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 4, 2023

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 4, 2023, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter of 2023. 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 4, 2023.
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 4, 2023

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

EXHIBIT 99.1

Celldex Reports First Quarter 2023 Financial Results and Provides Corporate Update

- Phase 2 CSU enrollment completion expected in Q3 2023 -
- Phase 1b CSU study and Phase 1 cholinergic cohort both accepted for oral presentation at EAACI 2023 -
- Phase 2 EoE study expected to initiate in June 2023 -

HAMPTON, N.J., May 04, 2023 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the first quarter ended March 31, 2023 and provided a corporate update.

“This quarter, we were excited to report additional positive data from our barzolvolimab Phase 1b multi-dose study in chronic spontaneous urticaria. We believe the rapid, durable and profound responses and the favorable safety profile observed in this study continue to position barzolvolimab as a potential best-in-class addition to a historically limited treatment landscape for patients and their physicians,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We look forward to presenting additional data from this study and also from the cholinergic cohort in the Phase 1b CIndU study at EAACI next month, where both data sets have been accepted for oral presentations.”

“Importantly, our Phase 2 studies in chronic urticaria continue to progress as planned and we are on track to complete enrollment of the Phase 2 CSU study by the end of the third quarter, with topline data expected late this year or in the first quarter of 2024. We continue to expand the barzolvolimab program into indications where we believe its unique mechanism could potentially provide new therapeutic options to patients suffering from these difficult diseases and look forward to providing updates on our eosinophilic esophagitis and prurigo nodularis studies throughout the 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.

- In June and July 2022, Celldex announced that the first patients had been dosed in the 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, parallel group 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. Based on current enrollment projections, Celldex anticipates that enrollment to the CSU study will be completed by the end of Q3 2023 and plans to report topline data either late this year or in the first quarter of 2024.

- Data from the Phase 1b multiple dose study in patients with antihistamine refractory CSU were presented at the American Academy of Allergy, Asthma & Immunology (AAAAI) Annual Meeting on Sunday, February 26, 2023 by Dr. Marcus Maurer, Professor of Dermatology and Allergy at Charité – Universitätsmedizin in Berlin and a lead investigator on the study. Updated data from this study have been accepted for oral presentation at the EAACI Hybrid Congress 2023, to be held in Hamburg, Germany, June 9 - 11 and on the EAACI Digital Events Platform.

  AAAAI 2023 Data Summary:

  As of the data cut-off date on November 29, 2022, enrollment was complete with 45 patients with moderate to severe CSU refractory to antihistamines enrolled and treated [35 barzolvolimab (n=9 in 0.5 mg/kg; n=8 in 1.5 mg/kg; n=9 in 3.0 mg/kg; n=9 in 4.5 mg/kg) and 10 placebo]. The 0.5 mg/kg, 1.5 mg/kg and 3.0 mg/kg cohorts had completed study participation through 24 weeks; 6 of 9 patients in the 4.5 mg/kg cohort had completed through the week 20 visit. Complete data were included for all patients in dose levels through 3.0 mg/kg through 24 weeks. All available data for the 4.5 mg/kg and placebo dose levels were presented for adverse events. Activity data for the 4.5 mg/kg dose level were reported through week 20. Activity data for the 0.5 mg/kg and placebo group were only included through week 12 because, as expected, most patients from these groups had significant symptoms ahead of week 24 and discontinued follow up. Two patients did not receive all doses of study treatment [4.5 mg/kg (1), placebo (1)].

  - Barzolvolimab resulted in rapid, marked and durable responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment. The 1.5 mg/kg, 3.0 mg/kg and 4.5 mg/kg dose groups showed similar markedly improved urticaria symptoms and disease control with sustained durability up to 24 weeks.

  - Mean reduction from baseline in urticaria activity (UAS7) at week 12 of 67% in the 1.5 mg/kg dose group (n=8), 67% in the 3.0 mg/kg dose group (n=9) and 82% in the 4.5 mg/kg dose group (n=9). Complete response (UAS7=0) at week 12 of 57% in the 1.5 mg/kg dose group, 44% in the 3.0 mg/kg dose group and 67% in the 4.5 mg/kg dose group.

- Well-controlled disease (UCT≥ 12) at week 12 of 75% in the 1.5 mg/kg dose group, 63% in the 3.0 mg/kg dose group and 89% in the 4.5 mg/kg dose group.

- Patients with prior omalizumab therapy had similar symptom improvement as all patients.

- Barzolvolimab was well tolerated with a favorable safety profile; effects of multiple dose administration were consistent with observations in single dose studies. Most AEs were mild or moderate in severity and resolved while on study.

- Celldex has completed enrollment in the barzolvolimab Phase 1b open label study in chronic inducible urticaria. Data from the cholinergic cohort in this study have been accepted for oral presentation at the EAACI Hybrid Congress 2023, to be held in Hamburg, Germany, June 9 - 11 and on the EAACI Digital Events Platform.

- Celldex has closed enrollment at 24 patients in the barzolvolimab Phase 1b multi-center, randomized, double-blind, placebo-controlled study in patients with prurigo nodularis (PN), a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. The study remains blinded. Celldex plans to present data from the ongoing study, including 24 weeks of follow-up, in the fourth quarter at a medical meeting and is planning for the initiation of a Phase 2 subcutaneous study in PN in late 2023 or early 2024.

- Celldex plans to initiate a Phase 2 international trial of barzolvolimab in eosinophilic esophagitis (EoE), the most common type of eosinophilic gastrointestinal disease, in June of 2023.

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.

- CDX-585 has successfully completed GMP manufacturing and IND-enabling studies to support clinical development. CDX-585 will initially be developed for the treatment of solid tumors either as monotherapy or in combination with other oncologic treatments and is expected to enter the clinic in mid-2023 in patients with advanced malignancies.

First Quarter 2023 Financial Highlights and 2023 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2023 were $278.4 compared to $305.0 million as of December 31, 2022. The decrease was primarily driven by cash used in operating activities of $28.6 million, partially offset by proceeds from stock issuances under employee benefit plans and unrealized gains due to higher interest rates. At March 31, 2023, Celldex had 47.2 million shares outstanding.

Revenues: Total revenue was $1.0 million in the first quarter of 2023, compared to $0.2 million for the comparable period in 2022. The increase in revenue was primarily due to an increase in services performed under our manufacturing and research and development agreement with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were $26.8 million in the first quarter of 2023, compared to $17.1 million for the comparable period in 2022. The increase in R&D expenses was primarily due to an increase in barzolvolimab clinical trial, barzolvolimab contract manufacturing, and personnel expenses.

G&A Expenses: General and administrative (G&A) expenses were $6.6 million in the first quarter of 2023, compared to $6.9 million for the comparable period in 2022. The decrease in G&A expenses was primarily due to a decrease in legal expenses, partially offset by an increase in stock-based compensation expense.

Changes in Fair Value Remeasurement of Contingent Consideration: The Company recorded a $0.5 million gain on fair value remeasurement of contingent consideration for the three months ended March 31, 2022, primarily due to changes in discount rates.

Net Loss: Net loss was $29.4 million, or ($0.62) per share, for the first quarter of 2023, compared to a net loss of $23.1 million, or ($0.49) per share, for the comparable period in 2022.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2023 are sufficient to meet estimated working capital requirements and fund planned operations through 2025, which include our ongoing Phase 1b studies in urticaria and prurigo nodularis and our ongoing and planned Phase 2 studies in CSU, CIndU and EoE.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. 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 inflammatory diseases and many forms of cancer. 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 effects of the outbreak of COVID-19 on our business and results of operations; 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,**	
	2023	**2022**
	(Unaudited)	
Revenues:		
Product development and licensing agreements	$ -	$ 30
Contracts and grants	967	144
Total revenues	967	174
Operating expenses:		
Research and development	26,798	17,056
General and administrative	6,640	6,911
Gain on fair value remeasurement of contingent consideration	-	(536)
Total operating expenses	33,438	23,431
Operating loss	(32,471)	(23,257)
Investment and other income, net	3,110	207
Net loss	$ (29,361)	$ (23,050)

Basic and diluted net loss per common share	$	(0.62)	$	(0.49)
Shares used in calculating basic and diluted net loss per share		47,214		46,739

Condensed Consolidated Balance Sheet Data	**March 31, 2023 (Unaudited)**	**December 31, 2022**
Assets		
Cash, cash equivalents and marketable securities	$ 278,387	$ 304,952
Other current assets	11,210	12,741
Property and equipment, net	3,995	3,747
Intangible and other assets, net	30,927	31,295
Total assets	$ 324,519	$ 352,735
Liabilities and stockholders' equity		
Current liabilities	$ 15,219	$ 18,610
Long-term liabilities	6,560	7,921
Stockholders' equity	302,740	326,204
Total liabilities and stockholders' equity	$ 324,519	$ 352,735