive payments from this arrangement will depend in part on Janssen's ability to successfully commercialize CD388.

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

- has significant discretion in determining the efforts and resources it will apply to developing, manufacturing, registering and commercializing CD388;
- may terminate the collaboration agreement at will, subject to certain limitations;
- may be subject to changes in key personnel or strategic focus, have limited available funding or be subject to other external factors diverting resources or creates competing priorities, all of which could negatively impact the development, manufacturing, registration and commercialization of CD388;
- may independently develop, or develop with third parties, products that compete directly or indirectly with CD388 if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- may use our intellectual property or proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential litigation;
- may not agree with certain development decisions resulting in the delay or termination of the program, or that result in costly litigation or arbitration that diverts management attention and resources;
- could be involved in a business combination and the continued pursuit and emphasis on CD388 could be delayed, diminished or terminated; and
- could be financially impacted by the COVID-19 pandemic, inflation or bank failures.

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

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

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

We face significant competition in seeking appropriate pharmaceutical or biotech collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, on the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

Those factors may include:

- the design or results of preclinical studies, CMC development activities or clinical trials;
- the likelihood of approval by the FDA or similar regulatory authorities outside the U.S.;
- the potential market for the product candidate in the territories that are the subject of the collaboration;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

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

We intend to continue to rely on third parties to conduct our clinical trials and to conduct some aspects of our research and preclinical testing and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research or testing.

We currently rely and expect to continue to rely on third parties, such as CROs, contract manufacturers of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and preclinical testing. Many of these third parties may terminate their engagements with us at any time. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If we need to enter into alternative arrangements, it would delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and other international regulatory authorities require us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at www.clinicaltrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

We have no experience manufacturing product candidates on a clinical or commercial scale and will be dependent on third parties for the manufacture of our product candidates. If we experience problems with any of these third parties, they could delay clinical development or marketing approval of our product candidates or our ability to sell any approved products.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our product candidates for preclinical studies and clinical trials and for commercial supply of any of these product candidates should we obtain marketing approval.

We have established agreements with third-party manufacturers for production of our products for clinical and commercial use, and our reliance on these-manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party, including the inability to supply sufficient quantities or to meet quality standards or timelines; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with current U.S. Good Manufacturing Practice requirements, or cGMPs, or similar regulatory requirements outside the U.S. Our failure, or the failure of our third-party manufacturers, to comply with cGMPs or other applicable regulations, even if such failures do not relate specifically to our product candidates or approved products, could result in sanctions being imposed on us or the manufacturers, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could adversely affect supplies of our product candidates and harm our business and results of operations.

Any product that we develop may compete with other product candidates and products for access to these manufacturing facilities. There are a limited number of manufacturers that operate under cGMPs and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers, including a failure that may not relate specifically to our product candidate or approved product or a failure due to the COVID-19 pandemic, could delay clinical development or marketing approval or adversely impact our ability to generate commercial sales. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Some of our third-party manufacturers which we use for the supply of materials for product candidates or other materials necessary to manufacture product to conduct preclinical tests and clinical trials are located in countries affected by COVID-19, and should they experience disruptions, such as temporary closures or suspension of services, we would likely experience delays in advancing these tests and trials.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We currently rely, and expect to continue to rely, on third parties to release, label, store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties, including a failure that may not relate specifically to our product candidate or approved product, could delay or otherwise adversely impact clinical development or marketing approval of our product candidates or commercialization of our drugs, producing additional losses and depriving us of potential revenue.

Moreover, our manufacturers and suppliers may experience difficulties related to their overall businesses and financial stability, which could result in delays or interruptions of supply of our product candidates or approved products.

We do not have alternate manufacturing plans in place at this time. If we need to change to other manufacturers, the FDA and comparable foreign regulators may have to approve these manufacturers' facilities and processes prior to our use, which would require new testing and compliance inspections. In addition, the new manufacturers would have to be educated in or independently develop the processes necessary for production. This would result in delays and costs, and in the case of approved products, the potential loss of revenue.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

If we are unable to take full advantage of regulatory programs designed to expedite drug development or provide other incentives, our development programs may be adversely impacted.

There are a number of incentive programs administered by the FDA and other regulatory bodies to facilitate development of drugs in areas of unmet medical need. In the U.S., rezafungin has been designated a Qualified Infectious Disease Product, or QIDP, a fast track product, and, with respect to the indication for treatment of candidemia and invasive candidiasis, rezafungin has also been designated as an orphan drug. Our product candidates may not qualify for, or maintain, designations under these or other similar incentive programs. For example, rezafungin may not receive orphan drug designation in the U.S. for the prophylaxis indication. Our inability to fully take advantage of these incentive programs may require us to run larger trials, incur delays, lose opportunities that may not otherwise be available to us, lose marketing exclusivity for which we would otherwise be eligible and incur greater expense in the development of our product candidates.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, our product candidates and our ability to generate revenue will be impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, release, safety, efficacy, regulatory filings, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the U.S. and by comparable authorities in other countries. For example, in order to commence clinical trials of our product candidates in the U.S., we must file an IND and obtain FDA agreement to proceed. The FDA may place our development program on clinical hold and require further preclinical testing prior to allowing our clinical trials to proceed.

We must obtain marketing approval in each jurisdiction in which we market our products. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not submitted a marketing application or received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process. As a company we may not be able to prepare our contract manufacturers and clinical sites for inspection associated with NDA review, or appearing before an FDA advisory committee. Our NDA may receive a Complete Response Letter rather than approval. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process, testing and release and inspection of manufacturing facilities and personnel by the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals, both in the U.S. and elsewhere, is expensive, may take many years and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. We cannot assure you that we will ever obtain any marketing approvals in any jurisdiction. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical or other studies, changes in the manufacturing process or facilities or clinical trials. Moreover, approval by the FDA or an equivalent foreign authority does not ensure approval by regulatory authorities in any other countries or jurisdictions, but a failure to obtain marketing approval in one jurisdiction may adversely impact the likelihood of approval in other jurisdictions. In addition, varying interpretations of the data obtained from preclinical testing, manufacturing and product testing and clinical trials could delay, limit or prevent marketing approval of a product candidate. Additionally, any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

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

Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.

Any product candidate for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of promotional materials and safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements for product facilities, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and related recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not comply with these restrictions, we may be subject to enforcement actions.

In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes and facilities or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on such products, manufacturers or manufacturing processes or facilities;
- restrictions on the labeling, marketing, distribution or use of a product;
- requirements to conduct post-approval clinical trials, other studies or other post-approval commitments;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties.

Our relationships with customers, health care professionals and third-party payors may be subject to applicable healthcare laws, which could expose us to penalties, including administrative, civil or criminal penalties, damages, fines, imprisonment, exclusion from participation in federal healthcare programs such as Medicare and Medicaid, reputational harm, the curtailment or restructuring of our operations and diminished future profits and earnings.

Healthcare professionals and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with customers, healthcare professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, among others:

- the federal healthcare anti-kickback statute, which prohibits persons and entities from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal false claims laws, which impose criminal and civil penalties, including civil whistleblower or qui tam actions under the federal civil False Claims Act, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates and their covered subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, which require, among other things, certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and information regarding physician ownership and investment interests; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business activities, including sales or marketing arrangements and claims involving healthcare items or services including, in some states, those reimbursed by non-governmental third-party payors, including private insurers, some state laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments or other transfers of value provided to physicians and other health care providers and entities, marketing expenditures, or drug pricing, state and local laws that require the registration of pharmaceutical sales representatives, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Interpretations of standards of compliance under these laws and regulations are rapidly changing and subject to varying interpretations and it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other laws that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations, any of which could diminish our future profits or earnings. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

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

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

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

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

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

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

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to manufacture or deliver our products.

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

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

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

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight;

restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business.

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

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

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

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

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

Additionally, the California Consumer Privacy Act of 2018, or CCPA, applies to personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA also provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. In addition, the California Privacy Rights Act of 2020, or CPRA, expands the CCPA's requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency to implement and enforce the CPRA. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states as well as at the federal and local levels. These developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

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

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

In addition, we may be unable to transfer personal data from Europe (including the EEA and UK), China, and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe, China and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer

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

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

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

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

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions (including in relation to clinical trials); limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

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

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the U.S., to sell our products abroad once we enter a commercialization phase and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly

authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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

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

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.*

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system, including cost-containment measures, that could reduce or limit coverage and reimbursement for newly approved drugs, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act and subsequent regulations revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. However, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024. Further, the Affordable Care Act imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance were also enacted under the Affordable Care Act, which may affect our business practices with healthcare practitioners. There have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act. For example, the Tax Act, included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

In addition, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

Further, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. In August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering

the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments will remain in effect until 2032 unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Additionally, in January 2013, the President signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drug products. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Under the new Drug Price Negotiation Program, the number of drugs subject to price negotiation will be 10 Part D drugs for 2026, another 15 Part D drugs for 2027, another 15 Part D and Part B drugs for 2028, and another 20 Part D and Part B drugs for 2029 and later years. These drugs will be selected from among the 50 drugs with the highest total Medicare Part D spending and the 50 drugs with the highest total Medicare Part B spending. The number of drugs with negotiated prices available will accumulate over time. The IRA permits HHS to implement many of the statutory provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

We expect that additional healthcare reform measures will be adopted within and outside the U.S. in the future, any of which could add difficulty to the regulatory approval processes for our product candidates or limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. The continuing efforts of third-party payors to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability and the level of taxes that we are required to pay.

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to rezafungin, CD388, CD421, our other Cloudbreak compounds or our other product candidates or compounds are not adequate, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to rezafungin and our other product candidates and compounds. Any involuntary disclosure to or misappropriation by third parties of our proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our markets.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain and our commercial success will depend on our ability to obtain patents and maintain adequate protection for rezafungin, our DFCs and other compounds and product candidates in the U.S. and other countries. We

currently hold issued U.S. utility and foreign patents and multiple pending U.S. utility patent applications, pending U.S. provisional patent applications and pending international, foreign national and regional counterpart patent applications covering various aspects of rezafungin and our DFCs. The patent applications may fail to result in issued patents in the U.S. or in foreign countries or jurisdictions. Even if the applications do successfully issue, third parties may challenge the patents.

Further, the existing and/or future patents, if any, may be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by the patent and patent applications we own with respect to rezafungin or our DFCs or the patents we pursue related to any of our other product candidates or compounds is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize the product candidates or compounds. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced, although a patent term extension or supplementary protection certificate having varied scope may be available in certain jurisdictions to compensate for some of the lost patent term. In addition, we do not know whether:

- we were the first to make the inventions covered by each of our pending patent applications or our issued patents;
- we were the first to file patent applications for these inventions;
- others will independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our pending patent applications will result in issued patents;
- any of our patents, once issued, will be valid or enforceable or will issue with claims sufficient to protect our products, or will be challenged by third parties;
- any patents issued to us will provide us with any competitive advantages;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will have an adverse effect on our business.

In addition, patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office, or USPTO, developed new regulations and procedures to govern administration of the Leahy-Smith Act and many of the substantive changes to patent law associated with the Leahy-Smith Act and, in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and prospects.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable in one or more jurisdictions, inventions for which patents are difficult to enforce and any other elements of our drug discovery program that involve proprietary know-how, information and technology that is not covered by patents. Although we require all of our employees, consultants, advisers and third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or used in an unauthorized manner or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques.

There also may be challenges or other disputes concerning the inventorship, ownership or right to use our intellectual property. For example, our consultants and advisors may have obligations to assign certain inventions and/or know-how that they develop to third-party entities in certain instances, and these third parties may challenge our ownership or other rights to our intellectual property, which would adversely affect our business.

An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S. We may encounter significant problems in protecting, enforcing and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent unauthorized material disclosure of the intellectual property related to our technologies to third parties or are otherwise unable to protect, enforce or defend our intellectual property, we will not be able to establish or, if established, maintain a competitive advantage in our markets, which could materially adversely affect our business, operating results and financial condition.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various foreign or jurisdictional governmental patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm to pay these fees due to foreign patent agencies. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process.

We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. Such noncompliance events are outside of our direct control for (1) non-U.S. patents and patent applications owned by us and, (2) if applicable in the future, patents and patent applications licensed to us by another entity. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Third-party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents with claims to materials, methods of manufacture or methods of treatment related to the use or manufacture of rezafungin, our DFCs and/or our other product candidates or compounds. If any third-party patents were held by a court of competent jurisdiction to cover the rezafungin or DFC manufacturing process, any molecules formed during these processes or the final products or any use thereof, the holders of any such patents may be able to block our ability to commercialize the product unless we obtained a license under the applicable patent or patents or until such patents expire. These same issues and risks arise in connection with any other product candidates we develop as well. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, or at all. Any inability to obtain such a license under the applicable patents on commercially reasonable terms, or at all, would have a material adverse effect on our ability to commercialize the affected product until such patents expire.

In addition, third parties may obtain patents in the future and claim that our product candidates and/or the use of our technologies infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees in the case of willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products, which may be impossible and/or require substantial time and monetary expenditure. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of one or more of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, or at all. In that event, we would not be able to further develop and commercialize such product candidates, which could harm our business significantly.

We may be required to file lawsuits or take other actions to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our current or future patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our asserted patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Pursuit of these claims would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business.

Interference proceedings or derivative proceedings provoked by third parties or brought by the USPTO may be necessary to determine the entitlement to patent protection with respect to our patents or patent applications. An unfavorable

outcome could result in a loss of our patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or patent office proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws or legal process may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Issued patents covering our product candidates and technologies could be found invalid or unenforceable if challenged in court or the USPTO.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technologies, the defendant could counterclaim that the patent covering our product candidate or our technology, as applicable, is invalid and/or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity and/or unenforceability are commonplace and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or our technologies. The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art or that prior art that was cited during prosecution, but not relied on by the patent examiner, will not be revisited. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection directed to our product candidates or technologies. Such a loss of patent rights could have a material adverse impact on our business.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and are therefore costly, time-consuming and inherently uncertain. In addition, the U.S. has implemented wide-ranging patent reform legislation, including patent office administrative proceedings that offer broad opportunities to third parties to challenge issued patents. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, the USPTO and foreign governmental bodies and tribunals, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held in 2013 that certain claims to DNA molecules are not patentable and lower courts have since been applying this case in the context of other types of biological subject matter. We cannot predict how future decisions by the courts, the U.S. Congress, the USPTO or foreign governmental bodies or tribunals may impact the value of our patent rights.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the U.S. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws and legal processes of some foreign countries do not protect intellectual property to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents but enforcement is not as strong as that in the

U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any of our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of any of our current or future patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if any of our patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors, and academic or research institutions. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to U.S. Government Contracts and Grants

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

In order to continue our Cloudbreak programs for DFCs outside the scope of the Janssen Collaboration Agreement, we will need to seek funding from partnerships, the government or other sources of funding. There can be no assurances that we will be able to obtain funding from partnerships, or enter into new contracts with the U.S. government or obtain other sources of funding to support such programs. The process of completing a partnership or obtaining government contracts is lengthy and uncertain and we will have to compete with other companies and institutions in each instance. Further, with respect to government contracting, changes in government budgets and agendas may result in a decreased and de-prioritized emphasis on supporting the discovery and development of anti-infective products. If we cannot obtain or maintain government or other funding for our Cloudbreak programs for DFCs outside the scope of the Janssen Collaboration Agreement, we may be forced to discontinue those programs.

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

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

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

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

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

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

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

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

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

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

U.S. government agencies routinely audit and investigate government contractors and recipients of Federal grants. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

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

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

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Growth

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

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

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

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

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

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

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

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

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

Risks Related to Ownership of our Common Stock

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

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

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

- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial or development program;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- the impact of the COVID-19 pandemic on our business and industry as well as the global economy;
- changes in laws or regulations applicable to our products, including but not limited to requirements for approvals;
- changes in the structure of healthcare payment systems or limitations on the ability of hospitals and outpatient treatment centers to receive adequate reimbursement for the purchase and use of our products;
- adverse developments concerning our contract manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices or acceptable quality;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates successfully, or at all;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- the introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures, government grants or contracts or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our fungal infection, bacterial infection or other target markets;
- our ability to successfully enter new markets or develop additional product candidates;
- actual or anticipated variations in quarterly operating results;
- our cash position and our ability to raise additional capital and the manner and terms on which we raise it, and the expectation of future fundraising activities by us;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports or other media coverage about us or our industry or our therapeutic approaches in particular or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future or the expectation of such sales;
- the trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patent rights, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions including the military conflict in Ukraine and Russia and bank failures; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Capital Market, pharmaceutical companies and companies in the anti-infective sector in particular, have experienced extreme price and volume fluctuations that may or may not have been related or proportionate to the operating performance of these companies or their product potential. Broad market and industry factors, such as the COVID-19 pandemic and actions taken to slow its spread, may negatively affect the market price of our common stock, regardless of our actual operating performance. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of

litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

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

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

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

We incur significant costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Securities Exchange Act of 1934, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Capital Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the political environment and the level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to result in substantial legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. These costs could decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, these rules and regulations could make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.*

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We had 90,024,562 shares of common stock outstanding as of March 31, 2023. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate and may make it more difficult for you to sell shares of our common stock. In addition, shares of common stock that are either issuable upon the exercise of outstanding options or warrants or reserved for future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We believe, based on our current business plan, that our existing cash and cash equivalents will not be sufficient to fund our obligations for the twelve months following the filing of this report. Significant additional capital will be needed to continue our operations as currently planned, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, new investors could gain rights, preferences and privileges senior to our existing stockholders and our existing stockholders may be materially diluted by such subsequent sales.

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

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

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

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

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

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;

- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

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

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could adversely affect our business and financial condition.

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

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

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

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

Under current law, unused U.S. federal net operating losses generated in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As a result of capital raising and other transactions that have

occurred since our inception in 2012, we have identified several ownership changes that will impact our ability to utilize our net operating losses and credit carryforwards. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2022, we had U.S. federal net operating loss carryforwards of approximately $185.3 million, after adjustments for Section 382 limitations to date, portions of which will begin to expire in 2035, and which could be limited if we experience an "ownership change." In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

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

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

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

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

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and we may incur substantial costs to attempt to recover or reproduce the data. If any disruption or security breach resulted in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and/or the further development of our product candidates could be delayed.

Our operations are vulnerable to interruption by natural disasters, power loss, terrorist activity, public health crisis, pandemic diseases and other events beyond our control, the occurrence of which could materially harm our business.

Businesses located in California have, in the past, been subject to electrical blackouts as a result of a shortage of available electrical power and any future blackouts could disrupt our operations. We are also vulnerable to a major earthquake, wildfire, inclement weather and other natural and man-made disasters and public health crisis and pandemic diseases, such as coronavirus, and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster, public health crisis or pandemic diseases and do not have an applicable recovery plan in place. In addition, if any of our third-party contract manufacturers are affected by natural disasters, such

as earthquakes, power shortages or outages, floods, wildfire, public health crises, such as pandemics and epidemics, terrorism or other events outside of our control, our business and operating results could suffer. For example, as a result of the COVID-19 pandemic, we have experienced significant disruptions in the conduct of our clinical trials and our general business operations as the result of various federal, state and local stay-at-home, shelter-in-place and quarantine measures. We carry only limited business interruption insurance that would compensate us for actual losses from interruption of our business that may occur and any losses or damages incurred by us in excess of insured amounts could cause our business to materially suffer.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

On April 20, 2023, we entered into a Seventh Amendment to our lease, or the Amendment, which extended the term of the lease by an additional 36 months and increases the base rent to $133,371 per month effective January 1, 2024, subject to 4% increases every January. The 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 us.

ITEM 6. EXHIBITS

Exhibit	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.2(1)	Amended and Restated Bylaws of the Registrant, as currently in effect.
3.3(4)	Certificate of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock.
4.1(2)	Form of Common Stock Certificate of the Registrant.
4.2(3)	Form of Warrant to Purchase Common Stock issued to Pacific Western Bank.
4.3(4)	Form of Common Stock Purchase Warrant for First Private Placement.
10.1	Seventh Amendment to Lease by and between the Registrant and Nancy Ridge Technology Center, L.P., dated April 20, 2023.
31.1	Certification of Principal Executive Officer required by Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer required by Rule 13a-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer required by Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350.
32.2	Certification of Principal Financial Officer required by Rule 13a-14(b) promulgated under the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350.
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	The cover page from the Company's Quarterly Report on Form 10-Q has been formatted in Inline

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed on April 24, 2015.
(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-202740), as amended, originally filed with the SEC on March 13, 2015.
(3) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed on October 3, 2016.
(4) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed on May 21, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Cidara Therapeutics, Inc.

Date: May 11, 2023

By: /s/ Jeffrey Stein, Ph.D.
Jeffrey Stein, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 11, 2023

By: /s/ Preetam Shah, Ph.D., MBA
Preetam Shah, Ph.D., MBA
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 10.1

SEVENTH AMENDMENT TO LEASE DATED APRIL 20, 2023

Nancy Ridge Technology Center, L.P., a California limited partnership ("Lessor"), and Cidara Therapeutics, Inc., a Delaware corporation, ("Lessee"), hereby amend the Lease dated June 9, 2014 (as previously amended, the "Lease"), for Suites #101 through #105 at 6310 Nancy Ridge Drive, San Diego, CA 92121 ("Premises") as follows:

1) **Expiration Date:** The Lease Term is hereby extended and the Expiration Date shall be December 31, 2026.

2) **Increase in Base Rent:** On January 1, 2024 the Base Rent shall increase to $133,371 per month. On January 1, 2025, and every twelve (12) months thereafter, the Base Rent shall increase four percent (4%).

3) **Renewal Options:** The two two-year options to renew the Lease described in paragraph #57 of the Addendum to Lease have not been exercised, and remain in effect and available to Lessee.

4) **Confidentiality:** The terms of the Lease are confidential. No party to the Lease shall disclose any of the terms of the Lease to any other party, provided that Lessee may disclose such terms to Lessee's employees, directors, officers, agents and proposed transferees.

5) **No Default:** To each party's knowledge, neither party is currently in Default or Breach of any of the terms or conditions of the Lease.

6) **Authority to Execute:** Each person executing this Amendment represents and warrants to all parties that he or she is duly authorized to execute and deliver this Amendment on behalf of that party.

All other terms and conditions of the Lease shall remain in full force and effect. All capitalized terms used herein but not defined herein shall have the meanings ascribed thereto in the Lease.

Lessor: Nancy Ridge Technology Center, L.P., a California Limited Partnership
By: Nancy Ridge Technology Center, LLC, a California Limited Liability Company, its General Partner

By: /s/ Chris Loughridge Chris Loughridge, its Manager

Lessee: Cidara Therapeutics, Inc., a Delaware corporation By: /s/ Shane Ward

Printed: Shane Ward

Title: Chief Operating Officer

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) and 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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

1. I have reviewed this quarterly report on Form 10-Q of Cidara Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 11, 2023

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) and 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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

1. I have reviewed this quarterly report on Form 10-Q of Cidara Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 11, 2023

/s/ Preetam Shah, Ph.D., MBA
Preetam Shah, Ph.D., MBA
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the quarterly report of Cidara Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey Stein, Ph.D., President and Chief Executive Officer of the Company, certify, pursuant to the requirement in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), that, to the best of my knowledge:

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

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

Date: May 11, 2023

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

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

Exhibit 32.2

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

In connection with the quarterly report of Cidara Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Preetam Shah, Ph.D., MBA, Chief Financial Officer and Chief Business Officer of the Company, certify, pursuant to the requirement in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Securities Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), that, to my knowledge:

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

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

Date: May 11, 2023

/s/ Preetam Shah, Ph.D., MBA
Preetam Shah, Ph.D., MBA
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Principal Accounting Officer)

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