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 MARCH 31, 2016

☐ **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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark whether registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

As of April 30, 2016, the registrant had 13,854,792 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 par value amounts)	March 31, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 51,704	$ 62,562
Short-term investments	44,954	44,952
Prepaid expenses and other current assets	859	704
Total current assets	97,517	108,218
Property and equipment, net	1,634	1,684
Other assets	72	72
Total assets	$ 99,223	$ 109,974
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,266	$ 3,095
Accrued liabilities	1,545	1,415
Accrued compensation and benefits	1,245	1,464
Total current liabilities	4,056	5,974
Other long-term liabilities	89	88
Total liabilities	4,145	6,062
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued or outstanding at March 31, 2016 and December 31, 2015, respectively	-	-
Common stock, $0.0001 par value; 200,000,000 shares authorized at March 31, 2016 and December 31, 2015, respectively; 13,960,501 and 13,839,792 shares issued and outstanding, respectively, at March 31, 2016; 13,942,520 and 13,786,285 shares issued and outstanding, respectively, at December 31, 2015	1	1
Additional paid-in capital	150,365	149,416
Accumulated other comprehensive loss	(2)	(8)
Accumulated deficit	(55,286)	(45,497)
Total stockholders' equity	95,078	103,912
Total liabilities and stockholders' equity	$ 99,223	$ 109,974

See accompanying notes.

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

(In thousands, except share and per share data)	Three months ended March 31, 2016	2015
Operating expenses:		
Research and development	$ 7,189	$ 4,935
General and administrative	2,696	1,797
Total operating expenses	9,885	6,732
Loss from operations	(9,885)	(6,732)
Other income (expense):		
Interest income (expense), net	96	(5)
Total other income (expense)	96	(5)
Net loss	$ (9,789)	$ (6,737)
Other comprehensive income:		
Unrealized gain on short-term investments	6	-
Comprehensive loss	$ (9,783)	$ (6,737)
Basic and diluted net loss per share	$ (0.71)	$ (5.92)
Shares used to compute basic and diluted net loss per share	13,807,825	1,138,911

See accompanying notes.

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

(In thousands)	Three months ended March 31, 2016	2015
Operating activities:		
Net loss	$ (9,789)	$ (6,737)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	179	91
Stock-based compensation	833	639
Amortization of discount or premium on short-term investments	(37)	-
Amortization of debt issue costs	-	6
Deferred rent	1	(4)
Changes in assets and liabilities:		
Prepaid expenses and other current assets	(155)	(44)
Accounts payable and accrued liabilities	(1,699)	38
Accrued compensation	(219)	(41)
Net cash used in operating activities	(10,886)	(6,052)
Investing activities:		
Purchases of short-term investments	(9,959)	-
Maturities of short-term investments	10,000	-
Purchases of property and equipment	(54)	(31)
Net cash used in investing activities	(13)	(31)
Financing activities:		
Proceeds from issuance of Series B convertible preferred stock, net of offering costs	-	41,921
Deferred initial public offering costs	-	(626)
Proceeds from exercise of stock options	41	116
Net cash provided by financing activities	41	41,411
Net increase (decrease) in cash and cash equivalents	(10,858)	35,328
Cash and cash equivalents at beginning of period	62,562	22,796
Cash and cash equivalents at end of period	$ 51,704	$ 58,124
Non-cash investing activity:		
Property and equipment acquired but not yet paid	$ 74	$ 22
Non-cash financing activities:		
Deferred initial public offering costs incurred but not yet paid	$ -	$ 490
Vesting of early exercised stock options	$ 75	$ -

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 initial product portfolio is comprised of proprietary product candidates for the treatment of serious fungal infections.

In March 2016, the Company formed a wholly-owned subsidiary, Cidara Therapeutics UK Limited, in England 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 March 31, 2016, the Company had an accumulated deficit of $55.3 million. The Company expects to continue to incur net losses into the foreseeable future. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. The Company plans to continue to fund its losses from operations and capital funding needs through debt and equity financing or through collaborations or partnerships with other companies. Debt or equity financing or collaborations and partnerships with other companies 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 make reductions in spending, extend payment terms with suppliers, liquidate 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 accounting principles generally accepted in the United States, or GAAP, as found in the Accounting Standards Codification, or ASC, of the Financial Accounting Standards Board, or FASB. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim condensed consolidated financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended March 31, 2016 and 2015.

Basis of Consolidation—The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. 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, 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 financial statements relate to estimating the fair value of the Company's common shares used to account for share-based compensation and certain accruals, including those related to preclinical 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 income (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 (expense). 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 and 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 condensed consolidated statements of operations.

Income Taxes—The Company follows FASB ASC 740 *Income Taxes*, or ASC 740, in reporting deferred income taxes. ASC 740 requires a company to recognize deferred tax liabilities and assets for expected future income tax consequences of events that have been recognized in the Company's 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.

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 preclinical and clinical trial costs. The Company accrues 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 gains (losses) on short-term marketable securities. Comprehensive gains (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, restricted stock grants, and employee stock purchase plan rights by estimating the fair value on the date of grant using the Black-Scholes option pricing model. For awards subject to time-based vesting conditions, stock-based compensation expense is recognized ratably over the requisite service period of the awards, net of estimated forfeitures. The Company accounts for stock options granted to non-employees using the fair value approach. These option grants are subject to periodic revaluation over their vesting terms.

Net Loss Per Share—Basic net loss per share is computed by dividing the net loss 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 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 convertible preferred stock, unvested restricted common stock subject to repurchase, and options outstanding under the Company's stock option plan. 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):

	March 31,	
	2016	2015
Convertible preferred stock	-	7,561,380
Common stock options issued and outstanding	2,059,628	1,416,779
Common stock subject to repurchase	120,709	395,087
Total	2,180,337	9,373,246

Fair Value of Financial Instruments—The Company follows authoritative guidance with respect to fair value reporting issued by the FASB for financial assets and liabilities, which 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, prepaid expenses, accounts payable, and accrued liabilities. 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 marketable securities is based upon market prices quoted on the last day of the fiscal period or other observable market inputs.

Recently Issued Accounting Standards—During 2016, the FASB issued ASU 2016-02, "Leases," which requires that 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 is currently assessing the impact that this standard will have on its financial statements.

During 2016, the FASB issued ASU 2016-09, "Compensation-Stock Compensation," which simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The updated guidance is effective for interim and annual periods beginning after December 15, 2016, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its financial statements.

3. SHORT-TERM INVESTMENTS

The following table summarizes the available-for-sale securities held at March 31, 2016 and December 31, 2015 (in thousands):

As of March 31, 2016	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Certificates of deposit	$ 20,000	$ -	$ -	$ 20,000
Commercial paper	24,956	2	(4)	$ 24,954
Total	$ 44,956	$ 2	$ (4)	$ 44,954

As of December 31, 2015	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Certificates of deposit	$ 20,000	$ -	$ -	$ 20,000
Commercial paper	24,960	-	(8)	$ 24,952
Total	$ 44,960	$ -	$ (8)	$ 44,952

All available-for-sale securities held at March 31, 2016 and December 31, 2015 will mature in less than one year.

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 that should be determined based on assumptions that market participants would use in pricing an asset or liability.

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

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

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

Level 3: Unobservable inputs in 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 carrying amounts of the Company's financial instruments, including accounts payable, and accrued liabilities, approximate fair value due to their short maturities. At March 31, 2016 and December 31, 2015, the Company held certificates of deposit, which are valued at cost, and commercial paper, which is valued using observable market inputs including reported trades, broker/dealer quotes, bids and/or offers.

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:

	TOTAL	LEVEL 1	LEVEL 2	LEVEL 3
March 31, 2016				
Assets:				
Cash equivalents and money market funds	$ 3,941	$ 3,941	$ -	$ -
Certificates of deposit included in cash and cash equivalents	47,000	-	47,000	-
Certificates of deposit included in short-term investments	20,000	-	20,000	-
Commercial paper	24,954	-	24,954	-
Total assets at fair value	$ 95,895	$ 3,941	$ 91,954	$ -
December 31, 2015				
Assets:				
Cash equivalents and money market funds	$ 12,353	$ 12,353	$ -	$ -
Certificates of deposit included in cash and cash equivalents	50,000	-	50,000	-
Certificates of deposit included in short-term investments	20,000	-	20,000	-
Commercial paper	24,952	-	24,952	-
Total assets at fair value	$ 107,305	$ 12,353	$ 94,952	$ -

5. STOCKHOLDERS' EQUITY

On February 10, 2015, the Company sold 94,533,183 shares of Series B convertible preferred stock, or Series B preferred, for $42.0 million.

On April 2, 2015, the Company's board of directors and stockholders approved a 1-for-25.4 reverse stock split of its outstanding common stock. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

On April 20, 2015, the Company completed its initial public offering, or IPO, whereby the Company sold 4,800,000 shares of common stock at a price of $16.00 per share. Proceeds from the IPO were approximately $69.3 million, net of underwriting discounts and commissions and offering costs. In connection with the IPO, the outstanding shares of the Company's Series A convertible preferred stock, or Series A preferred, and Series B preferred automatically converted into 7,561,380 shares of common stock.

6. 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, or the 2015 EIP. Under the 2015 EIP, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, and other awards to individuals who are employees, officers, directors, or consultants of the Company.

Employee Stock Purchase Plan

In March 2015, the Company's board of directors and stockholders approved and adopted the 2015 Employee Stock Purchase Plan, or the ESPP. The 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 under the ESPP are limited to 15% of the employee's eligible compensation.

Restricted Stock

The Company permits early exercise of certain stock options. Any unvested shares are restricted and subject to repurchase by the Company until the conditions for vesting are met. At March 31, 2016 and December 31, 2015, the liabilities for the cash received from the early exercise of stock options were $266,000 and $341,000, respectively, and were 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 March 31, 2016, 120,709 unvested shares were subject to repurchase by the Company.

Stock Options

The following table summarizes stock option activity during the three months ended March 31, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years	Total Aggregate Intrinsic Value
Outstanding at December 31, 2015	1,437,583	$ 6.19		
Options granted	640,025	9.99		
Options exercised	(17,980)	2.29		
Outstanding at March 31, 2016	2,059,628	7.40	9.15	$ 11,210
Vested and expected to vest at March 31, 2016	2,059,628	7.40	9.15	$ 11,210
Exercisable at March 31, 2016	1,133,444	$ 5.30	8.73	$ 8,419

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

	Three months ended March 31,	
	2016	2015
Research and development	$ 356	$ 442
General and administrative	477	197
Total	$ 833	$ 639

The weighted-average grant date fair value of employee stock options granted by the Company during the three months ended March 31, 2016 was $6.86 per share. The total grant date fair value of employee stock options that vested during the three months ended March 31, 2016 was $0.6 million. As of March 31, 2016, total unrecognized share-based compensation expense related to unvested employee stock options of the Company was approximately $8.4 million. This unrecognized compensation cost is expected to be recognized over a weighted-average period of approximately 2.5 years.

As of March 31, 2016, total unrecognized compensation expense related to the Company's ESPP was approximately $0.4 million. This unrecognized compensation cost is expected to be recognized over approximately 1.7 years.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance is as follows:

	March 31, 2016	December 31, 2015
Stock options issued and outstanding	2,059,628	1,437,583
Authorized for future stock awards or option grants	1,706,071	1,788,396
Authorized for future issuance under employee stock purchase plan	365,429	226,004
Total	4,131,128	3,451,983

7. 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 March 31, 2016 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. The lease expires in December 2018 with two individual two-year extensions. The lease is subject to charges for common area maintenance and other costs. Rent expense is being recorded on a straight-line basis over the life of the lease. Future minimum payments required under the lease as of March 31, 2016 for the years ended December 31 are as follows (in thousands):

2016	530
2017	725
2018	747
Total minimum lease payments	$ 2,002

Rent expense was $179,000 and $104,000 for the three months ended March 31, 2016 and 2015, 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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited financial statements and related notes included in this Quarterly Report on Form 10-Q, or this Quarterly Report, and the audited financial statements and notes thereto as of and for the year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K, or our Annual Report, filed with the Securities and Exchange Commission, or the SEC, on March 18, 2016. Unless the context requires otherwise, references in this Quarterly Report to "we," "us," and "our" refer to Cidara Therapeutics, Inc.

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, 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 clinical candidates are echinocandins, a proven class of antifungals. Our initial product portfolio comprises two formulations of our novel echinocandin, CD101. CD101 IV is being developed as a once-weekly high exposure therapy for the treatment and prevention of serious, invasive fungal infections. CD101 topical is being developed for the treatment of vulvovaginal candidiasis, or VVC, and recurrent VVC, or RVVC, a prevalent mucosal infection. In addition, we have developed a proprietary immunotherapy technology platform, Cloudbreak™, which we use to create compounds designed to direct a patient's immune cells to attack and eliminate pathogens that cause infectious disease

CD101 IV

In January 2016, we obtained data from our multiple ascending dose Phase 1 clinical trial. This was a Phase 1, randomized, double-blind, placebo-controlled, dose-escalation study to determine the safety, tolerability, and pharmacokinetics of multiple intravenous doses of CD101 in healthy subjects. Results demonstrated that CD101 IV was well tolerated in all dose cohorts after multiple doses of 100 mg, 200 mg, and 400 mg in up to three weeks of dosing. CD101 IV exhibited a pharmacokinetic profile consistent with preclinical data and supportive of high exposure, once-weekly dosing. We conducted an End-of-Phase 1 meeting with the Food and Drug Administration, or FDA, and the results of our Phase 1 program support initiation of our Phase 2 clinical trial in Candidemia, the STRIVE study. We plan to enroll at least 90 patients with *Candida* bloodstream infections and expect results from this trial in the second half of 2017.

We plan to conduct a single randomized, double-blind, comparative Phase 3 pivotal clinical trial. Based on our interactions with the FDA to date, this Phase 3 trial, supported by data from our Phase 1 clinical program and our planned Phase 2 clinical trials in candidemia and invasive candidiasis, could suffice for approval of CD101 IV for the indications of candidemia and invasive candidiasis. A total safety database of at least 300 patients will be required, and possibly more if safety concerns are noted in the course of development. We plan to perform additional clinical research with CD101 IV in other populations with high unmet need.

CD101 Topical

We filed our Initial New Drug, or IND, application for CD101 topical in April 2016. We are planning to initiate a Phase 2 multi-site clinical trial, the RADIANT study, in mid-2016 to investigate the safety, tolerability, and initial efficacy of CD101 topical in women with VVC. We expect results from this trial in mid-2017.

The results of our Phase 2 clinical trial will inform the design of our Phase 3 program which we plan to present to the FDA prior to commencing our registration studies.

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 fungal, bacterial and viral infections. We plan to select a lead Cloudbreak development candidate in 2016.

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, research and development payments, 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 preclinical, clinical, regulatory and commercialization milestones, if at all, 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 preclinical development of our CD101 product candidates and our Cloudbreak immunotherapy technology platform, as well as clinical development of CD101 IV. Research and development expenses consist of 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 preclinical and clinical trial costs. The Company accrues 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.

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.

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 preclinical 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 preclinical 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 candidate; and
- the efficacy and safety profile of the product candidates.

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

	For the three months ended March 31,	
	2016	2015
CD101 IV	$ 2,170	$ 1,945
CD101 topical	1,164	587
Cloudbreak immunotherapy platform	600	404
Personnel costs	2,486	1,223
Other research and development expenses	769	776
Total research and development expenses	$ 7,189	$ 4,935

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

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

General and administrative expenses

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

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of our unaudited financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, 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. There were no material changes to our critical accounting policies and estimates during the three months ended March 31, 2016.

RESULTS OF OPERATIONS

Comparison of the three months ended March 31, 2016 and 2015

The following table summarizes our results of operations for the three months ended March 31, 2016 and 2015 (in thousands):

	Three months ended March 31,		
	2016	2015	Change
Research and development	$ 7,189	$ 4,935	$ 2,254
General and administrative	2,696	1,797	899
Other income (expense), net	96	(5)	101

Research and development expenses

Research and development expenses were $7.2 million for the three months ended March 31, 2016 compared to $4.9 million for the three months ended March 31, 2015. Expenses for our CD101 product candidates continued to increase as we prepared for the initiation of our Phase 2 clinical trials for CD101 IV and CD101 topical. In addition, we continued our preclinical development activities on our Cloudbreak platform. Personnel costs were greater than they were in the comparable quarter in the prior year (increased by $1.1 million) due to increases in headcount to support these activities.

General and administrative expenses

General and administrative expenses were $2.7 million for the three months ended March 31, 2016 compared to $1.8 million for the three months ended March 31, 2015. The increase in general and administrative expenses was primarily related to personnel costs (increased by $0.5 million), with share-based compensation costs accounting for more than half of the increase. In addition, we have incurred increased costs to operate as a publicly traded company, including insurance, professional fees, and investor and public relations expenses.

Other Income (Expense)

Other income, net, during the three month period ended March 31, 2016 relates primarily to income generated from cash held in interest-bearing investments.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have received $151.0 million in gross proceeds to fund our operations, primarily through private placements of convertible preferred stock, convertible notes, and our initial public offering.

As of March 31, 2016, we had $51.7 million in cash and cash equivalents. The following table shows a summary of our cash flows for the three months ended March 31, 2016 and 2015 (in thousands):

	Three months ended March 31,	
	2016	**2015**
Net cash provided by (used in):		
Operating activities	$ (10,886)	$ (6,052)
Investing activities	(13)	(31)
Financing activities	41	41,411
Net increase (decrease) in cash and cash equivalents	$ (10,858)	$ 35,328

Operating activities

Net cash used in operating activities was $10.9 million for the three months ended March 31, 2016 compared to $6.1 million for the three months ended March 31, 2015. The increase in net cash used in operating activities was attributable in part to a net loss of $9.8 million for the three months ended March 31, 2016 compared to a net loss of $6.7 million for the three months ended March 31, 2015. For all periods presented, the primary use of cash was to fund increased levels of 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

For the three months ended March 31, 2016, we purchased approximately $10.0 million of short-term investments and received proceeds of $10.0 million from the maturity of short-term investments.

Financing activities

Cash provided by financing activities during the three months ended March 31, 2016 consisted of cash received from the exercise of stock options. During the three months ended March 31, 2015, net proceeds from the sale of our Series B convertible preferred stock were $41.9 million. This cash inflow was partially offset by $0.6 million in deferred IPO costs incurred during the quarter as we pursued our IPO.

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 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. Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months. However, 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.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

There have been no material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed within "Management's Discussion and Analysis of Financial Condition and Results of Operations," as contained in our Annual Report.

Off-Balance Sheet Arrangements

As of March 31, 2016, we did not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our cash and cash equivalents without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

The market risk inherent in our financial instruments and in our financial position is the potential loss arising from adverse changes in interest rates. As of March 31, 2016, we had cash and cash equivalents of $51.7 million and short-term investments totaling $45.0 million. We generally hold our cash in checking and savings accounts and invest excess capital in money market funds, certificates of deposit, corporate debt, and commercial paper. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. To minimize our exposure to adverse shifts in interest rates, we invest in short-term securities and ensure that the maximum average maturity of our investments does not exceed 12 months. If a 10% change in interest rates had occurred on March 31, 2016, this change would not have had a significant impact on the fair value of our investment portfolio as of that date.

We sometimes contract for the conduct of clinical trials or other research and development and manufacturing activities with contract research organizations, clinical trial sites and contract manufacturers outside of the United States. We may be subject to exposure to fluctuations in foreign currency exchange rates in connection with these agreements. If the average exchange rate between the currency of our payment obligations under any of these agreements and the U.S. dollar were to strengthen or weaken by 10% against the corresponding exchange rate as of March 31, 2016, we estimate that the impact on our financial position, results of operations and cash flows would not be material. We do not hedge our foreign currency exposures.

We may seek to obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings 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.

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 chief executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of March 31, 2016, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2016.

Changes in Internal Control over Financial Reporting

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

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. 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" when evaluating our business. 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 Drug Discovery, Development and Commercialization

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

We have completed a Phase 1 clinical trial of CD101 IV and are planning to initiate two Phase 2 clinical trials for CD101 IV and CD101 topical in 2016. Because of the early stage of our development efforts, we are still in the process of determining the clinical development path for our current and future product candidates. As a result, the timing and costs of the 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 early-stage product candidates. The success of CD101 IV, CD101 topical, 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 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 payors;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not accomplish one or more of 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. 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 high rate of correlation for clinical efficacy for antifungals and 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;
- 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 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; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, 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; 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, and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

We may not be successful in our efforts to use and expand our Cloudbreak immunotherapy platform to build a pipeline of product candidates.

A key element of our strategy is to use and expand our Cloudbreak immunotherapy platform to build a pipeline of development candidates and progress these through clinical development for the treatment of a wide variety of infectious diseases, including fungal, bacterial and viral infections. Even if we are successful in continuing to build our pipeline, the potential development candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

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. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as our product candidates, and 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 and efficacy of approved medications 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; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our clinical trials 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 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.

All of our programs are in preclinical development or are in the early stages of clinical development and their risk of failure is high. 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. 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, that differentiate CD101 IV from other echinocandins could have side effects that we have not anticipated and the consequences of such side effects could be more severe than has been seen with other echinocandins that have shorter half-lives or are dosed at lower concentrations than we expect for CD101 IV. Additionally, CD101 topical is the first application of an echinocandin antifungal as a topical treatment and may have side effects related to the method of treatment delivery that are unexpected and different from those of other echinocandin antifungals. Further, the treatment advantages that we are predicting for CD101 IV, such as lower healthcare costs resulting from an ability to administer CD101 IV once-weekly or the predicted ability of CD101 IV to be effective against resistant strains of fungal pathogens, may not be realized.

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 agent. In addition, fungal 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. 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 market for a particular product candidate, we may relinquish valuable rights to that product candidate 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.

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 payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community for us to achieve commercial success. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant 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 treatments;
- the terms of any approvals and the countries in which approvals are obtained;
- 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 CD101 IV, 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 for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell some of our product candidates if and when they are approved.

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 retain or 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 devote the necessary resources and attention to sell and market our products effectively. 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.

CD101 IV will primarily compete with antifungal classes for the treatment of candidemia, which include polyenes, azoles and echinocandins. The approved branded therapies for this indication include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.) and Mycamine (micafungin, marketed by Astellas Pharma US, Inc.). 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 CD101 IV will compete with product candidates that we are aware of in clinical development by third parties, including SCY-078 (being developed by Scynexis, Inc.) and Cresemba (isavuconazole, being developed for the treatment of candidemia jointly by Astellas Pharma Inc. and Basilea Pharmaceutica Ltd.).

CD101 topical will primarily compete against azole agents (oral, topical and intravaginal), currently used in the treatment of VVC, as well as over-the-counter topical agents used to treat these conditions. The approved prescription therapies for VVC are Diflucan (fluconazole) and Terazol (terconazole). Several over-the-counter topical agents such as Monistat (miconazole), Gyne-Lotrimin (clotrimazole) or Gynazole-1 (butoconazole) are also used to treat VVC. In addition to approved therapies, we expect that CD101 topical will compete with product candidates that we are aware of in clinical development by third parties, including VT-1161 (being developed by Viamet Pharmaceuticals, Inc.), SCY-078 (being developed by Scynexis, Inc.), and albaconazole (being developed by Actavis plc).

We intend to develop product candidates from our Cloudbreak immunotherapy platform for the treatment of invasive fungal infection. The approved branded therapies for invasive fungal infection are Vfend (voriconazole, marketed by Pfizer, Inc.), AmBisome (amphotericin B liposome, market by Astellas Pharma Inc. and Gilead Sciences, Inc.), and Cresemba (isavuconazole, marketed by Basilea Pharmaceutica Ltd. and Pfizer Inc.). There are other generic products approved for the treatment of invasive fungal infection marketed by companies such as Sandoz (a Novartis Company), Teva Pharmaceutical Industries Ltd. and Glenmark Generics Inc., among others.

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 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 registration 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 and other third-party payors. Third-party payors decide which medications they will pay for and establish reimbursement levels. A significant trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payment for particular medications. Increasingly, third-party payors are requiring that drug companies provide predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, if reimbursement is available, the level of reimbursement may not be sufficient. 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 payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Commercial third-party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded programs and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize our approved products and our overall financial condition.

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 will face an even greater risk if we commercially sell any products that we may develop after 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 to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; 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 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.

Our Cloudbreak immunotherapy platform and other drug discovery efforts may not be successful in identifying molecules that could be developed as drug therapies. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons. In particular, our research methodology used may not be successful in identifying compounds with sufficient potency or bioavailability 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. To date, we have not in-licensed any such compounds.

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 current rely and expect to continue to rely on third parties, such as contract research organizations, 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 clinical trials 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 requires 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 our clinical development or marketing approval of our product candidates.

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 do not have a long-term supply agreement with any third-party manufacturers, and we purchase our required drug supply on a purchase order basis.

We may be unable to establish agreements with third-party manufacturers or to do so on terms favorable to us. 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; 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 applicable regulations could result in sanctions being imposed on us, 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 may 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 could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply for bulk drug substances. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

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 store and distribute drug supplies for our clinical trials. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our drugs, producing additional losses and depriving us of potential revenue. Although we believe that there are several potential alternative third parties who could store and distribute drug supplies for our clinical trials, we may incur added costs and delays in identifying and qualifying any such replacement.

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 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;
- 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 collaborators for any collaboration arrangements 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 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 collaborations 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.

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

For CD101 IV, we may not be eligible for and may not be able to obtain, breakthrough therapy designation or accelerated approval from the FDA. For CD101 topical, we may not be eligible for and may not be able to obtain, fast track, breakthrough therapy, or orphan drug designations or accelerated approval from the FDA. For any Cloudbreak development candidates and may not be able to obtain, QIDP, fast track, breakthrough therapy or orphan drug designations or accelerated approval from the FDA.

There are a number of incentive programs that the FDA administers to facilitate development of drugs in areas of unmet medical need. We have limited human safety and pharmacokinetic data on CD101 IV, and no human clinical data on any of our other product candidates. CD101 IV received the designation as a QIDP, Fast Track product, and is designated as an Orphan Drug. CD101 topical received the QIDP designation. Our product candidates may not qualify for additional incentive programs under any of the FDA's existing or future programs to expedite drug development in areas of unmet medical need. Without access to such benefits, we may require more time, larger trials 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, safety, efficacy, 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. 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 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 therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities 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, and clinical trials. In addition, varying interpretations of the data obtained from preclinical 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, 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 safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and 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 market our products for their approved indications, we may be subject to enforcement action for off-label marketing.

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

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

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

Healthcare professionals and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with customers, healthcare professionals and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we 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:

- the federal healthcare anti-kickback statute prohibits, among other things, 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 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, 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 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 requires, 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, may apply to our business activities, including sales or marketing arrangements and claims involving healthcare items or services including, in some states, those reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments or other transfers of value provided to physicians and other health care providers and entities 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. 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 governmental 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, imprisonment and the curtailment or restructuring of our operations. 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.

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 new 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 health care practitioners. Since its enactment there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to it in the future. 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 bills 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. 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 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 CD101 IV, CD101 topical or our other product candidates are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to CD101 IV, CD101 topical and our other product candidates, including our Cloudbreak immunotherapy platform. Any involuntary disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

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 CD101 IV, CD101 topical and other 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 CD101 IV, CD101 topical, 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 CD101 IV, CD101 topical or the patents we pursue related to any of our other product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize CD101 IV, CD101 topical and our other product candidates. 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 may be available in certain jurisdictions and having varied scope 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 patent;
- 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;
- any patents issued to us will provide us with any competitive advantages, or will be challenged by third parties;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will have an adverse effect on our business.

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, for processes for which patents are difficult to enforce and for 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, advisors 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 market, 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 United States Patent and Trademark Office, or 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 and this circumstance 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 for treatment related to the use or manufacture of CD101 IV, CD101 topical and/or our other product candidates. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. If any third-party patents were held by a court of competent jurisdiction to cover the CD101 manufacturing process, any molecules formed during the CD101 manufacturing process or the final CD101 products for any use thereof, the holders of any such patents may be able to block our ability to commercialize CD101 IV or CD101 topical 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 our other product candidates as well. We cannot predict whether we would be able to obtain a license on commercially reasonable terms, if at all. Any inability to obtain such a license under the applicable patents on commercially reasonable terms, or at all, may have a material adverse effect on our ability to commercialize CD101 IV, CD101 topical or any of our other product candidates 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 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 for 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 CD101 IV, CD101 topical or any of our other product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if 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 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 current 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. 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 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 and 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 is therefore costly, time-consuming and inherently uncertain. In addition, the United States has recently 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 patent 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 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 patent applications that issue into 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 patent applications that issue into 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, then 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. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to 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 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 $9.8 million and $6.7 million for three month periods ended March 31, 2016 and 2015, respectively. As of March 31, 2016, we had an accumulated deficit of $55.3 million. To date, we have financed our operations primarily through private placements of convertible preferred stock, convertible notes, and our initial public offering of our common stock. We have devoted substantially all of our financial resources and efforts to research and development. We initiated our first clinical trial for CD101 IV in July 2015, and plan to initiate the first clinical trial for CD101 topical in mid-2016. 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;
- advance CD101 IV through clinical development;
- advance CD101 topical into clinical trials;
- continue the preclinical development of product candidates from our Cloudbreak immunotherapy platform and advance a product candidate into clinical trials;
- identify additional lead candidates and advance them into preclinical development;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;

- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel;
- add operational, financial and management information 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, initially CD101 IV and CD101 topical, and our Cloudbreak lead 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 lead candidates;
- 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 March 31, 2016, our operations have been financed primarily by gross proceeds of approximately $151.0 million from the issuance of convertible debt securities, the sale of shares of convertible preferred stock, and the sale of shares of our common stock in our IPO. As of March 31, 2016, we had cash, cash equivalents, and short-term investments of $96.7 million. We expect that our existing cash, cash equivalents and marketable securities and anticipated interest income will enable us to fund our operating expenses and capital expenditure requirements through at least the next twelve months. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. 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 entering into collaborations, strategic alliances and licensing arrangements. 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. If we raise funds by entering into collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements 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, only recently, initiating our first clinical trial. 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 transition from a company with a research focus to a company capable of supporting development activities and, if a product candidate is approved, a company with commercial activities. We may not be successful in any step in such a transition.

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 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 advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors 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, regulatory affairs 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 or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- 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 clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial fungal infection 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 terms on which we raise it;
- 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 immunotherapy 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;
- 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 (1) (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.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be 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 initial public offering. We intend to take advantage of this new 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 current political environment and the current high 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 substantially increase our 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. The increased costs will 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, we expect these rules and regulations to 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 13,854,792 shares of common stock outstanding as of April 30, 2016. 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 make it more difficult for you to sell shares of our common stock. In addition, shares of common stock that are either outstanding options 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 provision 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. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to our existing stockholders.

Pursuant to the 2015 Plan, 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 Plan 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 the 2015 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 Plan and 2015 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 the 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 the clinical development of CD101 IV and CD101 topical, the preclinical development and early clinical trials for our current Cloudbreak development candidates, expansion of our Cloudbreak immunotherapy platform 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.

Because we have an even number of members of our board of directors, deadlocks may occur in our board of directors' decision-making process, which may delay or prevent critical decisions from being made.

Since we currently have an even number of directors, deadlocks may occur when such directors disagree on a particular decision or course of action. Our amended and restated certificate of incorporation and amended and restated bylaws do not contain any mechanisms for resolving potential deadlocks. While our directors are under a duty to act in the best interest of our company, any deadlocks may impede the further development of our business in that such deadlocks may delay or prevent critical decisions regarding our development.

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 our initial public offering, our most recent private placements 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, 2015, we had U.S. net operating loss carryforwards of approximately $39.3 million, which begin to expire in 2032, which could be limited if we experience an "ownership change."

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

Use of Proceeds

On April 14, 2015, our Registration Statements on Form S-1 (file Nos. 333-202740 and 333-203414) were declared effective by the SEC for our initial public offering of common stock, which was completed on April 20, 2015.

There has been no material change in the expected use of the net proceeds from our initial public offering as described in our final prospectus filed with the SEC. Through March 31, 2016, we have not used any of the net proceeds from the offering. Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

The amount and timing of our actual expenditures will depend upon numerous factors, including our ability to gain access to additional financing and the relative success and cost of our research, preclinical and clinical development programs.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

For a list of exhibits filed with this Quarterly Report, refer to the exhibit index.

SIGNATURES

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

Cidara Therapeutics, Inc.

Date: May 12, 2016

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

Date: May 12, 2016

By: /s/ Kevin Forrest, Ph.D.
Kevin Forrest, Ph.D.
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit Number	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.
4.1(2)	Form of Common stock Certificate of the Registrant.
4.2(2)	Second Amended and Restated Investor Rights Agreement, by and among the Registrant and certain of its stockholders, dated February 10, 2015
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(A) promulgated under the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial 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.
32.2	Certification of the Chief Financial 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.

Exhibit 31.1

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

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

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. 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

c. 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: May 12, 2016

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

Exhibit 31.2

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

I, Kevin Forrest, Ph.D., certify that:

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

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. 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

c. 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

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

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

Date: May 12, 2016

/s/ Kevin Forrest, Ph.D.
Kevin Forrest, Ph.D.
Chief Financial Officer and Chief Operating Officer
(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 March 31, 2016 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: May 12, 2016

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

Exhibit 32.2

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

In connection with the quarterly report of Cidara Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kevin Forrest, Ph.D., Chief Operating Officer and Chief Financial 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: May 12, 2016

/s/ Kevin Forrest, Ph.D.
Kevin Forrest, Ph.D.
Chief Operating Officer and Chief Financial Officer
(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.