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): May 6, 2024

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

Delaware	**000-15006**	**13-3191702**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

Perryville III Building, 53 Frontage Road, Suite 220
Hampton, New Jersey 08827
(Address of Principal Executive Offices) (Zip Code)

(908) 200-7500
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation 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 $.001	CLDX	Nasdaq Capital 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 2.02. Results of Operations and Financial Condition.

On May 6, 2024, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter of 2024. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

The information in this Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto 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 such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Press Release of Celldex Therapeutics, Inc., dated May 6, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Celldex Therapeutics, Inc.

Date: May 6, 2024

By: /s/ Sam Martin
Sam Martin
Senior Vice President and
Chief Financial Officer

EXHIBIT 99.1

Celldex Reports First Quarter 2024 Financial Results and Provides Corporate Update

- Phase 3 CSU studies expected to initiate in summer 2024 -
- Positive Phase 2 CSU 12 week data reported in late breaking oral presentation at AAAAI 2024; 52 week data to be reported in 2H 2024 -
- Enrollment completed in Phase 2 CIndU study; 12 week data expected 2H 2024 -
- Phase 2 PN study initiated; enrollment progressing in Phase 2 EoE study -
- Atopic dermatitis selected as next indication; Phase 2 study to initiate by YE 2024 -

HAMPTON, N.J., May 06, 2024 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the first quarter ended March 31, 2024 and provided a corporate update.

"During the first quarter we presented impressive best-in-field data from a large, randomized Phase 2 study in CSU," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "These results added to a rapidly growing body of data across multiple indications that support barzolvolimab's impressive potential to treat mast cell mediated diseases. This year, we continue to expand barzolvolimab's profile and, based on its unique mechanism of action and demonstrated improvement in pruritus, we are actively planning for the initiation of a Phase 2 study in atopic dermatitis, a setting where mast cell numbers are known to be increased and activated in the lesions associated with the disease and where, despite established systemic therapies, a significant unmet need still exists."

Mr. Marucci continued, "As the year progresses, we look forward to building on our leadership in the development of mast cell-targeted therapeutics. Importantly, the Company is well capitalized with more than $820M in cash to support the continued advancement and expansion of the barzolvolimab program and the introduction of our first bispecific for inflammatory diseases later this year."

Recent Program Highlights

Barzolvolimab - KIT Inhibitor Program

Barzolvolimab is a humanized monoclonal antibody developed by Celldex that binds the KIT receptor with high specificity and potently inhibits its activity. The KIT receptor tyrosine kinase is expressed in a variety of cells, including mast cells, which mediate inflammatory responses such as hypersensitivity and allergic reactions. KIT signaling controls the differentiation, tissue recruitment, survival and activity of mast cells.

- Celldex is conducting Phase 2 clinical studies of barzolvolimab for the treatment of chronic spontaneous urticaria (CSU) and the two most common forms of chronic inducible urticaria (CIndU) - cold urticaria (ColdU) and symptomatic dermographism (SD). These randomized, double-blind, placebo-controlled Phase 2 studies are evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients who remain symptomatic despite antihistamine therapy, to determine the optimal dosing strategies.
    - Celldex is currently planning two Phase 3 studies of barzolvolimab in CSU, which are expected to initiate this summer.
    - In February 2024, 12 week treatment results were reported from the Phase 2 CSU study at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting in a late breaking oral presentation. Barzolvolimab achieved the primary efficacy endpoint of the study, with a statistically significant mean change from baseline to week 12 of UAS7 (weekly urticaria activity score) compared to placebo across multiple dosing groups and was well tolerated. Secondary and exploratory endpoints in the study, including ISS7 (weekly itch severity score) and HSS7 (weekly hives severity score) and responder analyses strongly support the primary endpoint results. Importantly, barzolvolimab demonstrated rapid, durable and clinically meaningful responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment. Approximately 20% (n=41) of enrolled patients received prior treatment with omalizumab and more than half of these patients had omalizumab-refractory disease. These patients experienced a similar clinical benefit as the overall treated population within their individual dosing groups consistent with the barzolvolimab mechanism of action. Patients on study will continue to receive barzolvolimab for 52 weeks and the Company plans to report 52 week data in the second half of 2024.

      Data from this study on the impact of barzolvolimab on angioedema have been accepted for an oral presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Congress 2024 on Saturday, June 2nd from 3:00-4:30 CET in Valencia, Spain (9:00-10:30 am ET).
    - Enrollment to the Phase 2 CIndU study has been completed and 12 week primary endpoint data from this study are expected to be reported in the second half of 2024. The study enrolled 196 patients—97 patients with cold urticaria and 99 patients with symptomatic dermographism.
- A Phase 2 subcutaneous study in prurigo nodularis (PN) was initiated in early 2024. This randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of barzolvolimab in approximately 120

patients with moderate to severe PN who had inadequate response to prescription topical medications, or for whom topical medications are medically inadvisable, including patients who received prior biologics. Patients are receiving barzolvolimab injections of 150 mg Q4W after an initial loading dose of 450 mg, 300 mg Q4W after an initial loading dose of 450 mg, or placebo during a 24-week Treatment Phase.

- In July 2023, the first patient was dosed in the Phase 2 randomized, double-blind, placebo-controlled study in eosinophilic esophagitis (EoE); enrollment is ongoing. To optimize potential efficacy signal in this difficult to treat indication, in early 2024, the protocol was amended to dose 300 mg every 4 weeks rather than 8 weeks. Approximately 75 patients will be enrolled in total.

- Atopic Dermatitis has been selected as the fifth indication for the development of barzolvolimab. Atopic dermatitis (AD) is a chronically relapsing, inflammatory skin disease that is typified by pruritus (itching), eczematous lesions, dry skin, thickening of the skin and an increase in skin markings. AD is the most common inflammatory skin condition, with a lifetime prevalence of up to 20% and has a high itch burden—almost 90% of individuals with AD experience daily itching and 60% describe their itching as severe or unbearable. Barzolvolimab's novel mast cell depleting mechanism could play an important role in addressing patients with moderate to severe AD who do not achieve complete disease control on currently available systemic therapies. Mast cell numbers are increased and activated in AD lesions and produce key TH2 cytokines and neuropeptides that trigger disease progression and itch. Barzolvolimab has demonstrated impressive anti-pruritic effects in other itch driven conditions, including chronic urticarias and prurigo nodularis. Celldex plans to initiate a Phase 2 study in AD by year end.

Bispecific Antibody Platform

CDX-585 – Bispecific ILT4 & PD-1

CDX-585 combines highly active PD-1 blockade with anti-ILT4 blockade to overcome immunosuppressive signals in T cells and myeloid cells. ILT4 is emerging as an important immune checkpoint on myeloid cells.

- In May 2023, the first patient was dosed in the Phase 1 study of CDX-585. This open-label, multi-center study of CDX-585 is evaluating patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy. Enrollment is ongoing in the dose-escalation portion of the study.

First Quarter 2024 Financial Highlights and 2024 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2024 were $823.8 million compared to $423.6 million as of December 31, 2023. The increase was primarily driven by net proceeds of $432.3 million from our March 2024 underwritten public offering, partially offset by cash used in operating activities of $40.6 million. At March 31, 2024, Celldex had 65.9 million shares outstanding.

Revenues: Total revenue was $0.2 million in the first quarter of 2024, compared to $1.0 million for the comparable period in 2023. The decrease in revenue was primarily due to a decrease in services performed under our manufacturing and research and development agreements with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were $31.7 million in the first quarter of 2024, compared to $26.8 million for the comparable period in 2023. The increase in R&D expenses was primarily due to an increase in barzolvolimab clinical trial and personnel expenses, partially offset by a decrease in barzolvolimab contract manufacturing expenses.

G&A Expenses: General and administrative (G&A) expenses were $9.1 million in the first quarter of 2024, compared to $6.6 million for the comparable period in 2023. The increase in G&A expenses was primarily due to an increase in stock-based compensation and barzolvolimab commercial planning expenses.

Net Loss: Net loss was $32.8 million, or ($0.56) per share, for the first quarter of 2024, compared to a net loss of $29.4 million, or ($0.62) per share, for the comparable period in 2023.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2024 are sufficient to meet estimated working capital requirements and fund current planned operations through 2027.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company leading the science at the intersection of mast cell biology and the development of transformative therapeutics for patients. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with severe inflammatory, allergic, autoimmune and other devastating diseases. Visit www.celldex.com.

Forward Looking Statement
This release contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be

correct or that those goals will be achieved, and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to successfully complete research and further development and commercialization of Company drug candidates, including barzolvolimab (also referred to as CDX-0159), in current or future indications; the uncertainties inherent in clinical testing and accruing patients for clinical trials; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage and successfully complete multiple clinical trials and the research and development efforts for our multiple products at varying stages of development; the availability, cost, delivery and quality of clinical materials produced by our own manufacturing facility or supplied by contract manufacturers, who may be our sole source of supply; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company's programs to continue to develop; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; our ability to continue to obtain capital to meet our long-term liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we have initiated or plan to initiate; and other factors listed under "Risk Factors" in our annual report on Form 10-K and quarterly reports on Form 10-Q.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

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CELLDEX THERAPEUTICS, INC.
(In thousands, except per share amounts)

Consolidated Statements of Operations Data	**Three Months Ended March 31,**	
	2024	**2023**
	(Unaudited)	
Revenues:		
Product development and licensing agreements	$ 2	$ -
Contracts and grants	154	967
Total revenues	156	967
Operating expenses:		
Research and development	31,661	26,798
General and administrative	9,103	6,640
Total operating expenses	40,764	33,438
Operating loss	(40,608)	(32,471)
Investment and other income, net	7,800	3,110
Net loss	$ (32,808)	$ (29,361)
Basic and diluted net loss per common share	$ (0.56)	$ (0.62)
Shares used in calculating basic and diluted net loss per share	58,871	47,214

Condensed Consolidated Balance Sheet Data	**March 31**	**December 31,**

	2024 (Unaudited)	2023
Assets		
Cash, cash equivalents and marketable securities	$ 823,846	$ 423,598
Other current assets	11,478	8,095
Property and equipment, net	4,061	4,060
Intangible and other assets, net	29,462	29,874
Total assets	$ 868,847	$ 465,627
Liabilities and stockholders' equity		
Current liabilities	$ 26,291	$ 31,125
Long-term liabilities	3,943	5,331
Stockholders' equity	838,613	429,171
Total liabilities and stockholders' equity	$ 868,847	$ 465,627