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): August 8, 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 August 8, 2023, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second 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 August 8, 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: August 8, 2023

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

EXHIBIT 99.1

Celldex Reports Second Quarter 2023 Financial Results and Provides Corporate Update

- Phase 2 CSU enrollment completed; topline data by YE 2023 -
- Phase 1b PN data in Q4 2023 -
- First patient dosed in Phase 2 EoE study -

HAMPTON, N.J., Aug. 08, 2023 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the second quarter ended June 30, 2023 and provided a corporate update.

“Last month, we announced that enrollment in our Phase 2 chronic spontaneous urticaria trial was completed well ahead of schedule, exceeding projections by nearly 25%, driven by strong interest in barzolvolimab,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “Enrollment also continues to progress as planned in our Phase 2 study in chronic inducible urticaria. We are extremely pleased with the progress we have made across both of these studies and look forward to presenting topline data from the CSU study by the end of the year.”

“The rest of our pipeline also continues to advance and we were excited to recently initiate a Phase 2 study in eosinophilic esophagitis and are planning for the initiation of a Phase 2 study in prurigo nodularis in early 2024. In June, barzolvolimab was highlighted in multiple presentations at EAACI that continue to position the program as a potential best-in-class addition to a historically limited treatment landscape for patients and their physicians. We look forward to building on this momentum in the second half of the year,” concluded Marucci.

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. In July 2023, Celldex announced that enrollment to the CSU study had been completed. Given strong interest in barzolvolimab, enrollment projections were exceeded by ~25% and 208 patients were enrolled in the study. Topline data is anticipated by the end of 2023.

- Updated data from the Phase 1b multiple dose study in patients with antihistamine refractory CSU and new data from the Phase 1b single-dose cholinergic cohort included in the CIndU trial were presented at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress on June 10, 2023 by Dr. Marcus Maurer, Professor of Dermatology and Allergy at Charité – Universitätsmedizin in Berlin (CSU data) and Dr. Eva Grekowitz, Clinical Investigator, Department of Dermatology, Venerology and Allergy at Charité – Universitätsmedizin in Berlin (cholinergic data).

CSU EAACI 2023 Data Summary:

At EAACI 2023, data were presented on the complete 24 week experience for all patients. 45 patients with moderate to severe CSU refractory to antihistamines were 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]. Treatment data for the 0.5 mg/kg and placebo group are not included below because as expected, most patients from these groups had significant symptoms ahead of week 24 and discontinued follow up.

  - Multiple doses of barzolvolimab resulted in rapid dose-dependent decreases in itch and hives with durable and prolonged symptom control in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment.

  - Mean reduction from baseline in urticaria activity (UAS7) at week 24 was 80% in the 1.5 mg/kg dose group (n=7), 70% in the 3.0 mg/kg dose group (n=6) and 77% in the 4.5 mg/kg dose group (n=7).

  - Complete response (UAS7=0) at week 24 was 57% in the 1.5 mg/kg dose group, 67% in the 3.0 mg/kg dose group and 43% in the 4.5 mg/kg dose group. Well-controlled disease (UCT≥ 12) at week 24 was 75% in the 1.5 mg/kg dose group, 67% in the 3.0 mg/kg dose group and 67% in the 4.5 mg/kg dose group. During post-treatment follow up, 71% (10 of 14) of patients who had been treated with doses greater than or equal to 1.5 mg/kg and had a complete response (UAS7=0) at week 12, remained urticaria free at week 24.

- Profound and durable improvement in angioedema symptoms as measured through the angioedema activity score over 7 days (AAS7) was achieved across all dose levels evaluated with sustained activity observed with the 1.5 mg/kg and greater dose levels. 31 patients on study (n=26 barzolvolimab; 5=placebo) reported angioedema activity at baseline when enrolling in the study. 86% of the barzolvolimab treated patients at 1.5 mg/kg or greater were angioedema free at week 12 and 83% were angioedema free at week 24.

- Barzolvolimab was well tolerated with a favorable safety profile; effects of multiple dose administration were consistent with observations in single dose studies.

Cholinergic (CholU) EAACI 2023 Data Summary:

At EAACI 2023, 12 week treatment and safety data were presented from the cohort of patients with antihistamine refractory cholinergic urticaria (n=9) included in the open-label, Phase 1 trial of chronic inducible urticaria. Patients received a single intravenous 3.0 mg/kg barzolvolimab dose with a 12-week follow-up.

- 56% (5/9) patients achieved a complete response (negative test) with PCE (pulse-controlled ergometry) provocation testing with just one dose of barzolvolimab and most responses remained durable through to week 12. PCE testing included controlled exercise on a stationary bicycle with monitoring for development of itch and wheals.

- 63% (5/8) patients reported well controlled disease (UCT ≥12) at week 8 and 50% (4/8) at week 12, respectively. 100% (6/6) patients who reported on quality of life (QoL) measurements at week 8 had clinically significant improvements in QoL. These improvements in QoL were sustained through week 12 for the majority (5/7, 71%) of patients.

- The kinetics of tryptase and mast cell reduction mirrored clinical activity.

- Barzolvolimab was generally well tolerated in patients with CholU, with a similar safety profile to what was reported previously in the cold contact and symptomatic dermographism cohorts in this study.

- Celldex 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 Company plans to present data from the 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 early 2024.

- In June, Celldex initiated a Phase 2 study of eosinophilic esophagitis (EoE) and the first patient was dosed in July. EoE, the most common type of eosinophilic gastrointestinal disease, is a chronic inflammatory disease of the esophagus characterized by the infiltration of eosinophils. The randomized, double-blind, placebo-controlled, parallel group Phase 2 study is evaluating the efficacy and safety profile of subcutaneous barzolvolimab in patients with active EoE. Approximately 60 patients will be enrolled. The primary endpoint of the study is reducing esophageal intraepithelial infiltration of mast cells as assessed by peak esophageal intraepithelial mast cell count. Secondary endpoints include the reduction of symptoms of dysphagia and esophageal intraepithelial infiltration of eosinophils and safety. When all clinical trial sites are open, the study will include approximately 60 clinical trial centers across 8 countries, including the United States.

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, Celldex announced that the first patient had been dosed in the Phase 1 study of CDX-585. This open-label, multi-center, intravenous study of CDX-585 is being evaluated in patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy. The dose-escalation phase of the study (n=~30 patients) is designed to determine a maximum tolerated dose (MTD) and to select CDX-585 dose(s) for future evaluation in tumor specific expansion cohorts.

Second Quarter 2023 Financial Highlights and 2023 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2023 were $252.7 million compared to $278.4 million as of March 31, 2023. The decrease was primarily driven by second quarter cash used in operating activities of $27.2 million, partially offset by net sales and maturities of marketable securities of $1.6 million for the three months ended June 30, 2023. At June 30, 2023, Celldex had 47.3 million shares outstanding.

Revenues: Total revenue was $0.3 million in the second quarter of 2023 and $1.2 million for the six months ended June 30, 2023, compared to $0.2 million and $0.3 million for the comparable periods in 2022. The increase in revenue was primarily due to an increase in services performed under our manufacturing and research and development agreements with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were $26.3 million in the second quarter of 2023 and $53.0 million for the six months ended June 30, 2023, compared to $20.7 million and $37.8 million for the comparable periods 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 $7.2 million in the second quarter of 2023 and $13.9 million for the six months ended June 30, 2023, compared to $7.2 million and $14.1 million for the comparable periods in 2022. The decrease in G&A expenses for the six months ended June 30, 2023, as compared to the six months ended June 30, 2022, 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 gain on fair value remeasurement of contingent consideration was $6.3 million for the second quarter of 2022 and $6.9 million for the six months ended June 30, 2022, primarily due to the Company's decision to deprioritize the CDX-1140 program in the second quarter of 2022.

Net Loss: Net loss was $30.5 million, or ($0.65) per share, for the second quarter of 2023, and $59.9 million, or ($1.27) per share, for the six months ended June 30, 2023, compared to a net loss of $36.0 million, or ($0.77) per share, for the second quarter of 2022, and $59.1 million, or ($1.26) per share, for the six months ended June 30, 2022.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 30, 2023 are sufficient to meet estimated working capital requirements and fund planned operations through 2025, which include our ongoing and planned Phase 2 studies in CSU, CIndU, EoE and PN.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited)		(Unaudited)	
Revenues:				
Product development and licensing agreements	$ 16	$ -	$ 16	$ 30
Contracts and grants	252	163	1,218	307
Total revenues	268	163	1,234	337
Operating expenses:				
Research and development	26,252	20,731	53,049	37,786
General and administrative	7,221	7,154	13,861	14,066
Gain on fair value remeasurement of contingent consideration	-	(6,326)	-	(6,862)
Litigation settlement loss	-	15,000	-	15,000
Total operating expenses	33,473	36,559	66,910	59,990
Operating loss	(33,205)	(36,396)	(65,676)	(59,653)
Investment and other income, net	2,703	392	5,813	599
Net loss	$ (30,502)	$ (36,004)	$ (59,863)	$ (59,054)
Basic and diluted net loss per common share	$ (0.65)	$ (0.77)	$ (1.27)	$ (1.26)
Shares used in calculating basic and diluted net loss per share	47,253	46,759	47,233	46,749

Condensed Consolidated Balance Sheet Data	June 30,	December 31,
	2023	2022
	(Unaudited)	
Assets		
Cash, cash equivalents and marketable securities	$ 252,697	$ 304,952
Other current assets	12,123	12,741
Property and equipment, net	3,938	3,747
Intangible and other assets, net	30,553	31,295
Total assets	$ 299,311	$ 352,735
Liabilities and stockholders' equity		
Current liabilities	$ 15,646	$ 18,610
Long-term liabilities	6,128	7,921
Stockholders' equity	277,537	326,204
Total liabilities and stockholders' equity	$ 299,311	$ 352,735