

**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): September 3, 2019

Cidara Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36912
(Commission
File Number)

46-1537286
(IRS Employer
Identification No.)

6310 Nancy Ridge Drive, Suite 101
San Diego, California
(Address of principal executive offices)

92121
(Zip Code)

Registrant's telephone number, including area code: (858) 752-6170

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, \$0.0001 par value 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.

Item 1.01 Entry into a Material Definitive Agreement.

Collaboration Agreement

On September 3, 2019, Cidara Therapeutics, Inc. (the “Company”) entered into a Collaboration and License Agreement (the “Collaboration Agreement”) with Mundipharma Medical Company (“Mundipharma”) for a strategic collaboration to develop and commercialize rezafungin in an intravenous formulation (the “Licensed Product”) for the treatment and prevention of invasive fungal infections.

Collaboration. Under the Collaboration Agreement, the Company will be responsible for leading the conduct of an agreed global development plan (the “Global Development Plan”) that includes the Company’s ongoing Phase 3 pivotal clinical trial of the Licensed Product for the treatment of candidemia and/or invasive candidiasis (the “ReSTORE Trial”) and the Company’s planned Phase 3 pivotal clinical trial of the Licensed Product for the prophylaxis of invasive fungal infections in adult allogeneic blood and marrow transplant recipients (the “ReSPECT Trial”), as well as specified GLP-compliant non-clinical studies and chemistry, manufacturing and controls (“CMC”) development activities for the Licensed Product. Mundipharma will be responsible for performing all development activities, other than Global Development Plan activities, that may be necessary to obtain and maintain regulatory approvals for the Licensed Product in the Mundipharma Territory, at Mundipharma’s sole cost.

Licenses. Pursuant to the Collaboration Agreement, the Company granted Mundipharma an exclusive, royalty-bearing license to develop, register and commercialize the Licensed Product outside of the United States and Japan (the “Mundipharma Territory”), subject to the Company’s retained right to lead a global development program for the Licensed Product in both the Mundipharma Territory and in the United States and Japan (the “Company Territory”) as described below.

The Company also granted Mundipharma an option to obtain exclusive licenses to develop, register and commercialize rezafungin in a formulation for subcutaneous administration (“Subcutaneous Product”) and in formulations for other modes of administration (“Other Products”) in the Mundipharma Territory, subject to similar retained rights of the Company to conduct mutually agreed global development activities for such products. In addition, the Company granted Mundipharma a co-exclusive, worldwide license to manufacture the Licensed Product and rezafungin.

Until the seventh anniversary of the first commercial sale of the Licensed Product in the Mundipharma Territory, each party has granted the other party an exclusive, time-limited right of first negotiation to obtain a license to any anti-fungal product (other than Licensed Product, Subcutaneous Product and Other Products) that such party proposes to out-license in the other party’s territory. However, in the event of the acquisition of a party by a third party, this right of first negotiation will not apply to any such anti-fungal product of the acquiring third party prior to consummation of the acquisition of such party, acquired by such acquiring third party from another third party after consummation of the acquisition of such party, or developed internally by the acquiring third party, either before or after consummation of the acquisition of such party, without the use of, reliance upon or reference to any technology of the acquired party that is licensed to the other party under the Collaboration Agreement, any technology of the other party that is licensed to the acquired party under the Collaboration Agreement, or any technology jointly developed by the parties pursuant to the Collaboration Agreement.

The Company’s Retained Rights. The Company retains the exclusive right to develop, register and commercialize the Licensed Product, Subcutaneous Product and Other Products in the Company Territory, and Mundipharma has granted the Company certain licenses under Mundipharma-controlled technology and jointly-developed technology to develop, register and commercialize Licensed Product, Subcutaneous Product and Other Products in the Company Territory and to manufacture such products and rezafungin worldwide.

Financial Terms. The parties have agreed to share equally (50/50) the costs of Global Development Plan activities (“Global Development Costs”), subject to a cap on Mundipharma’s Global Development Cost share of \$31.207 million. Cidara would receive additional financial support for Global Development Plan activities through a near-term milestone payment by Mundipharma of \$11.145 million. Mundipharma is entitled to credit the full amount of this milestone payment toward future royalties payable to the Company, subject to a limit on the amount by which royalty payments to the Company may be reduced in any quarter. If Mundipharma has not fully credited the amount of such milestone payment toward royalties payable to the Company before the earlier of (i) December 31, 2024 and (ii) termination of the Collaboration Agreement by Mundipharma, the Company will be obligated to refund the uncredited portion of such milestone payment to Mundipharma on the earlier of such dates.

In addition to the cost-sharing and the \$11.145 million milestone payment described above, the Company will receive under the Collaboration Agreement a \$30 million upfront payment, up to \$534.412 million in development, regulatory and commercial milestone payments on the Licensed Product, and double-digit royalties on tiers of annual net sales of the Licensed Product in the Mundipharma Territory in the teens.

Termination. Either party may terminate the Collaboration Agreement for uncured material breach by the other party. After September 3, 2020, Mundipharma may terminate the Collaboration Agreement at will, provided that if Mundipharma terminates the Collaboration Agreement in its entirety prior to the last visit of the last patient in both the ReSPECT Trial and the ReSTORE Trial, Mundipharma will continue to be liable for its share of Global Development Costs as described above. The Company may terminate the Agreement if Mundipharma or any of its affiliates or sublicensees, directly or indirectly through any Third Party, commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any of the Cidara patent rights licensed to Mundipharma, or upon an insolvency event of Mundipharma.

Stock Purchase Agreement

Concurrently with the execution of the Collaboration Agreement, the Company entered into a Stock Purchase Agreement (the “Purchase Agreement”) with Mundipharma AG (the “Purchaser”), pursuant to which the Company issued to the Purchaser 4,781,408 shares of its common stock (the “Shares”) in a private placement at a price per share of \$1.884 (a 20% premium to the volume weighted average price of the Company’s common stock for the 10 trading days prior to September 3, 2019) for an aggregate purchase price of approximately \$9.0 million.

Under the Purchase Agreement, until September 3, 2020 (the “Lock-Up Period”), the Purchaser may not transfer or sell the Shares without the prior written consent of the Company. In addition, the Company agreed to (i) no later than 90 days prior to the expiration of the Lock-Up Period, file a registration statement with the U.S. Securities and Exchange Commission covering the resale by the Purchaser of the Shares, (ii) cause such registration statement to become effective as soon as practicable following the filing thereof and (iii) take all other actions as may be necessary to keep such registration statement continuously effective during the timeframes set forth in the Purchase Agreement. If the Company fails to comply with certain obligations with respect to filing and securing effectiveness of such registration statement, the Company would be obligated to pay liquidated damages to the Purchaser in the amount of 1% of the total purchase price of the Shares for each applicable 30-day period, up to an aggregate maximum of 6% of the purchase price, so long as the event giving rise to the damages remains uncured.

The foregoing descriptions of the Collaboration Agreement and the Purchase Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements, copies of which will be attached to the Company’s quarterly report on Form 10-Q for the period ended September 30, 2019.

Item 3.02 Unregistered Sales of Equity Securities.

The description of the sale and issuance of the Company's common stock pursuant to the Purchase Agreement set forth under Item 1.01 above is incorporated by reference into this Item 3.02. The issuance and sale of the Shares has not been registered under the Securities Act of 1933, as amended (the “Securities Act”), or any state securities laws. The Company has relied on the exemption from the registration requirements of the Securities Act by virtue of Section 4(a) (2) thereof and Rule 506 of Regulation D thereunder. In connection with the Purchaser’s execution of the Purchase Agreement, the Purchaser represented to the Company that it is an “accredited investor” as defined in Regulation D of the Securities Act and that the Shares were acquired by the Purchaser solely for its own account and for investment purposes and not with a view to the future sale or distribution. This Current Report on Form 8-K is not an offer to sell or the solicitation of an offer to buy any such Securities.

Item 7.01 Regulation FD Disclosure.

On September 3, 2019, the Company issued a press release regarding the transactions with Mundipharma. A copy of the press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated September 3, 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.

Dated: September 3, 2019

Cidara Therapeutics, Inc.

By: /s/ Jeffrey Stein

Jeffrey Stein, Ph.D.

President and Chief Executive Officer



Cidara Therapeutics and Mundipharma Form Strategic Partnership to Develop and Commercialize Rezafungin

Collaboration combines strengths to develop and commercialize life-saving antifungal treatment and prophylaxis, an area of high unmet medical need

Mundipharma acquires exclusive rights to develop and commercialize rezafungin in all markets outside of the United States and Japan, which will be retained by Cidara

Cidara to receive upfront payment of \$30 million and equity investment of \$9 million, co-development funding, development milestones and tiered royalty stream

Total transaction value could exceed \$568 million

Cidara to host conference call today at 8:00 a.m. ET/5:00 a.m. PT

SAN DIEGO, CA AND CAMBRIDGE, UK, September 3, 2019 – Cidara Therapeutics, Inc. (Nasdaq: CDTX) and Mundipharma announced today that they have entered into a strategic partnership to develop and commercialize rezafungin for the treatment and prevention of invasive fungal infections. Rezafungin is a novel, once-weekly echinocandin antifungal being developed for the first-line treatment of candidemia and invasive candidiasis as well as for the prophylaxis of invasive fungal infections in patients undergoing allogeneic blood and marrow transplantation, for which no new therapies have been approved in over 13 years.

The partnership agreement follows Cidara's recent announcement of the successful completion of its STRIVE B Phase 2 trial. Under the terms of the agreement, in exchange for granting Mundipharma exclusive commercialization rights to rezafungin outside the U.S. and Japan, Cidara will receive a \$30 million upfront payment and Mundipharma will make a \$9 million equity investment in Cidara. Cidara will also receive an additional \$42 million in near-term funding to support the global Phase 3 ReSTORE and ReSPECT trials for the treatment and prevention of fungal infections. In addition, Cidara is eligible to receive development, regulatory and commercial milestone payments, representing a total potential transaction value of \$568 million plus double-digit royalties. Cidara will continue to lead the ongoing global Phase 3 development programs for rezafungin with the support of Mundipharma. The companies may pursue additional indications or formulations of rezafungin.

“This is a transformational collaboration for Cidara, and we look forward to working closely with our colleagues at Mundipharma, a highly successful, profitable company with a commercial presence spanning 120 markets worldwide and annual sales exceeding €2 billion,” said Jeffrey Stein, Ph.D., President and Chief Executive officer of Cidara. “Mundipharma is particularly well positioned globally with established hospital and hematology/oncology business units to fully leverage the commercial potential of rezafungin. Through this partnership, both companies fully commit to advancing rezafungin and helping to save the lives of patients who are highly vulnerable to these deadly infections.”

“By partnering with Cidara on rezafungin, we continue to serve our purpose - to move medicine forward,” said Alberto Martinez, Ph.D., M.B.A., President and Chief Executive officer of Mundipharma. “In a world where antifungal resistance is posing a major threat to the lives of vulnerable immunocompromised patients, rezafungin shows promise to address a major unmet medical need as well as potentially providing a wider spectrum of efficacy in a more convenient administration schedule. With our proven commercial excellence we are confident that we will maximize the potential of this differentiated and innovative asset. Rezafungin will be a significant addition to our pipeline that integrates well with our overall portfolio and sales force capabilities. We are excited to work with the team at Cidara to deliver such an important medicine to patients around the world.”

Conference Call and Webcast

Cidara management will host a conference call and webcast at 8:00 a.m. ET/5:00 a.m. PT today. The live call may be accessed by dialing (844) 358-8763 for domestic callers and (703) 736-7375 for international callers and entering the conference code: 6567991. The webcast will be made available on Cidara’s website at www.cidara.com under the Investors tab in the Events section. Following the live audio webcast, a replay will be available on Cidara's website.

About Invasive Fungal Infections

Invasive fungal infections (IFIs) represent a serious threat to millions of patients worldwide, resulting in more than 1.5 million deaths annually and mortality rates ranging from 15 to 65 percent. These infections continue to be a global health issue, especially for critically ill patients in hospitals and patients with compromised immune systems, including cancer and transplant patients. Approximately 90 percent of IFI-related deaths are associated with *Candida*, *Aspergillus*, and *Pneumocystis*.

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) and plans to commence a second Phase 3 trial of once-weekly rezafungin for prophylaxis against invasive fungal infections in patients undergoing allogeneic blood and marrow transplantation (ReSPECT) initially in Europe and Canada. 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.

About Mundipharma

Mundipharma is a global network of privately-owned independent associated companies whose purpose is to move medicine forward.

With a high performing and learning organisation that strives for innovation and commercial excellence through partnerships, we successfully transformed and diversified our portfolio of medicines to create value for patients, payers and wider healthcare systems across important therapeutic areas such as Diabetes, Respiratory, Oncology, Pain and Biosimilars.

For more information please visit: www.mundipharma.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 relating to the transformational nature and value of Cidara's collaboration with Mundipharma, Cidara's ability to develop new anti-infectives that are innovative or address unmet needs, including Cidara's ability to successfully complete the

ReSTORE and ReSPECT Phase 3 clinical trials, Cidara's ability to complete development of, obtain regulatory approval for and commercialize rezafungin including Cidara's ability to receive milestone payments for the achievement of development milestones, the potential for rezafungin to successfully treat or prevent invasive fungal infections and represent an improvement over current approaches, and the ability of Cidara's Cloudbreak program to successfully identify and develop product candidates to prevent and/or treat viral diseases, and other diseases. 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 most recent filings 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.

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