# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

# FORM 10-Q

**(Mark One)**

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

**FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2018**

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

**FOR THE TRANSITION PERIOD FROM TO**
**Commission file number: 001-36912**

# CIDARA THERAPEUTICS, INC.

**(Exact name of registrant as specified in its charter)**

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

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

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

Indicate by check mark whether 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 | ☐ | Smaller reporting company | ☒ |
| | | Emerging growth company | ☒ |

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

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

As of October 31, 2018, the registrant had 27,751,431 shares of Common Stock ($0.0001 par value) outstanding.

**CIDARA THERAPEUTICS, INC.**

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## PART I. FINANCIAL INFORMATION

### ITEM 1. FINANCIAL STATEMENTS

**CIDARA THERAPEUTICS, INC.**
**Condensed Consolidated Balance Sheets**

| (In thousands, except share and per share data) | September 30, 2018 (unaudited) | December 31, 2017 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 83,780 | $ 60,813 |
| Short-term investments | 4,494 | 14,501 |
| Accounts receivable | — | 321 |
| Prepaid expenses and other current assets | 3,687 | 2,035 |
| Total current assets | 91,961 | 77,670 |
| Property and equipment, net | 786 | 1,044 |
| Other assets | 62 | 321 |
| Total assets | $ 92,809 | $ 79,035 |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,439 | $ 2,590 |
| Accrued liabilities | 3,385 | 4,257 |
| Accrued compensation and benefits | 2,585 | 2,571 |
| Contingent forward purchase obligations | 4,486 | — |
| Current portion of term loan | 667 | 2,667 |
| Total current liabilities | 13,562 | 12,085 |
| Term loan, less debt issuance costs | 9,253 | 7,206 |
| Other long-term liabilities | 62 | — |
| Total liabilities | 22,877 | 19,291 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value; 10,000,000 shares authorized at September 30, 2018 and December 31, 2017: | | |
| Series X Convertible Preferred stock, $0.0001 par value; 5,000,000 shares authorized at September 30, 2018 and no shares authorized at December 31, 2017; 445,231 shares issued and outstanding at September 30, 2018; no shares issued and outstanding at December 31, 2017 | — | — |
| Common stock, $0.0001 par value; 200,000,000 shares authorized at September 30, 2018 and December 31, 2017; 27,751,431 and 27,751,413 shares issued and outstanding, respectively, at September 30, 2018; 20,534,993 and 20,525,688 shares issued and outstanding, respectively, at December 31, 2017 | 3 | 2 |
| Additional paid-in capital | 276,323 | 209,140 |
| Accumulated other comprehensive loss | (1) | (8) |
| Accumulated deficit | (206,393) | (149,390) |
| Total stockholders' equity | 69,932 | 59,744 |
| Total liabilities and stockholders' equity | $ 92,809 | $ 79,035 |

See accompanying notes.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| **(In thousands, except share and per share data)** | **2018** | **2017** | **2018** | **2017** |
| Operating expenses: | | | | |
| Research and development | $ 11,278 | $ 9,159 | $ 36,096 | $ 32,593 |
| General and administrative | 3,447 | 3,090 | 10,591 | 9,669 |
| Total operating expenses | 14,725 | 12,249 | 46,687 | 42,262 |
| Loss from operations | (14,725) | (12,249) | (46,687) | (42,262) |
| Other income (expense): | | | | |
| Change in fair value of contingent forward purchase obligations | 888 | — | (224) | — |
| Interest income (expense), net | 222 | (8) | 447 | (38) |
| Other expense | (4) | — | (210) | — |
| Total other income (expense) | 1,106 | (8) | 13 | (38) |
| Net loss | (13,619) | (12,257) | (46,674) | (42,300) |
| Recognition of beneficial conversion feature | — | — | (10,329) | — |
| Net loss attributable to common shareholders | $ (13,619) | $ (12,257) | $ (57,003) | $ (42,300) |
| Basic and diluted net loss per common share | $ (0.49) | $ (0.73) | $ (2.35) | $ (2.51) |
| Shares used to compute basic and diluted net loss per common share | 27,705,472 | 16,864,211 | 24,254,254 | 16,830,749 |

| | | | | |
|---|---|---|---|---|
| Net loss | $ (13,619) | $ (12,257) | $ (46,674) | $ (42,300) |
| Unrealized gain (loss) on short-term investments | 2 | (1) | 7 | — |
| Comprehensive loss | $ (13,617) | $ (12,258) | $ (46,667) | $ (42,300) |

See accompanying notes.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| **(In thousands)** | **2018** | **2017** |
| **Operating activities:** | | |
| Net loss | $ (46,674) | $ (42,300) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 412 | 528 |
| Stock-based compensation | 4,346 | 4,206 |
| Amortization of debt issuance costs and debt discount | 47 | 58 |
| Amortization of discount or premium on short-term investments | 36 | (45) |
| Deferred rent | 11 | (19) |
| Change in fair value of contingent forward purchase obligations | 224 | — |
| Contingent forward purchase obligation offering costs | 210 | — |
| Changes in assets and liabilities: | | |
| Accounts receivable | 321 | (337) |
| Prepaid expenses and other current assets | (1,652) | (952) |
| Accounts payable and accrued liabilities | (967) | (1,185) |
| Accrued compensation | 388 | (372) |
| Other assets | 259 | — |
| Net cash used in operating activities | (43,039) | (40,418) |
| | | |
| **Investing activities:** | | |
| Purchases of short-term investments | (14,548) | (9,880) |
| Maturities of short-term investments | 24,526 | 19,300 |
| Purchases of property and equipment | (137) | (166) |
| Net cash provided by investing activities | 9,841 | 9,254 |
| | | |
| **Financing activities:** | | |
| Proceeds from May 2018 Registered Direct Offering, net of offering costs | 49,521 | — |
| Proceeds from issuance of common stock under equity sales agreement, net of issuance costs | 6,440 | — |
| Proceeds from exercise of stock options | 204 | 152 |
| Repurchase of unvested restricted stock | — | (79) |
| Net cash provided by financing activities | 56,165 | 73 |
| Net increase (decrease) in cash and cash equivalents | 22,967 | (31,091) |
| Cash and cash equivalents at beginning of period | 60,813 | 85,367 |
| Cash and cash equivalents at end of period | $ 83,780 | $ 54,276 |
| | | |
| **Supplemental disclosure of cash flows:** | | |
| Interest paid | $ 432 | $ 378 |
| **Non-cash investing activities:** | | |
| Property and equipment acquired but not yet paid | $ 17 | $ 16 |
| **Non-cash financing activities:** | | |
| Proceeds from issuance of common stock pursuant to Employee Stock Purchase Plan | $ 374 | $ 301 |
| Vesting of early exercised stock options | $ 21 | $ 35 |

See accompanying notes.

## 1. THE COMPANY AND BASIS OF PRESENTATION

### *Description of Business*

Cidara Therapeutics, Inc., or the Company, was originally incorporated in Delaware in December 2012 as K2 Therapeutics, Inc., and its name was changed to Cidara Therapeutics, Inc. in July 2014. The Company is a biotechnology company focused on the discovery, development and commercialization of novel anti-infectives. The Company's portfolio is comprised of a proprietary product candidate for the treatment and prevention of serious fungal infections. The Company is also conducting research in bacterial and viral infection. The Company formed wholly-owned subsidiaries, Cidara Therapeutics UK Limited, in England, and Cidara Therapeutics (Ireland) Limited, in Ireland, in March 2016 and October 2018, respectively, for the purpose of developing its product candidates in Europe.

### *Basis of Presentation*

The Company has a limited operating history and the sales and income potential of the Company's business and market are unproven. The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has experienced net losses and negative cash flows from operating activities since its inception. At September 30, 2018, the Company had an accumulated deficit of $206.4 million. The Company expects to continue to incur net losses into the foreseeable future. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. The Company has prepared cash flow forecasts which indicate, based on its current cash resources available, that it will have sufficient resources to fund its business for at least the next 12 months from the date of this filing. The Company will need to raise additional capital to fund its losses from operations. It anticipates raising capital through debt and equity financing, through government funding or through collaborations or partnerships with other entities. Debt or equity financing, government funding or collaborations and partnerships with other entities may not be available on a timely basis on terms acceptable to the Company, or at all.

If the Company is not able to secure adequate additional funding, the Company may be forced to delay, reduce or eliminate its research and development programs or future commercialization efforts, or to make reductions in spending, extend payment terms with suppliers, liquidate or grant rights to assets where possible, or suspend or curtail planned programs. Any of these actions could materially harm the Company's business, results of operations and future prospects.

### *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 September 30, 2018 and 2017.

### *Basis of Consolidation*

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

### *Use of Estimates*

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. The Company evaluates its estimates and assumptions on an ongoing basis. The most significant estimates in the Company's consolidated financial statements relate to estimating the fair value of the Company's stock options, the fair value of the

Company's contingent forward purchase obligations, and certain accruals, including those related to nonclinical and clinical activities. Although the estimates are based on the Company's knowledge of current events, comparable companies, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

***Segment Information***

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Cash 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.

***Investments Available-for-Sale***

Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in accumulated other comprehensive loss. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization of premiums and accretion of discounts is included in interest income. Realized gains and losses and declines in value judged to be other-than-temporary, if any, on available-for-sale securities are included in other income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income. Securities with maturity dates of 12 months or less from the date of purchase are classified as short-term investments and securities with maturity dates of more than 12 months are classified as long-term investments.

***Concentration of Credit Risk***

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. Periodically, the Company maintains deposits in government insured financial institutions in excess of government insured limits. The Company invests its cash balances in financial institutions that it believes have high credit quality, has not experienced any losses on such accounts and does not believe it is exposed to significant credit risk.

***Patent Costs***

The Company expenses all costs as incurred in connection with patent applications (including direct application fees and the legal and consulting expenses related to making such applications), and such costs are included in general and administrative expenses in the accompanying statements of operations.

***Income Taxes***

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

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

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (the "Tax Act"), which among other provisions, reduced the U.S. corporate tax rate from 35% to 21%, effective January 1, 2018. Due to the timing of the enactment and the complexity involved in applying the provisions of the Tax Act, the Company made reasonable estimates of the effects and recorded provisional amounts in our financial statements as of December 31, 2017. As the Company collects and prepares necessary data, and continues to interpret the Tax Act and any additional guidance issued by the U.S. Treasury Department, the Internal Revenue Service (IRS) and other standard-setting bodies, the Company may make adjustments to the provisional amounts. Those adjustments may affect deferred tax balances. However, due to the valuation allowance position, the Company expects there will be no net impact to the financial statements. The Company did not make any such adjustments during the quarter ended September 30, 2018. Any adjustments to account for the tax effects of the Tax Act would be made in a subsequent quarter.

***Revenue Recognition***

The Company recognizes revenues when customers obtain control of promised goods or services, in an amount that reflects the consideration which it expects to receive in exchange for those goods or services. The Company recognizes revenues following the five step model prescribed under Accounting Standards Update ("ASU") No. 2014-09 ("ASU 2014-09"): (i) identify 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 revenues when (or as) the Company satisfies the performance obligation.

***Grant Funding***

The Company has received research and development funding through a grant from CARB-X, a public-private partnership focused on antibacterials. The Company has also been awarded a partnership grant with Rutgers University from the U.S. National Institute of Allergy and Infectious Diseases ("NIAID") of the National Institutes of Health ("NIH"), an agency of the United States Department of Health and Human Services. The Company has evaluated the terms of the grants to assess its obligations and the classification of funding received. Amounts billable for funded research and development are recognized in the statement of operations as a reduction to research and development expense over the grant period as the related costs are incurred to meet the Company's obligations.

***Research and Development Costs***

Research and development expenses consist of wages, benefits and stock-based compensation charges for research and development employees, scientific consultant fees, facilities and overhead expenses, laboratory supplies, manufacturing expenses, and nonclinical and clinical trial costs. The Company accrues nonclinical and clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies, and other events.

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

***Comprehensive Loss***

Comprehensive loss is defined as the change in equity during a period from transactions and other events and/or circumstances from non-owner sources. The Company’s only component of other comprehensive loss is unrealized losses on short-term investments. Comprehensive losses have been reflected in the condensed consolidated statements of operations and comprehensive loss for all periods presented.

***Stock-based Compensation***

The Company accounts for stock-based compensation expense related to employee stock options and employee stock purchase plan rights by estimating the fair value on the date of grant using the Black-Scholes option pricing model. The fair value of Restricted Stock Units (RSUs) and Performance-based RSUs (PRSUs) granted to employees is estimated based on the closing price of the Company's common stock on the date of grant. For awards subject to time-based vesting conditions, stock-based compensation expense is recognized ratably over the requisite service period of the awards. For awards subject to performance-based vesting conditions, the Company assesses the probability of achievement of the individual milestones under the stock-based awards and recognizes stock-based compensation expense over the implicit service period commencing once the Company believes the performance criteria is probable of achievement. The Company accounts for stock options, RSUs, and PRSUs granted to non-employees using the fair value approach. These stock-based awards are subject to periodic revaluation over their vesting terms.

***Net Loss Per Share***

Basic net loss per share is calculated by dividing the net loss allocable to common shares by the weighted-average number of common shares outstanding for the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss allocable to common shares by the weighted-average number of common shares and dilutive common stock equivalents outstanding for the period determined using the treasury-stock and if-converted methods. Dilutive common stock equivalents are comprised of warrants, unvested restricted common stock subject to repurchase, and RSUs and options outstanding under the Company's stock option plans. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding.

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

| | September 30, | |
|---|---|---|
| | **2018** | **2017** |
| Common stock warrants | 12,517,328 | 17,331 |
| Series X Convertible Preferred stock | 4,452,310 | — |
| Common stock options and RSUs issued and outstanding | 4,083,233 | 3,323,599 |
| Common stock subject to repurchase | 18 | 13,269 |
| Total | 21,052,889 | 3,354,199 |

***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, marketable securities, contingent forward purchase obligations, and long-term debt. Fair value estimates of these instruments are made at a specific point in time based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, prepaid expenses, accounts payable, and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The fair value of short-term investments is based upon market prices quoted on the last day of the fiscal period or other observable market inputs. The fair value of contingent forward purchase obligations is based on a probability-weighted valuation approach (See Note 4). The Company believes that the fair value of long-term debt approximates its carrying value.

***Recently Issued Accounting Standards***

During 2016, the FASB issued ASU 2016-02, "Leases," which requires that operating lease arrangements longer than 12 months result in an entity recognizing an asset and liability. The updated guidance is effective for interim and annual periods beginning after December 15, 2018, and early adoption is permitted. The Company currently expects that its operating lease commitments will be subject to the new standard and recognized as right-of-use assets and operating lease liabilities upon the adoption of ASU 2016-02, which will increase the total assets and total liabilities that it reports relative to such amounts prior to adoption.

During 2018, the FASB issued ASU 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting," which expanded the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Under the ASU, the guidance on such payments to nonemployees is aligned with the accounting for share-based payments granted to employees, including the measurement of equity-classified awards, which is fixed at the grant date under the new guidance. The updated guidance is effective for interim and annual periods beginning after December 15, 2018, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

During 2018, the FASB issued ASU 2018-13, "Changes to the Disclosure Requirements for Fair Value Measurement," which modifies certain disclosure requirements on fair value measurements. The updated guidance is effective for interim and annual periods beginning after December 15, 2019, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

**3. SHORT-TERM INVESTMENTS**

The following table summarizes the available-for-sale securities held at September 30, 2018 and December 31, 2017 (in thousands):

| As of September 30, 2018 | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Corporate debt | $ 2,498 | $ — | $ (1) | $ 2,497 |
| U.S. Treasury Bill | 1,997 | — | — | 1,997 |
| Total | $ 4,495 | $ — | $ (1) | $ 4,494 |

| As of December 31, 2017 | Amortized Cost | Unrealized Gains | Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Corporate debt | $ 14,509 | $ — | $ (8) | $ 14,501 |
| Total | $ 14,509 | $ — | $ (8) | $ 14,501 |

All available-for-sale securities held at September 30, 2018 and December 31, 2017 had maturities of less than one year. Unrealized gains and losses on available-for-sale securities are included as a component of other comprehensive loss. The securities in unrealized loss positions have not been in a continuous unrealized loss position for 12 months or longer. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity. The Company reviews its investments to identify and evaluate investments that have an indication of possible other-than-temporary impairment. Factors considered in determining whether a loss is other-than-temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. During the nine months ended September 30, 2018 and 2017, respectively, the Company did not recognize any impairment or gains or losses on sales of available-for-sale securities.

**4. FAIR VALUE MEASUREMENTS**

The Company follows ASC 820-10, Fair Value Measurements and Disclosures, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability. The carrying amounts of accounts payable and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments. Based on the borrowing rates available to the Company for loans with similar terms, which is considered a Level 2 input as described below, the Company believes that the fair value of long-term debt approximates its carrying value.

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

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

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

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

The Company classifies investments in money market funds and treasury bills within Level 1 as the prices are available from quoted prices in active markets. Investments in commercial paper, corporate debt and reverse repurchase agreements are classified within Level 2 as these instruments are valued using observable market inputs including reported trades, broker/dealer quotes, bids and/or offers.

As discussed in Note 6, on May 21, 2018, the Company entered into a securities purchase agreement with certain investors providing for the purchase and sale of up to an aggregate of $120.0 million of its common stock and preferred stock in three closings. The second and optional third closings and warrants related to the optional third closing, which are triggered by the Company's announcement of topline data of Part B of its STRIVE Phase 2 clinical trial of rezafungin, contain features for subsequent closings that are not solely within the control of the Company and that embody an obligation that the Company must settle by issuing a variable number of shares when the obligation is based predominantly on having a fixed value at inception. In accordance with ASC 480, "Distinguishing Liabilities from Equity," the Company determined that these closings are classified as liabilities and represent contingent forward purchase obligations. These liabilities are required to be recorded at their estimated fair value initially and on a recurring basis. The

contingent forward purchase obligations are classified within Level 3 of the fair value hierarchy as the Company is using a probability-weighted valuation approach, utilizing significant unobservable inputs including the probability and estimated timing of achieving positive or negative results associated with Part B of the STRIVE Phase 2 clinical trial and estimated discount rates related to the risk of achievement of the expected equity issuances. The liability was initially recorded at $4.3 million on May 21, 2018 and fair value adjustments resulting in a gain of $0.9 million and a loss of $0.2 million were recorded during the three and nine month periods ended September 30, 2018, respectively.

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 |
|---|---|---|---|---|
| **September 30, 2018** | | | | |
| Assets: | | | | |
| Money market funds | $ 83,064 | $ 83,064 | $ — | $ — |
| U.S. Treasury bill | 1,997 | 1,997 | — | — |
| Corporate debt | 2,497 | — | 2,497 | — |
| Total assets at fair value | $ 87,558 | $ 85,061 | $ 2,497 | $ — |
| | | | | |
| Liabilities: | | | | |
| Contingent forward purchase obligations | $ 4,486 | $ — | $ — | $ 4,486 |
| Total liabilities at fair value | $ 4,486 | $ — | $ — | $ 4,486 |
| | | | | |
| **December 31, 2017** | | | | |
| Assets: | | | | |
| Money market funds | $ 11,556 | $ 11,556 | $ — | $ — |
| U.S. Treasury reverse repurchase agreements | 48,000 | — | 48,000 | — |
| Corporate debt | 15,101 | — | 15,101 | — |
| Total assets at fair value | $ 74,657 | $ 11,556 | $ 63,101 | $ — |

**5. DEBT**

***Term Loans***— On October 3, 2016, the Company entered into a loan and security agreement, (the "Loan Agreement"), with Pacific Western Bank, as the collateral agent and a lender (the "Lender"), pursuant to which the Lender agreed to lend to the Company up to $20.0 million in a series of term loans. Contemporaneously, the Company borrowed $10.0 million from the Lender (the "Term A Loan").

Under the terms of the Loan Agreement, because the Company achieved positive clinical results from the STRIVE Phase 2 clinical trial of rezafungin by March 31, 2018, the Company could, at its sole discretion through October 3, 2018, borrow from the Lender up to an additional $10.0 million (the "Term B Loan," and together with the Term A Loan, the "Term Loans"). The Company did not borrow any funds available under the Term B Loan before the draw period ended. On June 13, 2018, the Company and the Lender entered into a First Amendment to the Loan Agreement, which reset the operating covenant to require the Company to achieve positive data from Part B of the STRIVE Phase 2 clinical trial of rezafungin on or prior to July 31, 2019 (the "Milestone"). Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Loan Agreement, the breach of certain of its other covenants under the Loan Agreement, including the Milestone, or the occurrence of a material adverse change, the collateral agent will have the right, among other remedies, to declare all principal and interest and other amounts due to the Lender under the Loan Agreement immediately due and payable.

The Company's obligations under the Loan Agreement are secured by a first priority security interest in substantially all of the Company's current and future assets, other than its intellectual property, which is subject to a double negative pledge.

On July 27, 2018, the Company and the Lender entered into a Second Amendment to the Loan Agreement, which amended, among other things, the interest-only period, the date of maturity (the "Maturity Date") and the interest rate. The Maturity Date is January 3, 2022. Payments under the Term Loans will be interest-only through July 31, 2019, which

will be extended to October 31, 2019 if the Milestone is achieved. The interest-only period will be followed by equal monthly payments of principal and interest. The Term Loans will bear interest at a variable annual rate equal to the greater of (i) 4.5% or (ii) the Lender's prime interest rate plus 0.75%. At September 30, 2018, the Term Loans bear interest at 6.0%.

The Company evaluated the First and Second Amendments to evaluate whether the amendments represented modifications or extinguishment of debt. The Company determined that the amendments did not represent a substantial change from the original Loan Agreement and accounted for the amendments as debt modifications. Costs previously deferred under the original terms of the Loan Agreement are amortized into interest expense over the new term of the Second Amendment.

As of September 30, 2018, future principal payments due under the Term A Loan are as follows (in thousands):

| **Year ended:** | |
|---|---|
| December 31, 2018 | $ — |
| December 31, 2019 | 1,667 |
| December 31, 2020 | 4,000 |
| December 31, 2021 | 4,000 |
| December 31, 2022 | 333 |
| Total future principal payments due under the Term A Loan | $ 10,000 |

**6. STOCKHOLDERS' EQUITY**

***May 2018 Registered Direct Offering***

On May 21, 2018, the Company entered into a securities purchase agreement with certain investors providing for the purchase and sale, in a registered direct offering, of up to an aggregate of $120.0 million of its common stock and preferred stock in three closings. On May 23, 2018, the Company completed the first closing, which was comprised of 6,185,987 shares of common stock at an offering price of $4.70 per share, 445,231 shares of Series X Convertible Preferred Stock at an offering price of $47.00 per share, and an option fee relating to the third closing paid by the investors for a total of $0.5 million. In a private placement concurrent with the first closing (the "First Private Placement"), the Company also sold warrants, at $0.125 per warrant share, to purchase an aggregate of 12,499,997 shares of common stock. Net proceeds for the first closing and the First Private Placement were $49.5 million.

The Company performed an analysis to allocate the proceeds from the May 2018 registered direct offering to the offering's various components on a relative fair value basis, including the contingent forward purchase obligations (discussed further in Note 4) as well as the common stock, Series X Convertible Preferred Stock, warrants, and option fee. With respect to the Series X Convertible Preferred Stock, because the adjusted conversion price on the commitment date (following the allocation of proceeds on a fair value basis) was below the fair value of the common stock at the date of issuance, a beneficial conversion feature with a calculated fair value of $10.3 million existed at the issuance date. The beneficial conversion feature is amortized as a deemed dividend to the preferred holders. As the Series X Convertible Preferred Stock is fully convertible at issuance, the full amortization of the $10.3 million was recorded at issuance as a one-time deemed dividend on May 23, 2018. This one-time, non-cash deemed dividend impacted net loss attributable to common stockholders and net loss attributable to common stockholders per share for the nine months ended September 30, 2018.

In the second closing of the offering, the Company may sell up to an additional $50.0 million in shares of common stock to investors who purchased at least $1.0 million of shares of common stock in the first closing of the offering at a purchase price per share that is equal to 75% of the volume weighted average price of the common stock for the five trading days following the Company's public release of topline data from Part B of its STRIVE global, randomized Phase 2 clinical trial of rezafungin, provided that the Company will not be obligated to complete the second closing of the offering if the purchase price is less than $4.70 per share.

In the optional third closing, which would be held five trading days following the second closing, purchasers who fully participate in the second closing may, at their option, purchase up to an additional $20.0 million of common stock at a purchase price per share equal to the purchase price of the shares purchased at the second closing.

At the Company's option, and prior to the completion of the second or third closing, as applicable, the Company may reduce the aggregate offering size of the such closing by the dollar amount received by the Company from any (i)

strategic partnership or other non-dilutive source of funding or (ii) sale of equity securities at a price greater than $6.81 per share.

The Company will also offer to each purchaser in the second or third closing the opportunity, in lieu of purchasing common stock, to purchase Series X Convertible Preferred Stock. For each share of Series X Convertible Preferred Stock purchased in the offering in lieu of common stock, the Company will reduce the number of shares of common stock being sold by 10 shares. Each share of Series X Convertible Preferred Stock is convertible into 10 shares of common stock.

As the issuance of the additional closings are outside the control of the Company, the second closing and optional third closing are accounted for as a liability in accordance with ASC 480, "Distinguishing Liabilities from Equity," which is measured at fair value on a recurring basis. See Note 4 to our financial statements for additional information.

In a private placement to be held concurrently with the optional third closing (the “Second Private Placement”), the Company would sell warrants to purchase up to 2,500,000 shares of Common Stock to the purchasers that participate, at a purchase price of $0.125 per warrant share (such warrants, together with the warrants sold in the First Private Placement, each, a “Warrant”, and collectively, the “Warrants”).

The Warrants are exercisable immediately for cash at an exercise price of $6.81 per share. The Warrants issued in the First Private Placement will expire upon the earliest of (i) five years from the date of the first closing of the offering, (ii) the date that the holder of such Warrant transfers or sells any of the shares of Common Stock purchased by such holder in the first closing of the offering, if such transfer or sale occurs prior to the date that is 120 calendar days following the closing of the first closing of the offering, (iii) the taking of any short position on the Common Stock by the holder of such Warrant prior to the completion of the second closing of the offering, and (iv) the failure by the holder of such Warrant to purchase its pro rata allocation of shares of Common Stock in the second closing of the offering.

The Warrants issued in the Second Private Placement will expire five years from the date of the third closing of the offering.

***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 September 30, 2018.

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. As of September 30, 2018, 445,231 shares of Series X Convertible Preferred Stock were issued and outstanding.

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

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

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

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

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

***Common Stock***

The Company had 200,000,000 shares of common stock authorized as of September 30, 2018. 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 rights of preferred stock, if any, then outstanding. The common stock has no preemptive rights, conversion rights, redemption rights or sinking fund provisions, and there are no dividends in arrears or default. All shares of common stock have equal distribution, liquidation and voting rights, and have no preferences or exchange rights.

In November 2017, the Company began to sell shares of common stock under a controlled equity sales agreement with Cantor Fitzgerald & Co. The Company voluntarily terminated the controlled equity sales agreement on May 20, 2018. During the nine months ended September 30, 2018, the Company sold 847,937 shares of common stock pursuant to the controlled equity sales agreement for net proceeds of approximately $6.4 million after deducting placement agent fees.

***Common Stock Reserved for Future Issuance***

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

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Common stock warrants | 12,517,328 | 17,331 |
| Series X Convertible Preferred Stock | 4,452,310 | — |
| Stock options and RSUs issued and outstanding | 4,083,233 | 3,099,173 |
| Authorized for future stock awards under the Company's option plans | 981,811 | 1,006,307 |
| Authorized for future issuance under the ESPP | 492,665 | 380,875 |
| Total | 22,527,347 | 4,503,686 |

**7. STOCK INCENTIVE PLANS**

***2015 Equity Incentive Plan***

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

Terms of stock award agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2015 EIP. Stock options granted by the Company generally vest over a three- or four-year period. Certain stock options are subject to acceleration of vesting in the event of certain change of control transactions. The stock options may be granted for a term of up to 10 years from the date of grant. The exercise price for stock options granted under the 2015 EIP must be at a price no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided that for an incentive stock option granted to an employee who at the time of grant owns stock representing more than 10% of the voting power of all classes of stock of the Company, the exercise price shall be no less than 110% of the estimated value on the date of grant.

***2015 Employee Stock Purchase Plan***

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

The ESPP allows substantially all employees to purchase the Company's common stock through a payroll deduction at a price equal to 85% of the lower of the fair market value of the stock as of the beginning or the end of each purchase period. An employee's payroll deductions under the ESPP are limited to 15% of the employee's eligible compensation. During the nine months ended September 30, 2018, 93,483 shares were issued pursuant to the ESPP.

***Restricted Stock***

The Company permits exercise of certain stock options prior to vesting. Any such exercised shares are restricted and subject to repurchase by the Company until the conditions for vesting are met. At September 30, 2018 there was no liability for cash received from the early exercise of stock options. At December 31, 2017, the liabilities for the cash received from the early exercise of stock options was $21,000 and was classified in accrued liabilities on the balance sheet. The Company reduces the liability as the underlying shares vest in accordance with the vesting terms outlined in the stock option agreements, which are generally 4 years. At September 30, 2018, 18 unvested shares were subject to repurchase by the Company.

***Restricted Stock Units***

The following table summarizes RSU and PRSU activity during the nine months ended September 30, 2018:

| | Number of RSUs and PRSUs |
|---|---|
| Outstanding at December 31, 2017 | 227,500 |
| RSUs and PRSUs granted | 30,000 |
| RSUs and PRSUs vested | — |
| RSUs and PRSUs canceled | (20,000) |
| Outstanding at September 30, 2018 | 237,500 |

For the nine months ended September 30, 2018, stock-based compensation expense related to RSUs and PRSUs was approximately $194,000. At September 30, 2018, estimated unrecognized compensation expense related to RSUs and PRSUs granted to employees was approximately $1.0 million.

***Stock Options***

The following table summarizes stock option activity during the nine months ended September 30, 2018:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Life in Years | Total Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding at December 31, 2017 | 3,099,173 | $ 7.74 | 8.10 | $ 2,264 |
| Options granted | 1,143,250 | 4.34 | | |
| Options exercised | (89,031) | 2.29 | | |
| Options canceled | (307,659) | 8.40 | | |
| Outstanding at September 30, 2018 | 3,845,733 | $ 6.80 | 7.49 | $ 1,236 |
| Vested and expected to vest at September 30, 2018 | 3,845,733 | $ 6.80 | 7.49 | $ 1,236 |
| Exercisable at September 30, 2018 | 2,207,784 | $ 7.32 | 6.91 | $ 914 |

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.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Research and development | $ 623 | $ 666 | $ 1,992 | $ 1,805 |
| General and administrative | 662 | 889 | 2,354 | 2,401 |
| Total | $ 1,285 | $ 1,555 | $ 4,346 | $ 4,206 |

The weighted-average grant date fair value of employee stock options granted by the Company during the nine months ended September 30, 2018 was $3.06 per share. The total grant date fair value of employee stock options that vested during the nine months ended September 30, 2018 was $2.7 million. As of September 30, 2018, total unrecognized share-based compensation expense related to unvested employee stock options of the Company was approximately $5.7 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 2.1 years.

As of September 30, 2018, total unrecognized compensation expense related to the ESPP was approximately $0.6 million. This unrecognized compensation cost is expected to be recognized over approximately 0.6 years.

***Common Stock Warrants***

A summary of warrant activity for the nine months ended September 30, 2018 is presented below:

| | Warrants | Weighted Average Exercise Price | Total Intrinsic Value |
|---|---|---|---|
| Outstanding at December 31, 2017 | 17,331 | $ 11.54 | $ — |
| Issued | 12,499,997 | 6.81 | — |
| Exercised | — | — | — |
| Canceled | — | — | — |
| Outstanding at September 30, 2018 | 12,517,328 | $ 6.82 | $ — |

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.

**8. SIGNIFICANT AGREEMENTS AND CONTRACTS**

***Combating Antibiotic Resistant Bacteria Accelerator (CARB-X) Subaward Agreement***

On March 30, 2017, the Company entered into a Cost Reimbursement Research Subaward Agreement (the "Subaward Agreement") with the Trustees of Boston University. Under the Subaward Agreement, the Company is a subawardee under the CARB-X program. CARB-X is a public-private partnership focused on antibacterials, created by the U.S. Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority (BARDA), and National Institute of Allergy and Infectious Diseases (NIAID). CARB-X is funded by BARDA and the London-based Wellcome Trust, a global charitable foundation (Wellcome), and administered by the Boston University School of Law.

The subaward was intended to support development of the Company's CD201 product candidate. Under the Subaward Agreement, during an initial phase that began on April 1, 2017 and ends upon acceptance by the U.S. Food and Drug Administration of an initial new drug application, CARB-X would reimburse up to $3.9 million of qualifying development expenses. If all of the milestones in such initial phase are met, the CARB-X Joint Oversight Committee will evaluate the progress made in such initial phase and determine whether to exercise its option to fund a second stage. During the second stage, CARB-X would reimburse up to $3.0 million of qualifying development expenses through a Phase 1 clinical trial. Such second stage would be subject to a new subaward agreement.

Under the Subaward Agreement, the Company is reimbursed for direct costs incurred plus allowable indirect costs which consist of fringe benefits and allowable general and administrative expenses. As of September 30, 2018, there were no billed or unbilled accounts receivable related to reimbursable expenses under the Subaward Agreement.

The Subaward Agreement can be terminated upon the delivery of 30 days written notice to the Company for default or convenience. Upon receipt of a notice of termination, the Company must discontinue contract activities and CARB-X must pay the Company a final settlement based on eligible expenses incurred under the Subaward Agreement.

Based on preclinical studies of CD201 as well as preclinical studies of antibody-drug conjugates (ADCs) from the Cloudbreak program, the Company decided in February 2018 to cease development of CD201 to focus on the more promising ADCs for the same indication. Based on the decision to focus efforts on the ADCs, the Company will no longer be seeking funding under the Subaward Agreement relating to CD201.

***Partnership Grant for the Development of Cloudbreak Antibody-Drug Conjugates***

In May 2018, the Company and Rutgers University were awarded a five year, $5.5 million partnership grant from the U.S. National Institute of Allergy and Infectious Diseases (NAIAD) and the National Institutes of Health (NIH), an agency of the United States Department of Health and Human Services. The grant will fund continued research and development of the Company's Cloudbreak ADC platform to identify novel immunotherapy agents for the treatment and prevention of serious and life-threatening viral infections and multi-drug resistant (MDR) Gram-negative bacterial infections in high-risk populations. The Company began work under this grant in July 2018 but has not recognized any potential reimbursements in the statements of operations for the three and nine month periods ended September 30, 2018 as the subaward agreement between the Company and Rutgers University has not yet been executed. As of September 30, 2018 there was no accounts receivable related to reimbursable expenses under this grant.

**9. COMMITMENTS AND CONTINGENCIES**

***Litigation***

From time to time, the Company may be involved in various lawsuits, legal proceedings, or claims that arise in the ordinary course of business. Management believes there are no claims or actions pending against the Company as of September 30, 2018 which will have, individually or in the aggregate, a material adverse effect on its business, liquidity, financial position, or results of operations. Litigation, however, is subject to inherent uncertainties, and an adverse result in such matters may arise from time to time that may harm the Company’s business.

***Lease Obligations***

In June 2014, the Company entered into an operating lease agreement for laboratory and office space in San Diego, California. Amendments for additional space were entered into in February 2015, March 2015, and August 2015. On June 29, 2018 the Company entered into a Fourth Amendment to its lease which extended the term of the lease by an additional 36 months and increases base rent to $70,000 per month effective January 1, 2019. The Company has also been granted an option, exercisable prior to September 30, 2019, to expand its leased premises on the same terms as the current lease, subject to compliance with specified conditions. The lease expires in December 2021 with options for two individual two-year extensions. The lease is subject to charges for common area maintenance and other costs, and base rent is subject to 3% annual increases every January. Rent expense is recorded on a straight-line basis over the life of the lease.

Future minimum payments required under the lease as of September 30, 2018 are summarized as follows (in thousands):

| | | |
|---|---|---|
| 2018 | $ | 189 |
| 2019 | | 836 |
| 2020 | | 861 |
| 2021 | $ | 887 |
| Total minimum lease payments | $ | 2,773 |

Rent expense was $568,000 and $530,000 for the nine months ended September 30, 2018 and 2017, respectively.

***Contractual Obligations***

The Company enters into contracts in the normal course of business with vendors for research and development activities, manufacturing, and professional services. These contracts generally provide for termination either on notice or within 30 days of notice.

## 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, 2017, filed with the Securities and Exchange Commission, or the SEC, on February 27, 2018.*

### *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. 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. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. 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 novel anti-infectives for the treatment of diseases that are inadequately addressed by current standard of care therapies. We are developing a balanced pipeline of product and development candidates, with an initial focus on serious fungal infections. Our lead product candidate is rezafungin acetate, an intravenous formulation of a novel echinocandin. Rezafungin is being developed as a once-weekly, high-exposure therapy for the treatment and prevention of serious, invasive fungal infections.

In addition, we are developing our antibody-drug conjugates, or ADCs, for viral infections, including influenza, and multidrug-resistant bacterial infections as part of our proprietary Cloudbreak™ platform. The Cloudbreak platform is designed to discover compounds that directly kill pathogens and also direct a patient's immune system to attack and eliminate pathogens.

### *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, including candidemia and invasive candidiasis, associated with high mortality rates.

*STRIVE clinical trial*

In March 2018, we reported topline results from Part A of our global, randomized Phase 2 clinical trial of rezafungin, called the STRIVE trial.

STRIVE is an international, multicenter, double-blind clinical trial evaluating the safety, tolerability and efficacy of once-weekly dosing of rezafungin compared to once-daily dosing of caspofungin in patients with candidemia and/or invasive candidiasis. In Part A, patients were randomized to one of two rezafungin arms or to the caspofungin arm. In the two rezafungin arms of the trial, patients received either 400 mg of rezafungin administered intravenously once weekly for two to four weeks (Group 1) or 400 mg for the first week followed by 200 mg once weekly for two to three weeks, for up to four weeks in total (Group 2). In the comparator arm (Group 3), patients received daily caspofungin administered intravenously according to the approved prescribing information, with an optional step down to oral fluconazole. The STRIVE trial results we reported include efficacy data from 92 treated patients (the microbiological intent-to-treat, or mITT, population) and safety and tolerability results from 104 patients, from 31 trial sites in North America and Europe. The trial was not statistically powered to demonstrate superiority or non-inferiority and therefore comparisons of efficacy are directional.

STRIVE Part A met its primary objectives related to tolerability and safety of rezafungin in the treatment of candidemia/invasive candidiasis. Topline efficacy data are summarized in Table 1. Overall success is defined as eradication

of *Candida* from the blood or infected organ, plus clinical cure, which is defined as resolution of clinical signs of infection which were present at baseline. Additionally, clinical response is assessed by the principal investigator based on the clinical and microbiological resolution of disease.

**Table 1: Overall Response, High APACHE II Score Response, and Principal Investigator (PI) Assessment of Clinical Response at Day 14 and All-Cause Mortality in the mITT Population[a]**

| | Group 1: Rezafungin once weekly 400 mg | Group 2: Rezafungin once weekly 400mg Week 1/200mg | Group 3: Caspofungin once daily 70 mg Day 1/50 mg |
|---|---|---|---|
| | | n (%) | |
| Overall Success (Day 14) | 19/26 (73%) | 22/28 (79%) | 18/26 (69%) |
| Invasive Candidiasis Patients | 1/2 (50%) | 5/5 (100%) | 1/3 (33%) |
| Response: High APACHE II Score Patients | 6/10 (60%) | 8/10 (80%) | 7/12 (58%) |
| Clinical Cure (Day 14) by PI Assessment[b] | 25/32 (78%) | 24/28 (86%) | 20/28 (71%) |
| All Cause Mortality (Day 30)[c] | 5/33 (15%) | 1/31 (3%) | 3/28 (11%) |

[a]Excludes indeterminate responses (inability to assess outcome due to missing data point(s)).
[b]Outcome that most closely approximates the primary outcome in prior candidemia/invasive candidiasis clinical trials.
[c]Primary outcome measure for FDA for planned Phase 3 ReSTORE trial to assess rezafungin in treatment of candidemia and/or invasive candidiasis.

Rezafungin was generally well-tolerated at both dosing regimens. Treatment emergent adverse events were observed in most patients, with an incidence of 88.6 percent in Group 1, 94.4 percent in Group 2, and 81.8 percent in Group 3.

The rates of severe adverse events were 37.1 percent, 27.8 percent, and 39.4 percent, respectively. There were six adverse events leading to study drug discontinuation across all study groups: four in Group 1, one in Group 2 and one in Group 3. Two of the six adverse events were considered possibly related to study drug, one in Group 1 and one in Group 3.

There were two serious adverse events possibly related to study drug: one in Group 2 and one in Group 3, and both patients fully recovered. There were no deaths related to study drug, and there were no concerning trends in System Organ Class groups or specific adverse events.

*Clinical development plans*

Based on the STRIVE Part A trial results, we have initiated one Phase 3 clinical trial of rezafungin, and plan to initiate a second Phase 3 clinical trial:

- Phase 3 ReSTORE Treatment Trial: A single, global, randomized, double-blind, controlled Phase 3 pivotal clinical trial in patients with candidemia and/or invasive candidiasis. The design is similar to the STRIVE trial, except that only rezafungin dosing regimen that will be studied is 400 mg for the first week followed by 200 mg once weekly for up to four weeks in total, in comparison to caspofungin in a 1:1 randomization regime. The primary efficacy outcome for the FDA is all-cause mortality at day 30, and the primary efficacy outcome for the EMA is expected to be global response at day 14. We expect this trial to enroll approximately 184 mITT patients. This trial began in the third quarter of 2018 and we expect to produce topline results in mid-2020.

  With the expected size of the ReSTORE trial, we estimate that the total number of patients exposed to our selected dose and duration of rezafungin treatment will be less than the target safety database of 300 patients. For this reason, as well as to maintain enrollment momentum before the start of the Phase 3 trial, we are continuing enrollment at STRIVE trial sites. This continuation of the STRIVE trial, which we call STRIVE Part B, will evaluate the 400mg/200mg dose selected from the initial portion of the STRIVE trial in comparison to caspofungin in a 2:1 randomization regime. We expect to announce topline results of Part B in the second quarter of 2019.

- Phase 3 ReSPECT Prophylaxis (Prevention) Trial: A single, global, randomized, double-blind, controlled Phase 3 pivotal clinical trial in patients undergoing allogeneic bone marrow transplant to assess rezafungin in a 90-day prophylaxis regimen to prevent infections due to *Candida*, *Aspergillus* and *Pneumocystis*. Subject to approval of the Phase 3 trial by the U.S. and E.U. regulatory authorities, rezafungin will be dosed once weekly and compared to a regimen containing two drugs (an azole and Bactrim) dosed once daily for 90 days. The primary efficacy outcome for the FDA is expected to be fungal-free survival at day 90. The primary efficacy outcome for the EMA

is expected to be prophylaxis success at day 90. We expect this trial to enroll approximately 462 patients. We plan to conduct an interim futility analysis after primary endpoint data is available for approximately 50% of the trial's subjects. Based on these considerations, we expect to commence the trial in the first quarter of 2019.

We also plan to conduct a trial with the National Institutes of Health (NIH) to evaluate safety, tolerability, and pharmacokinetics for a subcutaneous formulation of rezafungin. We expect to commence this study in the first quarter of 2019.

*QT clinical trial*

In March 2018 we also announced the results of our definitive Phase 1 QT clinical trial of rezafungin. The QT clinical trial was a Phase 1, single-center, randomized, comparative study of the effect of single-ascending doses of rezafungin, IV placebo, and a single oral dose of moxifloxacin (positive control) in healthy adult subjects. The primary objective was to assess the effects of rezafungin on QT interval. Secondary objectives included assessments of other cardiac conduction parameters, including PR intervals, QRS intervals and heart rate.

The trial enrolled 60 healthy adult subjects into two cohorts of 30 subjects, each with three dose groups, rezafungin (600 mg IV in Cohort 1 and 1400 mg IV in Cohort 2), IV placebo and oral moxifloxacin. The rezafungin doses of 600 mg and 1400 mg were selected to achieve peak concentrations up to 2.5-fold higher than the expected peak concentration of the 400 mg dose given once-weekly for three weeks. The trial was conducted in accordance with FDA feedback and relevant guidance.

The results of the trial indicated that rezafungin in single doses up to 1400 mg IV had no significant effect on QT prolongation or on any of the other cardiac conduction parameters tested.

*DDI clinical trial*

We conducted a Phase 1 drug-drug interaction study to evaluate the potential effects of rezafungin on other drugs. We evaluated the pharmacokinetics (PK) of several drug combinations with and without rezafungin. The results suggested no clinically significant interactions with any of the drugs tested including: tacrolimus, repaglinide, metformin, rosuvastatin, pitavastatin, caffeine, efavirenz, midazolam and digoxin. Together with *in vitro* experiments, these results indicate that no drug interactions are expected via common drug metabolism or transport pathways.

***Cloudbreak Immunotherapy Platform***

We continue to advance our Cloudbreak immunotherapy platform, which we believe has broad potential applications across a wide spectrum of infectious diseases, including bacterial, fungal and viral infections. We believe that our Cloudbreak immunotherapy platform is a fundamentally new approach for the treatment of infectious disease. We have generated preclinical, *in vivo* proof of concept data in our Cloudbreak antibacterial program and our Cloudbreak antiviral program.

In May 2018, we and Rutgers University were awarded a five year, $5.5 million partnership grant from the U.S. National Institute of Allergy and Infectious Diseases (NAIAD) and the NIH, an agency of the United States Department of Health and Human Services. The grant will fund continued research and development of our Cloudbreak antibody-drug conjugate (ADC) platform to identify novel immunotherapy agents for the treatment and prevention of serious and life-threatening multi-drug resistant (MDR) Gram-negative bacterial infections in high-risk populations. We began work under this grant in July 2018.

## FINANCIAL OPERATIONS OVERVIEW

### *Revenues*

To date, we have not generated any revenues. 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 and CD201 product candidates and our Cloudbreak immunotherapy technology platform, as well as clinical development of rezafungin and CD101 topical. Research and development expenses consist of wages, benefits and stock-based compensation for research and development employees, as well as the cost of scientific consultants, facilities and overhead expenses, laboratory supplies, manufacturing expenses and nonclinical and clinical trial costs. We accrue clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on patient enrollment, completion of studies or activities within studies and other events.

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

We have received potential research and development funding through a grant from CARB-X and a partnership grant from NIAID. We have evaluated the terms of the grants to assess our obligations and the classification of funding received. Amounts received for funded research and development are recognized in the statement of operations as a reduction to research and development expense over the grant period as the related costs are incurred to meet our obligations.

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

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

- per patient trial costs;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the phase of development of the product candidates; 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Rezafungin | $ 6,650 | $ 5,202 | $ 22,025 | $ 18,432 |
| CD101 topical | — | 119 | — | 1,313 |
| Cloudbreak immunotherapy platform | 977 | 731 | 2,219 | 2,610 |
| Personnel costs | 2,857 | 2,622 | 9,354 | 8,211 |
| Other research and development expenses | 794 | 485 | 2,498 | 2,027 |
| Total research and development expenses | $ 11,278 | $ 9,159 | $ 36,096 | $ 32,593 |

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.

In February 2017, we reported results from our Phase 2 clinical trial of CD101 topical, which was designed to evaluate gel and ointment topical formulations of CD101 in women with moderate-to-severe vulvovaginal candidiasis, or VVC. The study found that while the gel and ointment topical formulations of CD101 tested in the study were well tolerated, both formulations were similar in efficacy to each other but lower in clinical and mycological cure rates compared to oral fluconazole. As a result, we discontinued the CD101 topical development program for VVC.

***General and administrative expenses***

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal, business development, commercial planning, and support functions. Other general and administrative expenses include facility and overhead costs not otherwise included in research and development expenses, consultant expenses, travel expenses and professional fees for auditing, tax, legal, and other services.

***Beneficial conversion feature***

For the nine months ended September 30, 2018, we recognized the fair value of an embedded beneficial conversion feature of $10.3 million on the Series X Convertible Preferred Stock issued in connection with the financing transaction that closed on May 23, 2018.

**CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

In March 2017, we entered into a Subaward Agreement with CARB-X, under which CARB-X will reimburse us for qualifying development expenses for CD201. In May 2018, we together with Rutgers University were awarded a partnership grant from the U.S. National Institute of Allergy and Infectious Diseases (NAIAD) and the National Institutes of Health (NIH), an agency of the United States Department of Health and Human Services, under which we will be reimbursed for qualifying expenses for the Company's Cloudbreak ADC platform. We reflect the costs reimbursed under these agreements as a reduction of our research and development expenses. See Notes 2 and 8 to our financial statements for additional information.

In 2017 and 2018, we granted Restricted Stock Units (RSUs) and Performance-based RSUs (PRSUs) to employees. We estimate the fair value of RSUs and PRSUs based on the closing price of the Company's common stock on the date of grant. For awards subject to time-based vesting conditions, stock-based compensation expense is recognized ratably over the requisite service period of the awards. For awards subject to performance-based vesting conditions, we assess the probability of achievement of the individual milestones under the stock-based awards and recognize stock-based compensation expense over the implicit service period commencing once we believe the performance criteria is probable of achievement.

On May 21, 2018, we entered into a securities purchase agreement with certain investors providing for the purchase and sale, in a registered direct offering, of up to an aggregate of $120.0 million of our common stock and preferred stock in

three closings. On May 23, 2018, we completed the first closing, which was comprised of 6,185,987 shares of common stock at an offering price of $4.70 per share, 445,231 shares of Series X Convertible Preferred Stock at an offering price of $47.00 per share, and an option fee relating to the third closing paid by the investors for a total of $0.5 million. In a private placement concurrent with the first closing, we also sold warrants to purchase an aggregate of 12,499,997 shares of common stock at $0.125 per warrant share. Net proceeds for the first closing and the concurrent private placement were $49.5 million. We determined that warrants and future closings represented derivative instruments requiring bifurcation under ASC 815. Accordingly, we determined a fair value for each component of the securities purchase agreement and allocated the expected proceeds across each component on a relative fair value basis. Key estimates within the valuation include the expected timing for completion and estimated probability of success of our STRIVE Part B study. See Note 4 of the Notes to the Financial Statements for additional information.

The preparation of our 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 reported periods. We believe that the estimates, assumptions and judgments involved in the accounting policies described in Management's Discussion and Analysis of Financial Condition and Results of Operations and under Note 2 to our financial statements contained in our Annual Report have the greatest potential impact on our financial statements, so we consider them to be our critical accounting policies and estimates. Other than our accounting for those items discussed above, there were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2018.

## RESULTS OF OPERATIONS

***Comparison of the three months ended September 30, 2018 and 2017***

The following table summarizes our results of operations for the three months ended September 30, 2018 and 2017 (in thousands):

| | Three Months Ended September 30, | | |
|---|---|---|---|
| | 2018 | 2017 | Change |
| Research and development | $ 11,278 | $ 9,159 | $ 2,119 |
| General and administrative | 3,447 | 3,090 | 357 |
| Other income (expense), net | 1,106 | (8) | 1,114 |

*Research and development expenses*

Research and development expenses were $11.3 million for the three months ended September 30, 2018, compared to $9.2 million for the three months ended September 30, 2017. The increase in research and development expense is primarily due to higher clinical expenses associated with the rezafungin STRIVE study and start up activities associated with the ReSTORE and ReSPECT studies, as well as higher personnel costs.

*General and administrative expenses*

General and administrative expenses were $3.4 million for the three months ended September 30, 2018 and $3.1 million for the three months ended September 30, 2017. The increase in general and administrative expense is primarily due to higher legal and consulting expense.

*Other Income (Expense)*

Other income during the three month period ended September 30, 2018 related primarily to the $0.9 million change in the fair value of the contingent forward purchase obligations. Other expense during the three month periods ended September 30, 2018 and 2017 also included interest expense incurred in connection with our loan from Pacific Western Bank and income generated from cash held in interest-bearing investments.

***Comparison of the nine months ended September 30, 2018 and 2017***

The following table summarizes our results of operations for the nine months ended September 30, 2018 and 2017 (in thousands):

| | Nine Months Ended September 30, | | |
|---|---|---|---|
| | 2018 | 2017 | Change |
| Research and development | $ 36,096 | $ 32,593 | $ 3,503 |
| General and administrative | 10,591 | 9,669 | 922 |
| Other income (expense), net | 13 | (38) | 51 |

*Research and development expenses*

Research and development expenses were $36.1 million for the nine months ended September 30, 2018 compared to $32.6 million for the nine months ended September 30, 2017. The increase in research and development expense is primarily due to higher clinical expenses associated with rezafungin, which was partially offset by decreases in CD101 topical expenses due to the discontinuation of that program in February 2017.

*General and administrative expenses*

General and administrative expenses were $10.6 million for the nine months ended September 30, 2018 and $9.7 million for the nine months ended September 30, 2017. The increase in general and administrative expense is primarily due to higher legal and consulting expense.

*Other Income (Expense)*

Other income for the nine month period ended September 30, 2018 related primarily to income generated from cash held in interest-bearing investments partially offset by interest expense in connection with our loan from Pacific Western Bank, the change in the fair value of the contingent forward purchase obligation and related issuance costs. Other expense during the nine month period ended September 30, 2017 included interest expense incurred in connection with our loan from Pacific Western Bank and income generated from cash held in interest-bearing investments.

**LIQUIDITY AND CAPITAL RESOURCES**

Since our inception through October 31, 2018, we have received $269.4 million in gross proceeds to fund our operations, primarily through private placements of convertible preferred stock, convertible notes, our initial public offering, our entry into a debt facility in October 2016 with Pacific Western Bank, our October 2016 public offering of common stock, our October 2017 private placement of common stock, sales of common stock under our controlled equity sales agreement, and our May 2018 registered direct offering.

As of September 30, 2018, we had $83.8 million in cash and cash equivalents and $4.5 million in short term investments. The following table shows a summary of our cash flows for the nine months ended September 30, 2018 and 2017 (in thousands):

| | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Net cash provided by (used in): | | |
| Operating activities | $ (43,039) | $ (40,418) |
| Investing activities | 9,841 | 9,254 |
| Financing activities | 56,165 | 73 |
| Net increase (decrease) in cash and cash equivalents | $ 22,967 | $ (31,091) |

*Operating activities*

Net cash used in operating activities was $43.0 million for the nine months ended September 30, 2018, compared to $40.4 million for the nine months ended September 30, 2017. The increase in net cash used in operating activities was attributable primarily to our net loss of $46.7 million for the nine months ended September 30, 2018 compared to a net loss of $42.3 million for the nine months ended September 30, 2017. 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 primary investing activities during the nine months ended September 30, 2018 and 2017 consisted of purchases and maturities of short-term investments. For the nine months ended September 30, 2018 and 2017, we received proceeds of $24.5 million and $19.3 million, respectively, from the maturity of short-term investments. We purchased approximately $14.5 million and $9.9 million of short-term investments during the nine months ended September 30, 2018 and 2017, respectively.

*Financing activities*

Net cash provided by financing activities during the nine months ended September 30, 2018 primarily consisted of net proceeds from the sale of common stock, Series X Convertible Preferred Stock, and warrants.

***Operating Capital Requirements***

To continue to fund operations, we will need to raise additional capital. We may obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings, through government funding or through collaborations or partnerships with other companies. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts, make reductions in spending, extend payment terms with suppliers, liquidate or grant rights to assets where possible or suspend or curtail planned programs. Any of these actions could materially harm our business, results of operations and future prospects.

Management performed an analysis of our ability to continue as a going concern. We believe, based on our current operating plans, that our existing cash, cash equivalents and marketable securities, potential proceeds from the second and third tranches of our May 2018 registered direct offering, and anticipated interest income will be sufficient to fund our operating expenses and capital expenditure requirements through at least the next twelve months.

Our ability to successfully transition to profitability will be dependent upon achieving a level of product sales adequate to support our cost structure. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

***Off-Balance Sheet Arrangements***

As of September 30, 2018, we did not have any off-balance sheet arrangements.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not required for smaller companies.

## 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 and 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 September 30, 2018, we carried out an evaluation under the supervision and with the participation of our management, including our principal executive and 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 and financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2018.

***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 and 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

*You should carefully consider the following risk factors, as well as the other information in this 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 Our Financial Position and Need for Additional Capital

***We are an early stage biotechnology company that has incurred significant operating losses since our inception and we anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or maintain profitability.***

Since our inception, we have incurred significant operating losses. Our net loss was $46.7 million and $42.3 million for the nine month periods ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $206.4 million. To date, we have financed our operations primarily through private placements of convertible preferred stock and convertible notes, our initial public offering of our common stock, or our IPO, our October 2016 term loan facility with Pacific Western Bank, or Pacific Western, our October 2016 follow-on public offering of common stock, our October 2017 private placement of common stock, sales of common stock during the fourth quarter of 2017 and the first quarter of 2018 under our controlled equity sales agreement with Cantor Fitzgerald & Co., which has since been terminated, and our May 2018 registered direct offering of common stock. We have devoted substantially all of our financial resources and efforts to research and development. We have completed Part A of our STRIVE Phase 2 clinical trial of rezafungin and we are conducting Part B of the STRIVE study, the ReSTORE Phase 3 clinical trial of rezafungin, Phase 1 and non-clinical studies of rezafungin and preclinical studies of our ADCs, and we are planning to conduct a Phase 3 clinical trial of rezafungin for the prevention of invasive fungal infections. We expect that it will be many years, if ever, before we receive regulatory approval and have a product candidate available for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- submit INDs to the FDA and equivalent filings to other regulatory authorities and seek approval of our clinical protocols by institutional review boards, or IRBs, at clinical trial sites;
- continue to advance rezafungin through clinical development;
- continue the preclinical development of our ADCs or any other product candidates from our Cloudbreak immunotherapy platform or otherwise, and advance one or more of such product candidates into clinical trials;
- seek marketing approvals for our 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 the value of the company 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.

***We will need substantial additional funding to advance the development of our product candidates. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our drug development and discovery programs or commercialization efforts.***

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate clinical trials of and seek marketing approval for our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution of the approved product. Furthermore, we expect to incur additional costs associated with operating as a public company. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our product candidates and Cloudbreak platform;
- the costs, timing and outcome of any regulatory review of our product candidates;
- the costs and timing of commercialization activities, including manufacturing, marketing, sales and distribution, for any 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;
- our ability to establish and maintain collaborations, when and if necessary, on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential development candidates and conducting preclinical studies and clinical trials are time consuming, expensive and uncertain processes that take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales for any of our current or future product candidates. In addition, our product candidates, if approved, may not achieve commercial success.

Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, we will need substantial additional funding in connection with our continuing operations and to achieve our goals. Since December 6, 2012 (inception) through September 30, 2018, our operations have been financed primarily by gross proceeds of approximately $269.4 million from the issuance of convertible debt securities, the sale of shares of convertible preferred stock, the sale of shares of our common stock in our IPO, our October 2016 term loan facility with Pacific Western, our October 2016 follow-on public offering of common stock, our October 2017 private placement of common stock, sales of common stock during the fourth quarter of 2017 and the first quarter of 2018 under our controlled equity sales agreement with Cantor Fitzgerald & Co., which has since been terminated, and our May 2018 registered direct offering of common stock. As of September 30, 2018, we had $83.8 million in cash and cash equivalents and $4.5 million in short term investments.

We have prepared cash flow forecasts which indicate, based on current cash resources available, that we will have sufficient resources to fund our business for at least the next 12 months from the issuance of these financial statements. We plan to continue to fund our operating expenses and capital expenditure requirements through debt and equity financing, through government funding or through collaborations or partnerships with other entities. Debt or equity financing, government funding or collaborations and partnerships with other entities may not be available on a timely basis, on acceptable terms, or at all.

For example, investors that participated in our May 2018 registered direct offering are required to invest $50 million on a pro rata basis in a second closing triggered by our receipt of topline data from Part B of the STRIVE study, and those investors also have the option to invest an additional $20 million on a pro rata basis at such time, in each case subject to certain conditions. The price at which we would sell common stock in the second and optional third closings would be 75% of the volume weighted average price of our common stock for the five trading days following our announcement of

topline data from Part B of the STRIVE clinical trial. However, if such price at which we would sell the common stock to investors is less than $4.70, which was the price of the common stock in the initial closing, we would be required to obtain the approval of our stockholders prior to the second or optional third closing. The stockholder approval process could be lengthy and expensive, and there is no assurance that the stockholders would provide their approval. Further, investors from the first closing may refuse to participate in the second closing or may decline the option to participate in the optional third closing.

If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts, make reductions in spending, extend payment terms with suppliers, liquidate or grant rights to assets where possible or suspend or curtail planned programs.

Any of these actions could materially harm our business, results of operations and future prospects. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional financing due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our operating plans.

***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 and debt financings, as well as potentially entering into collaborations, strategic alliances and licensing arrangements or receiving government and/or charitable grants or contracts. Other than our term loan facility with Pacific Western and the obligation of the investors from our May 2018 registered direct offering to participate in the second closing after we announce data from Part B of the STRIVE study, each of which is subject to the fulfillment of specified conditions, we do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, 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. There can be no assurances that we will be able to enter into contracts with or receive grants from the United States government or charitable organizations to support our programs. The process of obtaining grants and contracts is lengthy and uncertain and we will have to compete with other companies and institutions for each grant or contract. United States government grants and contracts typically contain unfavorable termination provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. If we receive a United States government grant or contract, we would be required to comply with numerous laws and regulations relating to the formation, administration and performance of the grant or contract, which can make it more difficult for us to retain our rights under such grant or contract and result in increased costs. If we raise funds by entering into collaborations, strategic alliances or licensing arrangements with third parties or by receiving charitable grants, 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. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances, licensing arrangements or government or charitable programs when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***Our short operating history may make it difficult for you to evaluate the success of our business to date and assess our future viability.***

We were founded in December 2012 and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential development and product candidates, undertaking preclinical studies and conducting clinical trials. We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials required for regulatory approval of our product candidates, obtain marketing approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes many years to develop one new product from the time it is discovered to when it is commercially available. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or if we had product candidates in advanced clinical trials.

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

***The terms of our term loan facility place restrictions on our operating and financial flexibility and failure to comply with covenants or to satisfy certain conditions of the agreement governing the debt facility may result in acceleration of our repayment obligations and foreclosure on our pledged assets, which could significantly harm our liquidity, financial condition, operating results, business and prospects and cause the price of our common stock to decline.***

In October 2016, we entered into a loan and security agreement with Pacific Western, or the Loan Agreement, as amended in June 2018 and July 2018, under which we borrowed $10.0 million, subject to certain terms and conditions set forth therein.

The outstanding principal balance under the Loan Agreement is secured by a security interest in substantially all of our assets, other than intellectual property, which is subject to a double negative pledge. The Loan Agreement requires us to comply with a number of customary affirmative and restrictive covenants, including covenants that limit our ability to, among other things: transfer any part of our business or property; merge or consolidate with another entity or otherwise experience a change in control, incur additional indebtedness; encumber the collateral securing the loan, declare or pay any cash dividend or make distributions on our capital stock, repurchase or redeem any class of stock or other equity interest, acquire, own or make investments, and make certain capitalized expenditures over a specified threshold, in each case subject to exceptions. In addition, the Loan Agreement contains an operating covenant, which requires us to achieve positive data from Part B of the STRIVE clinical trial of rezafungin on or before July 31, 2019. The Loan Agreement also includes standard events of default, including a provision that Pacific Western could declare an event of default upon the occurrence of any event that it interprets as having a material adverse effect on (i) our operations, business or financial condition and subsidiaries taken as a whole; (ii) our ability to perform or pay the secured obligations under the Loan Agreement and related agreements; or (iii) the collateral pledged to Pacific Western under the Loan Agreement. Upon such determination, Pacific Western could declare all obligations under the Loan Agreement immediately due and payable. Although, in and of itself, the occurrence of adverse results or delays in any clinical study or the denial, delay or limitation of approval of or taking of any other regulatory action by the FDA or another governmental entity will not constitute a material adverse effect under the Loan Agreement, Pacific Western may determine that such an event together with contemporaneous events or circumstances constitutes a material adverse effect upon our business, operations, properties, assets, or financial condition or upon our ability to perform or pay the secured obligations under the Loan Agreement. If we default under the facility, Pacific Western may accelerate all of our repayment obligations. At such time, we may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required. If we are unable to access funds to meet those obligations or to renegotiate the Loan Agreement, Pacific Western could take control of and may sell our pledged assets. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. If our assets were liquidated, Pacific Western's right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration by Pacific Western of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

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

## Risks Related to Drug Discovery, Development and Commercialization

***We are very early in our development efforts, which may not be successful.***

We have completed three Phase 1 clinical trials of rezafungin, as well as Part A of the STRIVE Phase 2 clinical trial of rezafungin in candidemia and invasive candidiasis. We are also conducting preclinical studies of antibody-drug conjugates, or ADCs, from our Cloudbreak program for viral infections and infections caused by multidrug-resistant Gram-negative pathogens. Because of the early stage of our development efforts, the timing and costs of the clinical development and regulatory paths we will follow and marketing approvals remain uncertain. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of rezafungin and any other product candidates we may develop will depend on many factors, including the following:

- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials;
- demonstrating safety and efficacy;

- receipt of marketing approvals from applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and technologies;
- launching commercial sales of the product candidates, if and when approved, whether alone or selectively in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payers;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not accomplish one or more of these goals in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

***If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, 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 failure of one or more clinical trials could occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a particular clinical trial do not necessarily predict final results of that trial. For example, the fact that Part A of the STRIVE study met its primary objectives related to tolerability and safety of rezafungin in the treatment of candidemia and invasive candidiasis does not guarantee success in the ongoing Part B of the STRIVE study or in our planned Phase 3 trials in treatment and prophylaxis of invasive fungal infections.

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 antifungals, antibacterials and other 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 may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including that:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or in a given country;
- 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 or institutional review boards 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 studies due to financial constraints.

We plan to conduct an interim futility analysis for our Phase 3 ReSPECT Prophylaxis (Prevention) Trial after primary endpoint data is available for approximately 230 subjects. The futility analysis will be conducted based on conditional power. If the conditional power is below a pre-specified cutoff for both primary endpoints, the study may be stopped for futility. Alternatively, based on the aggregate rate of fungal-free survival at the day 90 visit, we may choose to increase the ReSPECT study's sample size. In addition, based on discussions with current and potential collaborators, we may consider changes to the study design to assess efficacy and safety in alternative or additional populations. These discussions and potential design changes could lead to delays in the commencement and completion of the ReSPECT study.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or analogous regulatory authorities outside the United States or if we do not believe that the number of patients required by such regulatory agencies in any clinical trial can be enrolled in a reasonable timeframe. In addition, some of our competitors may have ongoing or new clinical trials for product candidates that would treat the same indications as our product candidates 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 is also affected by other factors, including:

- severity of the disease under investigation;
- availability, safety and efficacy of approved medications or other investigational medications being studied clinically for the disease under investigation;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under study;

- 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 our product candidates address.

Our inability to enroll a sufficient number of patients for our clinical trials, or to enroll such patients in a timely manner, would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and could limit our ability to obtain additional financing.

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

Because it is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval, the risk of each of our programs is high. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. For example, the pharmacokinetic properties, such as a longer half-life or less frequent dosing regimen, that differentiate rezafungin from other echinocandins could have side effects that we have not anticipated and the consequences of such side effects could be more severe than have been seen with other echinocandins that have shorter half-lives or more frequent dosing regimens or are dosed at lower concentrations than we expect for rezafungin. Further, the treatment advantages that we are predicting for rezafungin, such as lower healthcare costs resulting from an ability to administer rezafungin once-weekly or the predicted ability of rezafungin to be effective against resistant strains of fungal pathogens, may not be realized. For our ADCs, 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, fungal and bacterial infections can occur in patients with co-morbidities and weakened immune systems, and there may be adverse events and deaths in our clinical trials that are attributable to factors other than investigational use of our product candidates.

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

We have limited financial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential than opportunities we pursue. For example, because we believe that an NDA filing for rezafungin for prophylaxis can be supported by one Phase 3 trial in prophylaxis, together with the data from our planned Phase 3 clinical trial in the treatment of candidemia and invasive candidiasis and the remainder of our rezafungin treatment program, if financial constraints require us to choose between our planned rezafungin treatment and prophylaxis programs, we may be required to choose our treatment program and forego or delay our prophylaxis program.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target markets for a particular product candidate or opportunity, we may relinquish valuable rights to that product candidate or opportunity through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or opportunity.

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

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers 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 agency;
- 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 coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

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

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product, we must either develop a sales and marketing organization or outsource these functions to third parties.

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

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

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

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

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

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Regulatory incentives to develop drugs for treatment of infectious diseases have increased interest and activity in this area and will lead to increased competition for clinical investigators and clinical trial subjects, as well as for future prescriptions, if any of our product candidates are successfully developed and approved. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are

pursuing the development of products for the treatment of the indications on which we are focusing our product development efforts. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Rezafungin will primarily compete with antifungal classes for the treatment and prevention of systemic fungal infections such as candidemia and invasive candidiasis, which include polyenes, azoles and echinocandins. Approved branded echinocandin antifungal therapies include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer Inc.) and Mycamine (micafungin, marketed by Astellas Pharma US, Inc.). We expect that there will be generics of all of the current echinocandins available at the time of rezafungin market approval, which will create added competition. In addition, there are other generic products approved for candidemia, marketed by companies such as Baxter Healthcare Corporation, Mylan Inc. and Glenmark Generics Inc., among others. In addition to approved therapies, we expect that rezafungin will compete with product candidates that we are aware of in clinical development by third parties, such as SCY-078 (being developed by Scynexis, Inc.).

Our ADCs will compete against approved and investigational agents for the treatment or prevention of bacterial and viral infections. We may develop other product candidates from our Cloudbreak immunotherapy platform for the treatment or prevention of invasive bacterial, fungal or viral infections. We are aware of a number of approved and investigational therapies in these areas.

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

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

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

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health programs, private health insurers, integrated delivery networks and other third-party payers. Third-party payers 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 payers have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payers are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient for commercial success. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval.

If coverage and reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and adequate reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for coverage and reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Coverage and reimbursement rates may vary according to the use of the drug and the medical circumstances under which it is used may be based on reimbursement levels already set for lower cost products or procedures or may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payers and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Commercial third-party payers 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 payers for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

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

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

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

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

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees in our workplace, including those resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic

tort claims that may be asserted against us in connection with our storage or disposal of biological, chemical, hazardous or radioactive materials.

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

***We may not be successful in our efforts to identify, discover, in-license or acquire potential product candidates.***

We are developing our ADCs for the treatment of viral infections and multidrug-resistant bacterial infections, including those caused by pathogens harboring the *mcr-1* gene. We currently do not have any development candidates from the Cloudbreak platform. Our Cloudbreak immunotherapy platform and other drug discovery efforts may not be successful in identifying additional molecules that could be developed as drug therapies. Our research programs may initially show promise in identifying such 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, financial and human resources. We may choose to focus our efforts and resources on potential product candidates that ultimately prove to be unsuccessful. If we are unable to identify, in-license or acquire suitable compounds for preclinical and clinical development, we will not be able to generate product revenue, which would harm our financial position and adversely impact our stock price.

## Risks Related to Our Dependence on Third Parties

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

We currently rely and expect to continue to rely on third parties, such as contract research organizations, contract manufacturers of clinical supplies, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials and to conduct some aspects of our research and preclinical testing. Any 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 agencies require us to comply with standards, commonly referred to as Good Clinical Practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, available at www.clinicaltrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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

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

We may be unable to establish agreements with third-party manufacturers for preclinical, clinical or commercial supply on terms favorable to us, or at all. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;

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

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

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

Any performance failure on the part of our existing or future manufacturers, including a failure that may not relate specifically to our product candidate or approved product, could delay clinical development or marketing approval or adversely impact our ability to generate commercial sales. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer.

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

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

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

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

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

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We do not currently have any such collaborations.

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

***To the extent we enter into any collaborations, we may depend on collaborators for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of our product candidates.***

We may selectively seek third-party collaborators for the development and commercialization of our product candidates. Our likely potential collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We do not currently have any such arrangements and if we enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates pose many risks to us, including that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates or products 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;
- a collaborator with marketing and distribution rights to one or more product candidates or products may not commit sufficient resources to the marketing and distribution of such drugs;
- collaborators may not properly maintain or defend our intellectual property rights or may use our 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;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or products or that result in costly litigation or arbitration that diverts management attention and resources;
- we may lose certain valuable rights under circumstances identified in our collaboration agreements if we undergo a change of control;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all; and
- if a future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

If our ability to generate revenue under any of our collaboration agreements is adversely impacted by any of these risks, our share of the revenues generated by the product, if approved, under the terms of the collaboration could be insufficient to allow us to achieve or maintain profitability or the product may be less valuable to us than if we had not entered into the collaboration.

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

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

There are a number of incentive programs administered by the FDA and other regulatory bodies to facilitate development of drugs in areas of unmet medical need. Rezafungin received the designations as a Qualified Infectious Disease Product, or QIDP, a fast track product and an orphan drug in the U.S. for the treatment of candidemia and invasive candidiasis Rezafungin also received QIPD and Fast Track designation in the U.S. for the development of rezafungin for the prevention of invasive fungal infections in adults undergoing allogeneic bone marrow transplantation. We have also either applied for or are planning to seek orphan drug designation for rezafungin for treatment and prophylaxis in Europe. Our product candidates may not qualify for or maintain designations under these or other incentive programs under any of the FDA's existing or future programs to expedite drug development in areas of unmet medical need. Our inability to fully take advantage of these incentive programs may require us to run larger trials, incur delays, lose opportunities that may not otherwise be available to us, lose marketing exclusivity for which we would otherwise be eligible and incur greater expense in the development of our product candidates.

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

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

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

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

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

Any product candidate for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of promotional materials and safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements for product facilities, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and related recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. 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 payers will 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 payers 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 payers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute our medicines for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following, among others:

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

- HIPAA, as amended by HITECH, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute enacted under HIPAA, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements under the Affordable Care Act, which require, among other things, certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous state 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 payers, including private insurers, and 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 or marketing expenditures.

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

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

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, in March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to, among other things, broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Affordable Care Act and subsequent regulations revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners. Since its enactment there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal and replace certain aspects of the Affordable Care Act and we expect such challenges to continue. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been enacted. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain fees mandated by the Affordable Care Act, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans and also increases in 2019 the percentage that a drug manufacturer must discount the cost of prescription drugs from 50 percent under current law to 70 percent. Congress also could consider additional legislation to repeal or repeal and replace other elements of the Affordable Care Act. Although the full effect of the Affordable Care Act remains uncertain, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, there have been several recent Congressional inquiries and proposed and enacted 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. Further, the Trump administration's budget proposal for fiscal year 2019 contains additional drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid and to eliminate cost sharing for generic drugs for low-income patients. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing 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 United States in the future, any of which could add difficulty to the regulatory approval processes for our product candidates or limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. The continuing efforts of third-party payors to contain or reduce costs of healthcare may adversely affect the demand for any drug products for which we may obtain regulatory approval, our ability to set a price that we believe is fair for our products, our ability to obtain coverage and reimbursement approval for a product, our ability to generate revenues and achieve or maintain profitability and the level of taxes that we are required to pay.

## Risks Related to Our Intellectual Property

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

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

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain and our commercial success will depend on our ability to obtain patents and maintain adequate protection for rezafungin, our ADCs and other compounds and product candidates in the United States and other countries. We currently hold issued U.S. utility and foreign patents and multiple pending U.S. utility patent applications, pending U.S. provisional patent applications and pending international, foreign national and regional counterpart patent applications covering various aspects of rezafungin, our ADCs and our Cloudbreak immunotherapy platform and other technology. The patent applications may fail to result in issued patents in the United States or in foreign countries or jurisdictions. Even if the applications do successfully issue, third parties may challenge the patents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Interference proceedings or derivative proceedings provoked by third parties or brought by the USPTO may be necessary to determine the entitlement to patent protection with respect to our patents or patent applications. An unfavorable outcome could result in a loss of our patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or patent office proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws or legal process may not protect those rights as fully as in the United States.

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

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

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

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

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

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

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

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

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

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

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

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

****Provisions in our contract with the Trustees of Boston University, or BU, relating to the Combating Antibiotic Resistant Bacteria Accelerator, or CARB-X, program, required by the U.S. government or the Wellcome Trust may affect our intellectual property rights.***

Certain of our activities relating to our Cloudbreak program are subject to the terms and conditions of our Cost Reimbursement Research Subaward Agreement, or the CARB-X Subaward Agreement, with the Trustees of Boston University. CARB-X is funded by the U.S. Biomedical Advanced Research and Development Authority, or BARDA, and the Wellcome Trust, or Wellcome, a global charitable foundation. When new technologies are developed with U.S. government funding, the government obtains certain rights in any resulting patents, including the right to a nonexclusive license authorizing the government to use the invention. These rights may permit the government to disclose our

confidential information to third parties and to exercise "march-in" rights to use or allow third parties to use our patented technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the U.S. government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations or to give preference to U.S. industry. In addition, U.S. government-funded inventions must be reported to the government, U.S. government funding must be disclosed in any resulting patent applications and our rights in such inventions may be subject to certain requirements to manufacture products in the U.S.

In addition, subject to such march-in rights, if we have not exploited or further developed intellectual property rights relating to the product candidates subject to reimbursement under the CARB-X program by the date that is five years after the end of the activities funded by CARB-X under the CARB-X Subaward Agreement in any country, Wellcome will have the option to take responsibility for the exclusive commercialization and exploitation of such intellectual property rights in such country. In such event, such intellectual property rights relating to such country will be assigned to Wellcome and Wellcome will share revenues and equity holdings relating to such exploitation with us on a 50%/50% basis, net of Wellcome's related costs. In the event we license such intellectual property rights to a third party prior to the exercise of such option rights by Wellcome, such option rights shall terminate, provided that the third party license agreement contains a requirement for the licensee to use diligent efforts to exploit such intellectual property rights, with a reversion right to us in the event of a violation of such diligence requirement and provided that Wellcome has approved such third party license agreement in writing.

If the U.S. government or Wellcome takes any of these actions with respect to our intellectual property rights, such actions may adversely impact our product candidates or our ability to develop future candidates, we may be unable to obtain a significant commercial advantage from our intellectual property and our potential revenue opportunities could be limited substantially.

**Risks Related to U.S. Government Contracts and Grants**

***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.

***If we do not receive all of the funds under our CARB-X Subaward Agreement or are unable to generate additional revenues from additional contracts, we may be forced to suspend or terminate one or more of our preclinical programs.***

A substantial amount of our development activities relating to our CD201 program were funded under our CARB-X Subaward Agreement. Based on our decision to cease development of CD201, we will no longer be seeking funding for CD201 under this agreement. We have been awarded a partnership grant with Rutgers University from NIAID for our ADC program, and we may also seek funding under our CARB-X agreement for the ADC program. Each of these contracts is expected to cover only a portion of our Cloudbreak development expenses. There can be no assurances that we will be able to enter into new contracts with the United States government or other sources of funding to support any program resulting from our Cloudbreak platform. The process of obtaining government contracts is lengthy and uncertain and we will have to compete with other companies and institutions for each contract. Further, 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 programs, we may be forced to discontinue those programs.

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

United States government agencies routinely audit and investigate government contractors and recipients of Federal grants. These agencies review a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards. BU also has the right to audit our activities under our CARB-X Subaward Agreement.

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

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

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

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

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

We must comply with numerous laws and regulations relating to the formation, administration and performance of government contracts, which can make it more difficult for us to retain our rights under 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 maintain our existing CARB-X Subaward Agreement and obtain new contracts, which could limit our ability to conduct our business and materially adversely affect our results of operations.

## Risks Related to Employee Matters and Managing Growth

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

We are highly dependent upon our senior management team, as well as the other principal members of our research and development teams. All of our executive officers are employed "at will," meaning we or they may terminate the employment relationship at any time. We maintain "key person" insurance for our Chief Executive Officer but not for any of our other 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 likely to be highly volatile and could be 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:

- the commencement, timing, enrollment or results of the current and planned clinical trials of our product candidates or any future clinical trials we may conduct or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter, "complete response" letter, or a request for additional information;
- adverse results, suspensions, terminations or delays in pre-clinical or clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial or development program;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to requirements for approvals;
- 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;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future or the expectation of such sales;
- the trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patent rights, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The Nasdaq Global Market and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our

common stock, regardless of our actual operating performance. You may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

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

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

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

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

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company through 2020, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (a) December 31, 2020, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1 billion, (c) the last day of the fiscal year in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th and (d) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

***We incur significant costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives.***

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, which require, among other things, that we file with the Securities and Exchange Commission, or the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this legislation but cannot guarantee that we will not be required to implement these requirements

sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the political environment and the level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We had 27,751,413 shares of common stock outstanding as of September 30, 2018. 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 expect that significant additional capital may be needed in the future to continue our planned operations, 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, investors may be materially diluted by subsequent sales and new investors could gain rights, preferences and privileges senior to our existing stockholders. For example, investors that participated in our May 2018 registered direct offering are required to invest $50 million on a pro rata basis in a second closing triggered by our receipt of topline data from Part B of the STRIVE study, and those investors also have the option to invest an additional $20 million on a pro rata basis at such time, in each case subject to certain conditions. The price at which we would sell common stock in the second and optional third closings would be 75% of the volume weighted average price of our common stock for the five trading days following our announcement of topline data from Part B of the STRIVE clinical trial.

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

to increase the number of shares available for future grant each year under the 2015 EIP and the ESPP, our stockholders may experience additional dilution, which could cause our stock price to fall.

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

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

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

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

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

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

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

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and

other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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

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

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of capital raising and other transactions that have occurred since our inception in 2012, we may or may not have experienced an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As of December 31, 2017, we had U.S. net operating loss carryforwards of approximately $122.5 million, which begin to expire in 2033, which could be limited if we experience an "ownership change."

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

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

***Our operations are vulnerable to interruption by natural disasters, power loss, terrorist activity 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 vulnerable to a major earthquake, wildfire, inclement weather and other natural and man-made disasters and we have not undertaken a systematic analysis of the potential consequences to our business as a result of any such natural disaster and do not have an applicable recovery plan in place. 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

***Recent Sales of Unregistered Securities***

None.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

## ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

**ITEM 5. OTHER INFORMATION**

None.

**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 |
| 4.4(4) | Form of Common Stock Purchase Warrant for Second Private Placement |
| 10.1(5) | Second Amendment to Loan and Security Agreement by and between the Registrant and Pacific Western Bank, dated July 27, 2018. |
| 31.1 | Certification of the Principal Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934. |
| 32.1 | Certification of the Chief Executive Officer pursuant to 18 U.S.C. Section 1350 and Rule 13a-14(B) promulgated under the Securities Exchange Act of 1934. |
| 101.INS | XBRL Instance Document. |
| 101.SCH | XBRL Taxonomy Extension Schema Document. |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document. |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document. |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document. |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document. |

(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.
(5) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed on July 31, 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: November 8, 2018

By: /s/ Jeffrey Stein, Ph.D.
Jeffrey Stein, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my 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: November 8, 2018

/s/ Jeffrey Stein, Ph.D.

Jeffrey Stein, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial 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 September 30, 2018 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 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: November 8, 2018

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

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.