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): July 26, 2022

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 Stock Market LLC

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.

License Agreement with Melinta Therapeutics, Inc.

On July 26, 2022, Cidara Therapeutics, Inc. (the "Company") entered into a License Agreement (the "License Agreement") with Melinta Therapeutics, Inc. ("Melinta"), pursuant to which the Company granted Melinta an exclusive license to develop and commercialize products that contain or incorporate rezafungin (the "Product") in the United States (the "Territory").

Financial Terms. The Company will receive under the License Agreement a $30.0 million upfront payment, and may receive up to $60.0 million in regulatory milestone payments and up to $370.0 million in commercial milestone payments. The Company will also be entitled to royalties on tiers of annual net sales of Products in the Territory at rates ranging from the low double digits to the mid-teens, on a Product-by-Product basis, until the earlier of (a) the end of the first calendar quarter in which one or more generic products for such Product account for 10% or more of aggregate unit sales of such Product and such generic product(s) in the Territory; and (b) the latest of: (i) the expiration of the last-to-expire valid claim of the Company's patent rights licensed to Melinta and listed in the FDA's Orange Book for such Product (or, in the case of any claim of a pending patent application within such patent rights, if issued would be listable in the FDA's Orange Book) that, in the absence of the license granted to Melinta, would be infringed by the manufacture, use, sale, offer for sale or importation of such Product in the Territory; (ii) expiration of all regulatory exclusivity for such Product in the Territory; and (iii) 10 years from the first commercial sale of such Product in the Territory.

Melinta will have the right to deduct from royalties payable to the Company certain development and regulatory expenses incurred by Melinta, as more fully described in the paragraph headed "Continued Development and Regulatory Activities" below, provided that the total expenses incurred by Melinta in any calendar year that may be offset against the royalties payable to the Company will not exceed 110% of the estimated expenses set forth in an annual expense budget to be jointly approved by the parties through the joint steering committee to be established under the License Agreement ("JSC"). Subject to the foregoing annual limitation, to the extent that such expenses exceed the amount of royalties payable to the Company in any calendar quarter, the excess will roll forward and be offset against royalties payable to the Company in future periods until all such expenses have been fully credited against royalties payable to the Company.

License. Pursuant to the License Agreement, the Company granted Melinta an exclusive, royalty-bearing license to develop, register and commercialize the Product for all uses in humans and non-human animals in the Territory, subject to the Company's retained right described below.

Until the fifth anniversary of the first commercial sale of the first Product in the Territory, neither the Company nor Melinta, nor any of their respective majority-owned subsidiaries may, directly or indirectly, itself or in collaboration with any Third Party, develop, manufacture for development or commercialization, or commercialize any product in the echinocandin class of drugs ("Competing Product") in the Territory without the other party's prior written consent, subject to certain provisos in connection with a change of control of a party.

Commercialization. Melinta will be solely responsible for the commercialization of the Product in the Territory, at its sole expense, and, following receipt of the first NDA approval for the Product in the Territory, is obligated to use commercially reasonable efforts to commercialize the Product in the Territory for each indication for which NDA approval is obtained in the Territory and to maximize net sales of the Product in the Territory.

The Company's Retained Rights. The Company retains the non-exclusive right to practice the intellectual property rights licensed to Melinta in the Territory solely for the purpose of performing (a) its obligations under the License Agreement, including Development Plan activities, the filing and maintenance of Product Filings in the Territory for such purpose, and the use of Product in the Territory for the foregoing purposes, and (b) its obligations under the Collaboration and License Agreement by and between the Company and Mundipharma Medical Company, dated September 3, 2019 (the "Mundipharma Agreement"), including the Global Development Plan under the Mundipharma Agreement in the Territory, the filing and maintenance of Product Filings in the Territory for such purpose, and the use of Product in the Territory for such purpose. The Company also retains the right to grant licenses under the intellectual property rights licensed to Melinta to third parties to which the Company has granted licenses or rights to market, promote and sell Product outside the Territory, to make and have made Product anywhere in the world solely to develop, register, use, sell, have sold, offer for sale, commercialize and import Product outside the Territory, subject to the terms of the License Agreement.

Continued Development and Regulatory Activities. Under the License Agreement, the Company will be solely responsible, at its sole expense, for conducting, and is obligated to use commercially reasonable efforts to complete, an agreed development plan (the "Development Plan") that includes, without limitation, (a) the conduct and completion of the Company's ongoing ReSPECT Phase 3 pivotal clinical trial of the Product (the "ReSPECT Trial") for the prophylaxis of invasive fungal infections in adult allogeneic blood and marrow transplant recipients (the "Prophylaxis Indication"), (b) preparation and submission to the FDA of a supplemental new drug application for the Product in the Prophylaxis Indication, (c) site close-out activity worldwide

(outside of China) for the Company's ReSTORE Phase 3 pivotal clinical trial of the Product (the "ReSTORE Trial") for the treatment of candidemia and invasive candidiasis (the "Treatment Indication"), (d) certain nonclinical studies and other nonclinical activities, (e) certain chemistry, manufacturing and controls activities for the Product, and (f) all other development activities that are required by the FDA to obtain marketing approval of the Product in the Treatment Indication and the Prophylaxis Indication in the Territory. If, before the date that the Company transfers any Product Filings to Melinta as described below, the FDA requires the conduct of any post-marketing requirement or post-marketing commitment, such as a surveillance study of the Product in the Treatment Indication, as a condition to obtaining or maintaining marketing approval for the Product in the Treatment Indication in the Territory, then the Company and Melinta will discuss in good faith, and the JSC will approve, an amendment to the Development Plan to add any such post-marketing requirement or post-marketing commitment that is a human clinical trial, and the Company will be obligated to use commercially reasonable efforts to perform such clinical trial, at the Company's sole expense.

The Company will remain the holder of all FDA submissions, including investigational new drug applications, new drug applications, including supplemental new drug applications (such new drug applications, collectively, "NDAs"), and all NDA approvals, with respect the Product in the Treatment Indication and the Prophylaxis Indication in the Territory (collectively, "Product Filings"), until 90 days after the earliest of: (a) the date on which the FDA notifies Cidara of the approval of the NDA for the Product in the Prophylaxis Indication in the Territory; (b) if the FDA delivers a Complete Response Letter to the Company in response to an NDA filed by Cidara for the Product in the Prophylaxis Indication ("Prophylaxis Indication CRL") then: (i) if it is unanimously determined by the JSC, or if the JSC is unable to reach a unanimous determination and it is determined by an independent expert, that it is commercially reasonable to undertake the activities identified in the Prophylaxis Indication CRL, taking into consideration both the estimated time and costs to conduct and complete such activities and the increase in the market potential of the Product in the Territory that would reasonably be anticipated to result from marketing approval of the Product in the Prophylaxis Indication in the Territory, then the date that Cidara has completed each of the activities in the Prophylaxis Indication CRL, and (ii) if it is unanimously determined by the JSC, or if the JSC is unable to reach a unanimous determination and it is determined by an independent expert, that it is not commercially reasonable to undertake such activities, then the date of such determination; (c) the date on which, following the availability of complete topline efficacy data from the ReSPECT Trial, Cidara and Melinta jointly determine in good faith, that such data are insufficient to support the filing of an NDA for the Product in the Prophylaxis Indication in the Territory; (d) the date on which Cidara and Melinta jointly determine that (i) the ReSPECT Trial cannot be completed due to safety reasons or the requirements of the FDA or other Regulatory Authority, or (ii) it is not commercially reasonable for Cidara to continue the conduct of the ReSPECT Trial; and (e) if the ReSPECT Trial has not been completed by June 30, 2028, the date on which Cidara notifies Melinta in writing that Cidara is terminating the ReSPECT Trial; provided that in each case of clauses (a) through (e), following such date, Cidara will be responsible for any wind-down, close-out, reporting and other such obligations for the ReSPECT Trial required by applicable law, at Cidara's sole expense (the "Transfer Date"). Upon the Transfer Date, the Company will assign all Product Filings to Melinta.

Following the Transfer Date, Melinta will be responsible for performing all activities that may be necessary to maintain NDA approvals for the Product in the Treatment Indication and the Prophylaxis Indication in the Territory, at Melinta's sole expense, subject to Melinta's right to deduct from royalties payable to the Company the internal expenses (not to exceed a specified dollar amount per calendar year) and out-of-pocket expenses incurred by Melinta on or after the Transfer Date for (a) preparing, obtaining, maintaining, and renewing marketing approval for the Product for the Treatment Indication in the Territory; (b) preparing, obtaining, maintaining, and renewing marketing approval for the Product for the Prophylaxis Indication in the Territory; (c) the conduct by or on behalf of Melinta of any post-marketing requirement or post-marketing commitment clinical trial or other study or analysis of the Product required to be conducted by the FDA as a condition of maintaining marketing approval for the Product in the Treatment Indication and the Prophylaxis Indication in the Territory; (d) development activities conducted by or on behalf of Melinta necessary or recommended to eliminate from the FDA approved label for the product any limited use indication statement initially required to be included in such label, unless it is unanimously determined by the JSC, or if the JSC is unable to reach a unanimous determination and it is determined by an independent expert, that it is not commercially reasonable to undertake such activities into consideration both the estimated time and costs to conduct and complete such activities and the increase in the market potential of the Product in the Territory that would reasonably be anticipated to result from removing the limited use indication statement from the label; (e) payment of applicable FDA-imposed prescription drug program fees and prescription drug user fees specifically with respect to the Product for the Lead Indications; and (f) compliance by Melinta with the obligations imposed by applicable U.S. laws, rules and regulations on the holder of the Product Filings for the Product in the Treatment Indication or the Prophylaxis Indication in the Territory.

Supply and Transfer of CMC activities. Until Melinta assumes responsibility for the manufacture and supply of the Product for development and commercialization in the Territory, which it may do by direct purchase from the Company's contract manufacturing organizations for the Product or by having a manufacturing technology transfer to Melinta or its designee performed at Melinta's sole expense, which, in either case, will be no later than December 31, 2026, the Company will be responsible for the manufacture and supply of the Product for development and commercialization by Melinta in the Territory,

and during such period, shall supply Product to Melinta pursuant to the terms of a supply agreement to be negotiated by the parties. Under such supply agreement, the supply price for Product supplied by or on behalf of the Company to Melinta (a) for use in clinical trials and other development and registration activities in the Territory shall be equal to the Company's cost of goods and (b) for commercial distribution in the Territory shall be equal to 110% of the Company's cost of goods.

Termination. Either party may terminate the License Agreement for uncured material breach by the other party. After July 26, 2023, Melinta may terminate the License Agreement at will. The Company may terminate the Agreement if Melinta 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 patent rights licensed to Melinta by the Company.

The foregoing description of the License Agreement and the transactions contemplated thereby does not purport to be complete and is subject to, and qualified in its entirety by reference to, the complete text of the License Agreement, which will be filed with the Securities and Exchange Commission as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2022.

Item 8.01 Other Events.

On July 22, 2022, the Company submitted a new drug application ("NDA") to the U.S. Food and Drug Administration for rezafungin for the treatment of candidemia and invasive candidiasis. The Company expects to be assigned a Prescription Drug User Fee Act target action date in the first quarter of 2023, if the NDA is accepted for review following application validation.

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: July 27, 2022

/s/ Jeffrey Stein, Ph.D.

Jeffrey Stein, Ph.D.

President and Chief Executive Officer
(Principal Executive Officer)