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 17, 2021

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

Delaware	**001-36912**	**46-1537286**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(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 7.01 Regulation FD Disclosure.

On August 17, 2021, Cidara and Mundipharma Medical Company (“Mundipharma”) issued a press release announcing the completion of recruitment for the Phase 3 ReSTORE trial evaluating the efficacy and safety of rezafungin as a potential first-line treatment for candidemia and invasive candidiasis. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained or incorporated in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of 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 Exchange Act or the Securities Act except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 8.01 Other Events.

On August 17, 2021, Cidara and Mundipharma issued a press release announcing the completion of recruitment for the Phase 3 ReSTORE trial evaluating the efficacy and safety of rezafungin as a potential first-line treatment for candidemia and invasive candidiasis. The trial includes 184 patients diagnosed with candidemia and/or invasive candidiasis. Cidara expects to announce top-line data from the ReSTORE trial by the end of 2021 and anticipates filing a New Drug Application for rezafungin in the U.S. and similar regulatory filings outside the U.S. in the middle of 2022.

Forward Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements about Cidara’s expectations with respect to the anticipated timing for the announcement of top-line data from the ReSTORE trial and filing of a New Drug Application in the U.S. and similar regulatory filings outside the U.S. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “believes,” “anticipates,” “plans,” “expects,” “intends,” “will,” “goal,” “potential” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Cidara’s current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with unanticipated delays in or negative results from Cidara’s clinical trials, impacts of the COVID-19 pandemic on patient enrollment or other obstacles to the development of rezafungin. Additional factors that could cause actual results to differ materially from those stated or implied by Cidara’s forward-looking statements are disclosed in its filings with the SEC, including in the section captioned “Risk Factors” in Cidara’s quarterly report on Form 10-Q for the quarterly period ended June 30, 2021. All forward-looking statements contained in this report 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued August 17, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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 17, 2021

/s/ Jeffrey L. Stein

Jeffrey L. Stein
President and Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 99.1

Cidara Therapeutics and Mundipharma Announce Completion of Enrollment in the Phase 3 ReSTORE Trial of Rezafungin for the Treatment of Candidemia and Invasive Candidiasis

Top-line data anticipated in late 2021

Single Phase 3 trial serves as basis for global regulatory filings

SAN DIEGO and CAMBRIDGE, England, August 17, 2021 (GLOBE NEWSWIRE) — Cidara Therapeutics, Inc. (Nasdaq: CDTX) and Mundipharma today announced that the companies have completed recruitment of the pivotal Phase 3 ReSTORE trial evaluating the efficacy and safety of rezafungin as a potential first-line treatment for candidemia and invasive candidiasis.

The trial includes 184 patients diagnosed with candidemia and/or invasive candidiasis. Candidemia and invasive candidiasis continue to be an area of significant unmet need, especially for critically ill patients in hospitals and patients with compromised immune systems. Despite a number of available treatments, mortality rates are as high as 40%.[1]

“Rezafungin is a novel once-weekly antifungal that has the potential to help critically ill, vulnerable patients battling these invasive *Candida* infections,” said George Thompson, M.D., principal investigator in the ReSTORE trial and associate professor of clinical medicine at the University of California, Davis, School of Medicine. “Completion of enrollment of the ReSTORE trial is a tremendous milestone for all of us, most importantly our patients.”

Jeffrey Stein, Ph.D., president and chief executive officer of Cidara, added, “We would like to thank our investigators and especially our patients who enabled us to achieve this important milestone. If approved, rezafungin would be the first new therapy for the treatment of this deadly disease in over a decade. With the completion of enrollment of ReSTORE, we remain on track to announce top-line data by the end of this year and anticipate filing our New Drug Application (NDA) in the U.S. and similar regulatory filings outside the U.S. in mid-2022.”

Cidara has partnered with Mundipharma who will be responsible for bringing rezafungin to patients outside the U.S. and Japan.

Brian Sheehan, Ph.D., chief scientific officer at Mundipharma, commented, “Despite current advances in antifungal therapy, invasive fungal infections remain an area of significant unmet patient need associated with high mortality, particularly in immunocompromised and critically ill patients. We believe rezafungin has the potential to be the first effective and well tolerated once weekly treatment option for patients with candidemia and/or invasive candidiasis and would like to thank the patients and the clinicians who participated in this important trial.”

ReSTORE (NCT03667690) is 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 caspofungin, the current standard of care, to treat patients with candidemia and/or invasive candidiasis. The trial design is similar to Cidara's Phase 2 STRIVE trial (NCT02734862), which met its primary safety and efficacy objectives. The ReSTORE trial is designed as a non-inferiority trial to evaluate one rezafungin dosing regimen of 400 milligrams (mg) for the first week followed by 200 mg of rezafungin once weekly for up to four weeks in total. This treatment arm is compared to caspofungin dosed once daily in a 1:1 randomization. This global trial has been conducted at over 100 clinical trial centers across 18 countries. Study sites in China will continue recruiting patients for submission of rezafungin to the Centre of Drug Evaluation.

The primary efficacy endpoint of ReSTORE, which will be used to support a U.S. Food and Drug Administration NDA submission, is all-cause mortality at Day 30. The primary efficacy endpoint for the European Medicines Agency is global response at Day 14.

The ongoing global Phase 3 ReSPECT trial (NCT04368559) evaluating rezafungin versus the standard antimicrobial regimen to prevent invasive fungal disease due to *Candida*, *Aspergillus* and *Pneumocystis* in subjects undergoing allogeneic bone marrow transplants continues to enroll patients as planned.

About Invasive Candidiasis

Invasive candidiasis (IC) continues to be an area of significant unmet need, especially for critically ill patients in hospitals and patients with compromised immune systems. Despite a number of available treatments, mortality rates are as high as 40%.[1] IC is characterized as a severe, life-threatening systemic *Candida* infection of the bloodstream and/or deep/visceral tissues, known as candidaemia and deep-seated tissue candidiasis.[2]

About Rezafungin

Rezafungin is a novel once-weekly echinocandin being developed for both the treatment and prevention of serious fungal infections, such as candidemia and invasive candidiasis. The structure and properties of rezafungin are specifically designed to improve upon a validated mechanism intended to enhance its clinical profile. Cidara is currently conducting a Phase 3 clinical trial with rezafungin for the first-line treatment of candidemia and/or invasive candidiasis (ReSTORE trial) and a second Phase 3 clinical trial of once-weekly rezafungin for the prevention of invasive fungal disease in patients undergoing allogeneic blood and marrow transplantation (ReSPECT trial).

About Cidara Therapeutics

Cidara is developing long-acting therapeutics designed to transform the standard of care for patients facing serious fungal or viral infections. The Company's portfolio is comprised of its lead antifungal candidate, rezafungin, in addition to AVCs for the prevention and treatment of influenza and other viral diseases from Cidara's proprietary Cloudbreak® antiviral platform. Cidara is headquartered in San Diego, California. For more information, please visit www.cidara.com.

About Mundipharma

Mundipharma is a global healthcare company with a presence across Africa, Asia Pacific, Canada, Europe, Latin America, and the Middle East.

Mundipharma is dedicated to bringing innovative treatments to patients in the areas of Pain & Supportive Care and Consumer Healthcare as well as other severe and debilitating disease areas. Our guiding principles, centred around Integrity and Patient-Centricity, are at the heart of everything we do. For more information visit www.mundipharma.com

Forward-Looking Statements of Cidara

This release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. "Forward-looking statements" describe future expectations, plans, results, or strategies and are generally preceded by words such as "anticipates," "expect," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to the potential for rezafungin to be a safe and effective treatment for candidemia and invasive candidiasis, overcome significant limitations in current treatment choices and help critically ill, vulnerable patients battling these invasive *Candida* infections; and the timing of our announcement of top-line data from the ReSTORE trial and timing of our NDA and other regulatory filings. Such statements are subject to a multitude of risks and uncertainties that could cause future circumstances, events, or results to differ materially from those projected in the forward-looking statements, such as unanticipated delays in or negative results from Cidara's clinical trials, impacts of the COVID-19 pandemic on patient enrollment or other obstacles to the development of rezafungin. These and other risks are identified under the caption "Risk Factors" in Cidara's most recent Quarterly Report on Form 10-Q and other filings subsequently made with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Cidara does not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

INVESTOR CONTACT
Brian Ritchie
LifeSci Advisors
(212) 915-2578
britchie@lifesciadvisors.com

MEDIA CONTACT (US)
Patrick Bursey
LifeSci Communications
(203) 430-9545
pbursey@lifescicomms.com

MEDIA CONTACT (Ex-US and Japan)
Jan Milton-Edwards
Mundipharma
+44 7341 739 984
jan.milton-edwards@mundipharma.com

References:

1. Kullberg BJ, Arendrup MC. Invasive Candidiasis. N Engl J Med 2015; 373:1445-1456.
2. Cortes JA, Corrales IF. Invasive Candidiasis: Epidemiology and Risk Factors. November 2018. Available at https://www.intechopen.com/books/fungal-infection/invasive-candidiasis-epidemiology-and-risk-factors. Last accessed December 2020.