

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 8, 2018

Cidara Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

001-36912
(Commission File Number)

46-1537286
(I.R.S. Employer
Identification Number)

6310 Nancy Ridge Drive, Suite 101
San Diego, California 92121
(858) 752-6170
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

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

In this report, “Cidara Therapeutics,” “Cidara,” “Company,” “we,” “us” and “our” refer to Cidara Therapeutics, Inc.

Item 2.02 Results of Operations and Financial Condition.

On November 8, 2018, we issued a press release reporting our financial results for the third quarter ended September 30, 2018. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B-2 of Form 8-K, the information contained or incorporated herein, including the press release filed as Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued November 8, 2018, reporting financial results for the third quarter ended September 30, 2018.

SIGNATURES

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

Cidara Therapeutics, Inc.

Date: November 8, 2018

/s/ Jeffrey L. Stein

Jeffrey L. Stein

President and Chief Executive Officer

(Principal Executive Officer and Principal Financial Officer)



FOR IMMEDIATE RELEASE

Cidara Provides Corporate Update and Reports

Third Quarter 2018 Financial Results

SAN DIEGO, November 8, 2018 - Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing novel anti-infectives including immunotherapies, today reported financial results for the three months ended September 30, 2018 and provided an update on its corporate activities and product pipeline.

“We made considerable progress during the third quarter of 2018 with the initiation of our Phase 3 ReSTORE trial of rezafungin, for the treatment of invasive candida infections, and the granting by the FDA of Qualified Infectious Disease Product status for our rezafungin prophylaxis development program,” said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. “In addition, we have expanded our Cloudbreak program to encompass antiviral drug applications and strengthened our board with the appointment of David Gollaher as a director of the company. With our ReSTORE trial underway, our efforts are focused on initiating our Phase 3 ReSPECT prophylaxis trial in the first quarter of 2019.”

Third Quarter 2018 and Subsequent Highlights

- **Initiated Phase 3 trial of rezafungin for treatment of invasive candida infections:** In September 2018, the first trial site was activated for ReSTORE, a global, randomized, double-blind, controlled Phase 3 pivotal clinical trial evaluating the efficacy and safety of once-weekly intravenous dosing of rezafungin compared to once-daily dosing of
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casprofungin in patients with candidemia and/or invasive candidiasis. The primary efficacy endpoint of ReSTORE, which will be used for a U.S. Food and Drug Administration (FDA) New Drug Application submission, is all-cause mortality at day 30. The primary efficacy endpoint for the European Medicines Agency (EMA) is expected to be global response at day 14.

- **Granted QIDP and Fast Track designations from the FDA for rezafungin prophylaxis development program:** In September 2018, the FDA granted both Qualified Infectious Disease Product (QIDP) and Fast Track designations for the company's prophylaxis (prevention) development program for rezafungin for injection. Specifically, the QIDP designation is for the development of rezafungin for the prevention of invasive fungal infections in adults undergoing allogeneic bone marrow transplantation. The company previously announced QIDP designation for rezafungin for the treatment of invasive fungal infections caused by *Candida*.
 - **Appointed David Gollaher, Ph.D. to Board of Directors:** In September 2018, the company appointed industry leader David Gollaher, Ph.D., to its Board of Directors. Dr. Gollaher served as vice president of worldwide government affairs and policy for Gilead Sciences from early 2014 to mid-2018, and previously served for 20 years as co-founder and chief executive officer of the California Healthcare Institute (CHI).
 - **Presented new Cloudbreak™ data at ECCMID/ASM Conference and 16th Annual Discovery on Target Meeting:** In September 2018, the company presented new data highlighting the Cloudbreak™ immunotherapy discovery platform at the European Society of Clinical Microbiology and Infectious Diseases (ESCMID)/American Society for Microbiology (ASM) Conference on Drug Development to Meet the Challenge of Antimicrobial Resistance, in Lisbon, Portugal, and the 16th Annual Discovery on Target Meeting, in Boston. The data highlighted the potential of Cloudbreak™ immunotherapy candidates for the treatment of multi-drug resistant Gram-negative bacterial infections.
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- **Presented new rezafungin data at the 2018 Hot Topics in Infectious Disease Conference:** In October 2018, the company presented new data from studies of rezafungin at the 2018 Hot Topics in Infectious Diseases (HTIDE) Conference in Mestre, Venice. Two posters highlighted analyses of rezafungin in special patient populations and by geographic outcomes based on results from Cidara's Phase 2 STRIVE trial. The third poster highlighted the *in vivo* efficacy of rezafungin in aspergillosis.
- **Presented results from successful Phase 2 STRIVE trial evaluating rezafungin at IDWeek 2018:** In October 2018, the company presented data at IDWeek 2018 in San Francisco showing that the STRIVE trial successfully achieved its primary endpoints, demonstrating the efficacy and safety of once-weekly dosing of rezafungin compared to once-daily dosing of caspofungin in patients with candidemia and/or invasive candidiasis. The rezafungin data showcased the broad clinical utility of Cidara's novel once-weekly antifungal agent.

Third Quarter 2018 Financial Results

- Cash, cash equivalents and short-term investments totaled \$88.3 million as of September 30, 2018, compared with \$103.2 million as of June 30, 2018.
 - As of October 31, 2018, Cidara had 27,751,431 common shares outstanding, and 445,231 shares of Series X convertible preferred stock outstanding, which are convertible into 4,452,310 shares of common stock.
 - Research and development expenses were \$11.3 million and \$36.1 million for the three and nine months ended September 30, 2018, respectively, compared to \$9.2 million and \$32.6 million for the same periods in 2017. The changes were primarily attributable to clinical development activities for rezafungin.
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- General and administrative expenses were \$3.4 million and \$10.6 million for the three and nine months ended September 30, 2018, compared to \$3.1 million and \$9.7 million for the same periods in 2017. The increase was primarily due to higher consulting costs.
- Net loss for the three months ended September 30, 2018 was \$13.6 million, compared to a net loss of \$12.3 million for the third quarter of 2017. For the nine months ended September 30, 2018 and 2017, the company's net loss was \$46.7 million and \$42.3 million, respectively. Net loss attributable to common stockholders, which includes a one-time, non-cash beneficial conversion feature expense from the second quarter of 2018, \$57.0 million for the nine months ended September 30, 2018.

About Cidara Therapeutics

Cidara is a clinical-stage biotechnology company focused on developing new anti-infectives that have the potential to transform the standard of care and save or improve patients' lives. The company is currently advancing its novel echinocandin antifungal, rezafungin acetate, in a Phase 3 clinical trial in the treatment of candidemia and invasive candidiasis and plans to initiate a second Phase 3 trial in the prophylaxis of invasive fungal infections. Rezafungin has improved pharmacokinetics compared to existing echinocandins and the potential for expanded utility across patient settings. It is the only once-weekly product candidate in development for the treatment and prevention of life-threatening invasive fungal infections. Cidara also is leveraging its novel Cloudbreak™ platform to develop antibody-drug conjugates for the treatment of serious viral and Gram-negative bacterial infections. Cloudbreak is the first immunotherapy discovery platform designed specifically to create compounds that directly kill pathogens and also direct a patient's immune cells to attack and eliminate bacterial, fungal or viral pathogens. Cidara is headquartered in San Diego, California. For more information, please visit www.cidara.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the initiation of rezafungin Phase 3 pivotal trials, the potential for rezafungin to be a novel treatment and prophylactic agent against deadly invasive fungal infections, and rezafungin's potential for expanded utility across patient settings. Risks that contribute to the uncertain nature of the forward-looking statements include: the success and timing of Cidara's preclinical studies and clinical trials; regulatory developments in the United States and foreign countries; changes in Cidara's plans to develop and commercialize its product candidates; Cidara's ability to obtain additional financing; Cidara's ability to obtain and maintain intellectual property protection for its product candidates; and the loss of key scientific or management personnel. These and other risks and uncertainties are described more fully in Cidara's Form 10-Q most recently filed with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Cidara undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Cidara Therapeutics, Inc.
Condensed Consolidated Balance Sheets

(In thousands)	September 30, 2018		December 31, 2017	
	(unaudited)			
ASSETS				
Cash, cash equivalents, and short-term investments	\$	88,274	\$	75,314
Other current assets		3,687		2,356
Non-current assets		848		1,365
Total assets	\$	92,809	\$	79,035
LIABILITIES AND STOCKHOLDERS' EQUITY				
Total liabilities	\$	22,877	\$	19,291
Stockholders' equity		69,932		59,744
Total liabilities and stockholders' equity	\$	92,809	\$	79,035

Cidara Therapeutics, Inc.
Condensed Consolidated Statements of Operations

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

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