

**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): August 8, 2019

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))

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

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

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 August 8, 2019, we issued a press release reporting our financial results for the second quarter ended June 30, 2019. 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 August 8, 2019, reporting financial results for the second quarter ended June 30, 2019. |

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: August 8, 2019

/s/ Jeffrey L. Stein

Jeffrey L. Stein

President and Chief Executive Officer
(Principal Executive Officer)

FOR IMMEDIATE RELEASE**Cidara Provides Corporate Update and Reports****Second Quarter 2019 Financial Results**

SAN DIEGO, August 8, 2019 - Cidara Therapeutics, Inc. (Nasdaq: CDTX), a biotechnology company developing novel anti-infectives, including immunotherapies, today reported financial results for the three months ended June 30, 2019 and provided an update on its corporate activities and product pipeline.

"We have made important advances in both our rezafungin program to treat and prevent fungal disease as well as our Cloudbreak® immunotherapy program for the treatment and prevention of influenza," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "Rezafungin achieved positive topline results in its Phase 2 STRIVE B trial, which adds to the growing body of evidence supporting the efficacy and safety of this once-weekly treatment for candidemia and invasive candidiasis, and we continue to enroll patients in our Phase 3 ReSTORE trial. Our Cloudbreak influenza development candidate represents a truly novel approach that has the potential to provide both single-dose long term protection from, as well as rapid treatment of, influenza infections caused by all seasonal and pandemic strains of the virus. Our vision is to develop it as the first once-per-flu-season drug with universal activity."

Second Quarter 2019 and Subsequent Highlights

- **Announced positive topline results from Phase 2 STRIVE B trial of rezafungin:** In July 2019, Cidara reported that the Phase 2 STRIVE B trial evaluating its lead antifungal candidate rezafungin met all of its primary objectives for efficacy, safety and tolerability in the treatment of patients with candidemia and/or invasive candidiasis. While the objective of STRIVE B was to show comparability in efficacy and safety of rezafungin dosed once-weekly versus caspofungin dosed once-daily, the topline results showed that patients treated with rezafungin had numerically improved outcomes compared to caspofungin across all efficacy measures at the 400 mg/200 mg dosing regimen, which is the dosing regimen chosen for Phase 3. In addition, an analysis combining data across STRIVE Parts A and B also demonstrated that rezafungin achieved meaningful improvement in outcomes compared to caspofungin across all efficacy endpoints at the same 400 mg/200 mg dose. The comparisons of efficacy among the treatment arms in the

STRIVE trial are directional, as the STRIVE trial was not powered to show statistically significant differences or non-inferiority between treatment arms.

- **Began studies to support a future IND for its lead Cloudbreak influenza development candidate:** Our Cloudbreak development candidate targeting viral infections are called Antiviral Fc-Conjugates (AVCs) and are designed to apply the principles of immunotherapy to counter influenza in two ways: the antiviral agent targets the influenza virus directly, while the human antibody fragment engages a patient's immune system to attack the pathogen. In July 2019, Cidara began studies in support of a future IND for its lead influenza development candidate which continues to show potent antiviral activity and broad spectrum of coverage.
- **Presented preclinical data on a Cloudbreak influenza development candidate at ECCMID 2019:** In April 2019, Cidara presented results from nonclinical studies that evaluated the potential of a Cloudbreak influenza development candidate for the treatment and prevention of seasonal and pandemic influenza A as well as influenza B. The presentation described this AVC's potent antiviral activity against influenza A and B viruses.
- **Presented new data from multiple rezafungin studies at ECCMID 2019:** In April 2019, Cidara presented new data from multiple studies of rezafungin, during the 29th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) meeting. Three oral presentations at ECCMID showcased results from nonclinical and *in vivo* studies that demonstrated the potential of rezafungin to fight and protect against difficult-to-treat fungal infections. Additionally, researchers presented five rezafungin posters at the meeting, including new analyses from Cidara's Phase 2 STRIVE A trial investigating rezafungin for the treatment of candidemia and invasive candidiasis.
- **Presented new data on rezafungin and a Cloudbreak influenza development candidate at ASM Microbe 2019:** In June 2019, Cidara presented new data from studies of rezafungin, and a Cloudbreak influenza development candidate at the American Society for Microbiology (ASM) Microbe 2019 annual meeting in San Francisco. Three posters presented studies of rezafungin supporting its potential in the treatment of *Candida* infections and invasive aspergillosis. An additional poster featured new data from preclinical studies of an AVC evaluating its antiviral activity against seasonal and pandemic influenza A and influenza B strains compared to oseltamivir.

Second Quarter 2019 Financial Results

- Cash, cash equivalents and short-term investments totaled \$44.6 million as of June 30, 2019, compared with \$74.6 million as of December 31, 2018.
- As of July 31, 2019, Cidara had 26,767,989 shares of common stock outstanding, and 565,231 shares of Series X convertible preferred stock outstanding, which are convertible into 5,652,310 shares of common stock.
- Research and development expenses were \$10.7 million and \$23.4 million for the three and six months ended June 30, 2019, respectively, compared to \$11.6 million and \$24.8 million for the same periods in 2018. The decrease was primarily attributable to clinical development activities for rezafungin.
- General and administrative expenses were \$3.5 million and \$7.3 million for the three and six months ended June 30, 2019, compared to \$3.5 million and \$7.1 million for the same periods in 2018. The increase was primarily due to higher personnel-related costs and consulting costs to support the growth of operating activities.
- Net loss for the three months ended June 30, 2019 was \$13.5 million, compared to a net loss of \$16.3 million for the second quarter of 2018. For the six months ended June 30, 2019 and 2018, the company's net loss was \$30.1 million and \$33.1 million, respectively.

About Rezafungin

Rezafungin is a novel echinocandin antifungal and the only once-weekly drug candidate being developed for the first-line treatment and prevention of serious invasive fungal infections. Rezafungin has a unique pharmacokinetic profile with a prolonged half-life and front-loaded plasma exposure which, in contrast to all other echinocandins, allows for once-weekly IV therapy for inpatient and outpatient use. The U.S. Food and Drug Administration (FDA) has designated rezafungin as a Qualified Infectious Disease Product (QIDP) with Fast Track status and orphan drug designation related to its use in the treatment of candidemia and invasive candidiasis.

About Cidara Therapeutics

Cidara is a clinical-stage biotechnology company focused on the discovery, development and commercialization of novel anti-infectives that have the potential to transform the standard of care and save or improve patients' lives. Cidara is currently advancing its novel echinocandin antifungal, rezafungin acetate, in a Phase 3 clinical trial for the first-line treatment of candidemia and/or invasive candidiasis (ReSTORE). A second Phase 3 trial of once-weekly rezafungin for prophylaxis against invasive fungal infections in patients undergoing allogeneic blood and marrow transplantation (ReSPECT) is planned pending adequate funding and approval from the

relevant regulatory authorities. In addition to its robust rezafungin clinical program, Cidara is applying its proprietary Cloudbreak® platform to develop antiviral conjugates (AVCs) for the prevention and treatment of influenza and other viral diseases. The Cloudbreak platform is designed to discover compounds that both directly kill pathogens and direct a patient's immune system to attack and eliminate 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, the potential of Cidara's anti-infectives to transform the standard of care and save or improve patients' lives and the anticipated timing of the ReSPECT clinical trial. Risks that contribute to the uncertain nature of the forward-looking statements include: the success and timing of Cidara's 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-K 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) | June 30, 2019 | | December 31, 2018 | |
|----------------------------------------------------|----------------------|---------------|--------------------------|---------------|
| | (unaudited) | | | |
| ASSETS | | | | |
| Cash, cash equivalents, and short-term investments | \$ | 44,573 | \$ | 74,562 |
| Other current assets | | 3,173 | | 2,567 |
| Non-current assets | | 4,006 | | 1,983 |
| Total assets | \$ | 51,752 | \$ | 79,112 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | | |
| Total liabilities | \$ | 19,970 | \$ | 19,973 |
| Stockholders' equity | | 31,782 | | 59,139 |
| Total liabilities and stockholders' equity | \$ | 51,752 | \$ | 79,112 |

Cidara Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(unaudited)

| (In thousands, except share and per share data) | Three Months Ended | | Six Months Ended | |
|--------------------------------------------------------------------|---------------------------|--------------------|-------------------------|------------------|
| | June 30, | | June 30, | |
| | 2019 | 2018 | 2019 | 2018 |
| Operating expenses: | | | | |
| Research and development | \$ 10,743 | \$ 11,619 | \$ 23,412 | \$ 24,818 |
| General and administrative | 3,525 | 3,533 | 7,260 | 7,144 |
| Total operating expenses | 14,268 | 15,152 | 30,672 | 31,962 |
| Loss from operations | (14,268) | (15,152) | (30,672) | (31,962) |
| Other income (expense): | | | | |
| Change in fair value of contingent forward purchase obligations | 681 | (1,112) | 411 | (1,112) |
| Interest income, net | 40 | 164 | 153 | 225 |
| Other expense | — | (206) | — | (206) |
| Total other income (expense) | 721 | (1,154) | 564 | (1,093) |
| Net loss attributable to common shareholders | (13,547) | (16,306) | (30,108) | (33,055) |
| Recognition of beneficial conversion feature | — | (10,329) | — | (10,329) |
| Net loss attributable to common shareholders | \$ (13,547) | \$ (26,635) | (30,108) | (43,384) |
| Basic and diluted net loss per common share | \$ (0.49) | \$ (1.13) | \$ (1.23) | \$ (1.93) |
| Shares used to compute basic and diluted net loss per common share | 27,786,808 | 23,592,763 | 24,538,443 | 22,500,061 |

INVESTOR CONTACT:

Robert H. Uhl
Westwicke IR
Managing Director
(858) 356-5932
Robert.Uhl@westwicke.com

MEDIA CONTACT:

Andrea Cohen
Sam Brown Inc.
(917) 209-7163
andreacohen@sambrown.com

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