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): February 28, 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 February 28, 2023, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended 2022. 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 February 28, 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: February 28, 2023

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

EXHIBIT 99.1

Celldex Reports Fourth Quarter and Year End 2022 Financial Results and Provides Corporate Update

- Phase 1b multi-dose CSU data presented at AAAAI on February 26 -
- Phase 2 CSU enrollment completion expected by Q3 2023 -

HAMPTON, N.J., Feb. 28, 2023 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the fourth quarter and year ended December 31, 2022 and provided a corporate update.

“Celldex made significant progress over the past year advancing our pipeline. We reported multiple positive data sets from our Phase 1b barzolvolimab program, including updated results from the Phase 1b multi-dose study in chronic spontaneous urticaria this past weekend at AAAAI,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “Our Phase 2 studies in both inducible and spontaneous urticaria are enrolling as planned and we expect to complete accrual of the Phase 2 CSU study by the end of the third quarter and, importantly, will be in a position to report topline data from this study either late this year or in the first quarter of 2024.”

Mr. Marucci continued, “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 initiating our Phase 2 study in eosinophilic esophagitis in the first half of 2023 and to presenting Phase 1 data from our prurigo nodularis program later this year. We also made considerable progress on our bispecific platform in 2022, advancing several candidates focused on important targets in inflammatory diseases and are poised to initiate a Phase 1 study of CDX-585, our ILT4 and PD-(L)1 oncology candidate, later this year. Finally, in direct support of our growth, we recently welcomed Dr. Rita Jain to the Celldex Board of Directors and we look forward to her contributions as we continue to advance our programs into later stage development.”

Recent Business Highlights

On February 16, 2023, Celldex announced that Rita Jain, M.D. was appointed to the Company’s Board of Directors. Dr. Jain is a rheumatologist and most recently served as Executive Vice President, Chief Medical Officer of ChemoCentryx, Inc. She currently serves as a member of the Board of Directors for Provention Bio, Inc. and serves on the supervisory board of AM Pharma. Celldex believes her deep background in drug development strongly complements the current Board’s skills and experiences.

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 have 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.

  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.

- On December 6, 2022, Celldex announced data from the Company's open label Phase 1b clinical trial of barzolvolimab in patients with antihistamine refractory chronic inducible urticarias, including new data from the Phase 1b 1.5 mg/kg cohort conducted in cold urticaria and long term follow data from the Phase 1b 3.0 mg/kg cohorts conducted in cold urticaria and symptomatic dermographism. The data were presented at the GA²LEN Global Urticaria Forum (GUF) held in Berlin, Germany.

  GUF 2022 Data Summary:

  Cold Urticaria 1.5 mg/kg intravenous cohort oral presentation: *"Cold urticaria patients achieve complete response with 1.5 mg/kg barzolvolimab"*

  10 patients received a single intravenous infusion of barzolvolimab at 1.5 mg/kg. Patients had high disease activity as assessed by provocation threshold testing. All patients had disease refractory to antihistamines and five patients had disease refractory to omalizumab. Safety results were reported for all 10 patients; activity results were reported for the 9 patients who received a full dose of barzolvolimab, including four patients with omalizumab refractory disease.

  -- All 9 of 9 (100%) patients evaluable for activity treated at 1.5 mg/kg experienced a complete response as assessed by provocation threshold testing, including 4 patients with disease refractory to omalizumab. Rapid onset of responses after dosing were observed with 6 of 9 patients experiencing complete response within a week of dosing. Responses were durable with a median duration of response of 51+ days (7+ weeks).

  -- Improvements in disease activity as reported by Urticaria Control Test (UCT) were consistent with the completed responses as measured by provocation testing. All patients entered the cohort with poorly controlled disease. Following barzolvolimab administration, all patients achieved well controlled disease with 7 of 9 achieving complete control.

  -- A single 1.5 mg/kg dose of barzolvolimab resulted in rapid, marked and durable suppression of serum tryptase. The kinetics of tryptase depletion mirrored changes in provocation threshold and UCT.

  -- Barzolvolimab was generally well tolerated and the safety profile at 1.5mg/kg was similar to the profile observed with 3.0 mg/kg. No new treatment emergent AEs of concern were noted.

  Long-term follow up 3.0 mg/kg intravenous cold urticaria and symptomatic dermographism poster presentation: *"Barzolvolimab-induced response and mast cell suppression are durable and linked"*

  21 patients received a single infusion of barzolvolimab at 3.0 mg/kg, including 11 (10 evaluable for activity) patients with cold urticaria and 10 with symptomatic dermographism. Patients had high disease activity as assessed by provocation threshold testing at baseline and poorly controlled disease by UCT. All patients had disease refractory to antihistamines and three patients had disease refractory to omalizumab. As previously reported, a single 3.0 mg/kg IV dose was generally well tolerated and demonstrated a 95% complete response (negative provocation testing) and 100% well controlled urticaria by Urticaria Control Test (UCT), including in all patients with disease refractory to omalizumab. Profound reduction in serum tryptase and skin mast cells during the 12 week follow up period were observed.

  14 patients consented to the optional long term follow up evaluation (6 cold, 8 symptomatic dermographism); 10 of the 14 still had complete control of their disease as assessed by provocation testing at week 12. Data were collected at one or more timepoints beyond week 12 through week 36.

  -- Most patients had return of symptoms and/or loss of urticaria control between 12 and 36 weeks. Remarkably, two patients remained provocation negative at 36 weeks, and four had well controlled disease (UCT ≥12) 36 weeks post dosing.

  -- Serum tryptase exhibited a similar rate of recovery as clinical symptoms, while skin mast cells return at a slower rate.

  -- Drug related adverse events noted during the study all resolved.

- Celldex has completed enrollment in the barzolvolimab Phase 1b open label study in chronic inducible urticaria. Patient follow up continues in the cholinergic cohort and is planned for presentation in mid-2023.
- 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. Data from this study is planned for presentation in the second half of 2023.
- Celldex plans to initiate a Phase 2 international trial of barzolvolimab in eosinophilic esophagitis (EoE), the most common type of eosinophilic gastrointestinal disease, in the first half of 2023.

Bispecific Antibody Platform

CDX-585 – Bispecific ILT4 & PD-(L)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 2023 in patients with advanced malignancies.

Fourth Quarter and Twelve Months 2022 Financial Highlights and 2023 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2022 were $305.0 million compared to $323.5 million as of September 30, 2022. The decrease was primarily driven by cash used in operating activities of $21.8 million, partially offset by proceeds from option exercises and unrealized gains due to higher interest rates. At December 31, 2022, Celldex had 47.2 million shares outstanding.

Revenues: Total revenue was $1.6 million in the fourth quarter of 2022 and $2.4 million for the year ended December 31, 2022, compared to $0.3 million and $4.7 million for the comparable periods in 2021. The decrease in revenue for the twelve months ended December 31, 2022 compared to the twelve months ended December 31, 2021 was primarily due to a decrease in services performed under our manufacturing and research and development agreements with Rockefeller University and Gilead Sciences.

R&D Expenses: Research and development (R&D) expenses were $22.9 million in the fourth quarter of 2022 and $82.3 million for the year ended December 31, 2022, compared to $14.7 million and $53.3 million for the comparable periods in 2021. 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 fourth quarter of 2022 and $27.2 million for the year ended December 31, 2022, compared to $6.2 million and $20.5 million for the comparable periods in 2021. The increase in G&A expenses was primarily due to our settlement agreement with SRS, barzolvolimab commercial planning and stock-based compensation expenses.

Changes in Fair Value Remeasurement of Contingent Consideration: The Company recorded a $6.9 million gain on fair value remeasurement of contingent consideration for the twelve months ended December 31, 2022, primarily due to the Company's decision to deprioritize the CDX-1140 program in the second quarter of 2022.

Litigation Settlement Related Loss: The Company recorded a one-time loss of $15.0 million in the second quarter of 2022 related to the $15.0 million paid to SRS pursuant to our settlement agreement.

Net Loss: Net loss was $26.5 million, or ($0.56) per share, for the fourth quarter of 2022, and $112.3 million, or ($2.40) per share, for the year ended December 31, 2022, compared to a net loss of $20.1 million, or ($0.43) per share, for the fourth quarter of 2021 and $70.5 million, or ($1.64) per share, for the year ended December 31, 2021. The litigation settlement related loss had a ($0.32) impact on net loss per share for the twelve months ended December 31, 2022. The gain on fair value remeasurement of contingent consideration had a $0.15 impact on net loss per share for the twelve months ended December 31, 2022.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 2022 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 December 31,**		**Year Ended December 31,**	
	2022	**2021**	**2022**	**2021**
	(Unaudited)			
Revenues:				
Product development and licensing agreements	$ 26	$ 1	$ 56	$ 31
Contracts and grants	1,587	332	2,301	4,620
Total revenues	1,613	333	2,357	4,651
Operating expenses:				
Research and development	22,900	14,678	82,258	53,311
General and administrative	6,598	6,241	27,195	20,488
Intangible asset impairment	-	-	-	3,500
Gain on fair value remeasurement of contingent consideration	-	(245)	(6,862)	(1,405)
Litigation settlement related loss	-	-	15,000	-
Total operating expenses	29,498	20,674	117,591	75,894
Operating loss	(27,885)	(20,341)	(115,234)	(71,243)
Investment and other income, net	1,398	193	2,909	505
Net loss before income tax benefit	(26,487)	(20,148)	(112,325)	(70,738)
Income tax benefit	-	-	-	227

Net loss	$ (26,487)	$ (20,148)	$ (112,325)	$ (70,511)
Basic and diluted net loss per common share	$ (0.56)	$ (0.43)	$ (2.40)	$ (1.64)
Shares used in calculating basic and diluted net loss per share	47,132	46,691	46,888	42,870

Condensed Consolidated Balance Sheet Data	**December 31, 2022**	**December 31, 2021**
Assets		
Cash, cash equivalents and marketable securities	$ 304,952	$ 408,250
Other current assets	12,741	2,589
Property and equipment, net	3,747	3,551
Intangible and other assets, net	31,295	30,264
Total assets	$ 352,735	$ 444,654
Liabilities and stockholders' equity		
Current liabilities	$ 18,610	$ 16,528
Long-term liabilities	7,921	8,650
Stockholders' equity	326,204	419,476
Total liabilities and stockholders' equity	$ 352,735	$ 444,654