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 7, 2024

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. ☐

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 7, 2024, we issued a press release reporting our financial results for the third quarter ended September 30, 2024. 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 attached 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

Exhibit No.	Description
99.1	Press release issued November 7, 2024, reporting financial results for the third quarter ended September 30, 2024.
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: November 7, 2024

/s/ Jeffrey Stein, Ph.D.

Jeffrey Stein, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Cidara Therapeutics Provides Corporate Update and Reports Third Quarter 2024 Financial Results

SAN DIEGO, November 7, 2024 — Cidara Therapeutics, Inc. (Nasdaq: CDTX) (the Company), a biotechnology company using its proprietary Cloudbreak® platform to develop drug-Fc conjugate (DFC) immunotherapies designed to save lives and improve the standard of care for patients facing serious diseases, today reported financial results for the third quarter ended September 30, 2024, and provided an update on its corporate activities and product pipeline.

"The recent initiation of our Phase 2b NAVIGATE clinical trial, which will evaluate the efficacy and safety of CD388 for the pre-exposure prophylaxis of seasonal influenza, represents an important clinical achievement for our company," said Jeffrey Stein, Ph.D., president and chief executive officer of Cidara. "Additionally, the realignment of our organization will ensure the most efficient use of our resources, enabling us to focus on advancing our promising CD388 clinical program. Based on the compelling data generated to date, we believe CD388 has the potential to provide long-term protection against both seasonal and pandemic strains of influenza with a single dose per flu season."

Recent Corporate Highlights

- **Dosed first subjects in Phase 2b NAVIGATE trial evaluating efficacy and safety of CD388 for the pre-exposure prophylaxis of seasonal influenza.** In September 2024, Cidara initiated a randomized, double-blind, controlled Phase 2b trial targeting enrollment of 5,000 healthy, unvaccinated adult subjects who are not at risk of complications from influenza. Three CD388 dose groups and one placebo group are being randomized in a 1:1:1:1 ratio and we administered CD388 at the beginning of this influenza season. Subjects will be followed for the remainder of the influenza season to monitor for breakthrough cases. Rates of laboratory and clinically confirmed influenza will be compared between subjects receiving the various single doses of CD388 or placebo. The study includes sites in the U.S. and UK.
- **Highlighted CD388 in two presentations at the 2024 IDWeek Conference.** In October 2024, positive Phase 2a human challenge study data were presented in an oral presentation, which demonstrated that a single subcutaneous dose of CD388 administered five days prior to influenza challenge was shown to be effective in preventing symptomatic disease. Positive first-in-human data from a Phase 1 trial studying the safety and PK of CD388 administered by intramuscular and subcutaneous injection were also presented. The results showed that CD388 was rapidly absorbed to achieve target exposure levels and slowly eliminated, regardless of administration route, with no concerning safety signals, supporting the potential for a single dose of CD388 per flu season.
- **Highlighted CD388 in an oral and poster presentation at the 2024 OPTIONS XII for the Control of Influenza conference.** Phase 1 and Phase 2a safety data from three clinical trials on the Company's CD388 asset were presented in oral presentation format, and pharmacokinetics and safety of CD388 following subcutaneous administration in healthy Japanese participants were presented. Overall, results were consistent with a previous Phase 1 clinical study in Western participants. CD388 injection was well tolerated, and the data support further clinical studies with CD388 in the Japanese population for the prevention of seasonal influenza.

- **Strengthened Scientific Advisory Board (SAB) with four infectious disease experts.** In September 2024, Rick Bright, Ph.D., Philip Krause, M.D., Mario Barro, Ph.D., and Frederick Hayden, M.D., FACP, were appointed to the Company's SAB. The new members' collective expertise working in infectious diseases including influenza, pandemic preparedness, and clinical and regulatory processes will be instrumental as Cidara conducts its CD388 Phase 2b NAVIGATE trial.
- **Appointed Jim Beitel as Chief Business Officer.** In August 2024, Jim Beitel joined Cidara as Chief Business Officer. Mr. Beitel brings over 20 years of experience in life science corporate development, including strategy, business development, commercialization, finance, and other roles.
- **Restructured workforce to focus on planned clinical development of CD388.** In September 2024, Cidara announced an approximate 30% reduction in workforce to focus on the clinical development of its novel DFC candidate for influenza A and B, CD388. This restructuring is expected to substantially reduce Cidara's capital needs related to recurring personnel costs.

Third Quarter 2024 Financial Results

- Cash and cash equivalents totaled $127.4 million as of September 30, 2024, compared with $35.8 million as of December 31, 2023.
- Revenue was zero and $1.3 million for the three and nine months ended September 30, 2024, respectively, compared to $9.2 million and $20.5 million for the same periods in 2023, respectively. Revenue for the three and nine months ended September 30, 2024 and 2023 related to research and development and clinical supply services provided to J&J Innovative Medicine, previously Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), under our license and collaboration agreement with Janssen (the Janssen Collaboration Agreement). The Janssen Collaboration Agreement was terminated upon the effectiveness of our license and technology transfer agreement with Janssen (the Janssen License Agreement) on April 24, 2024.
- Acquired in-process research and development expenses were $84.9 million for the nine months ended September 30, 2024 and related to an upfront payment of $85.0 million paid to Janssen under the Janssen License Agreement, on April 24, 2024, plus $0.4 million in direct transaction costs, offset by a settlement gain of $0.5 million to settle the preexisting Janssen Collaboration Agreement relationship.
- Research and development expenses were $12.4 million and $25.0 million for the three and nine months ended September 30, 2024, respectively, compared to $10.4 million and $28.8 million for the same periods in 2023, respectively. The increase in research and development expenses for the three months ended September 30, 2024, compared to the three months ended September 30, 2023 is primarily due to higher expenses associated with our CD388 Phase 2b NAVIGATE study and higher personnel costs, including $1.2 million for severance payments and employee benefits related to a reduction in force, offset by lower nonclinical expenses associated with our Cloudbreak platform. The decrease in research and development expenses for the nine months ended September 30, 2024, compared to the nine months ended September 30, 2023 is primarily due to lower nonclinical expenses associated with our Cloudbreak platform, offset by higher expenses associated with our CD388 Phase 2b NAVIGATE study and higher personnel costs, including $1.2 million for severance payments and employee benefits related to a reduction in force.
- Selling, general and administrative (SG&A) expenses were $5.0 million and $13.3 million for the three and nine months ended September 30, 2024, respectively, compared to $3.3 million and $10.1 million for the same periods in 2023, respectively. The SG&A expenses for all periods primarily relate to consulting, personnel and legal costs.

- On April 24, 2024, Cidara entered into an asset purchase agreement with Napp Pharmaceutical Group Limited (Napp) an affiliate of Mundipharma Medical Company, pursuant to which we sold to Napp all of our rezafungin assets and related contracts. We completed all conditions of the sale on April 24, 2024. We determined that the sale of rezafungin represented a strategic shift that will have a major effect on our operations and financial results. Accordingly, the sale of rezafungin is classified as discontinued operations. We have separately reported the financial results of rezafungin as discontinued operations in the condensed consolidated statements of operations and comprehensive loss for all periods presented. Net loss from discontinued operations for the three months ended September 30, 2024, was $0.5 million and net income from discontinued operations for the nine months ended September 30, 2024 was $0.4 million, compared to net loss from discontinued operations of $5.3 million and $2.8 million for the same periods in 2023, respectively.
- Net loss for the three and nine months ended September 30, 2024 was $16.0 million and $117.5 million, respectively, compared to a net loss of $9.1 million and $19.7 million for the same periods in 2023, respectively.
- On July 18, 2024, the Company's stockholders approved the issuance of up to 16,800,000 shares of common stock upon conversion of 240,000 shares of Series A Convertible Voting Preferred Stock issued in our private placement completed in April 2024. On July 19, 2024, the Company issued 2,469,250 shares of common stock upon automatic conversion of 35,275 shares of Series A Convertible Voting Preferred Stock.
- During the three and nine months ended September 30, 2024, Cidara did not sell any shares of common stock pursuant to its at-the-market sales agreement.
- As of September 30, 2024, Cidara had 7,046,633 shares of common stock outstanding, 204,725 shares of Series A Convertible Voting Preferred Stock outstanding, which are convertible into 14,330,750 shares of common stock, and 2,104,472 shares of Series X Convertible Preferred Stock outstanding, which are convertible into 1,052,236 shares of common stock, for a total of 22,429,619 shares of common stock equivalents outstanding.

About Cidara Therapeutics

Cidara Therapeutics is using its proprietary Cloudbreak® platform to develop novel drug-Fc conjugates (DFCs) comprising targeted small molecules or peptides coupled to a proprietary human antibody fragment (Fc). Cidara's lead DFC candidate, CD388, is a long-acting antiviral designed to achieve universal prevention of seasonal and pandemic influenza with a single dose by directly inhibiting viral proliferation. In June 2023, CD388 was granted Fast Track Designation by the U.S. Food and Drug Administration (FDA), and the Company announced initiation of a Phase 2b trial in September 2024. Additional DFCs have been developed for oncology and in July 2024 Cidara received IND clearance for CBO421 which is intended to target CD73 in solid tumors. Cidara is headquartered in San Diego, California. For more information, please visit www.cidara.com.

Forward-Looking Statements

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," "intends," "believes," "may," "plan" or "will". Forward-looking statements in this release include, but are not limited to, statements related to the potential of and future plans for CD388, the potential impacts and benefits of our realignment and restructuring, our Phase 2b NAVIGATE trial study design and locations for sites and the impact of new SAB members. 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 and other risks related to clinical development, delays in action by regulatory authorities, other obstacles on the enrollment of patients or other aspects of CD388 or other DFC development, the impacts of the realignment and restructuring being different than expected and other risks and uncertainties associated with Cidara's business in general. 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 SEC. 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.

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CIDARA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except share and per share data)	**2024**	**2023**	**2024**	**2023**
Revenues:				
Collaboration revenue	$ —	$ 9,217	$ 1,275	$ 20,527
Total revenues	—	9,217	1,275	20,527
Operating expenses:				
Acquired in-process research and development	—	—	84,883	—
Research and development	12,429	10,386	25,005	28,753
Selling, general and administrative	4,965	3,299	13,307	10,133
Total operating expenses	17,394	13,685	123,195	38,886
Loss from operations	(17,394)	(4,468)	(121,920)	(18,359)
Other income, net:				
Interest income, net	1,859	613	3,998	1,468
Total other income, net	1,859	613	3,998	1,468
Net loss from continuing operations before income tax expense	(15,535)	(3,855)	(117,922)	(16,891)
Income tax benefit (expense)	—	32	—	(8)
Net loss from continuing operations	(15,535)	(3,823)	(117,922)	(16,899)
Income (loss) from discontinued operations (including loss on disposal of discontinued operations of zero and $1,799 during the three and nine months ended September 30, 2024, respectively), net of income taxes	(450)	(5,284)	402	(2,819)
Net loss and comprehensive loss	$ (15,985)	$ (9,107)	$ (117,520)	$ (19,718)
Basic and diluted net loss per common share from continuing operations	$ (2.38)	$ (0.85)	$ (22.61)	$ (3.91)
Basic and diluted net earnings (loss) per common share from discontinued operations	(0.07)	(1.17)	0.08	(0.65)
Basic and diluted net loss per common share	$ (2.45)	$ (2.02)	$ (22.53)	$ (4.56)
Shares used to compute basic and diluted net earnings (loss) per common share	6,530,111	4,514,381	5,215,365	4,319,536

Condensed Consolidated Balance Sheet Data

	September 30, 2024	December 31, 2023
(In thousands)	(unaudited)	
Cash and cash equivalents	$ 127,386	$ 35,778
Total assets	162,331	67,030
Total liabilities	46,701	75,240
Total stockholders' equity (deficit)	115,630	(8,210)