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 9, 2022

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 November 9, 2022, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter of 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 November 9, 2022.
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: November 9, 2022

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

EXHIBIT 99.1

Celldex Reports Third Quarter 2022 Financial Results and Provides Corporate Update

- Multiple clinical-stage programs on track for data updates in upcoming months -

HAMPTON, N.J., Nov. 09, 2022 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the third quarter ended September 30, 2022 and provided a corporate update.

“Celldex continued to execute towards our clinical and corporate milestones, making strong progress across multiple programs; importantly, this includes the initiation of our Phase 2 studies in chronic spontaneous and chronic inducible urticaria this past summer. As we near the close of 2022 and look to 2023, we anticipate a consistent stream of data readouts from the barzolvolimab program, starting in December with additional data from our Phase 1 study in chronic inducible urticaria,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We are also enthusiastic about the potential of our bispecific platform and believe our strategic updates including the development of CDX-585, our ILT4 and PD-(L)1 bispecific antibody, which is expected to enter the clinic in 2023, will drive value for this platform.”

“In summary, our recent advances of the barzolvolimab program, development of our bispecific platform, and strong balance sheet continue to position us very well to execute across our upcoming key clinical milestones. We look forward to continued momentum across the company for the rest of the year and providing updates in the coming months,” concluded Mr. 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 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.

- On June 30, Celldex reported interim data from the barzolvolimab multiple dose Phase 1b study in CSU which were presented as a late-breaking electronic poster presentation as part of the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2022. The Company has since completed enrollment to the 3 and 4.5 mg/kg dose groups and plans to present 12-week treatment data from these dose groups in February 2023.

- EAACI 2022 Data Summary:

    - Barzolvolimab was well tolerated with a favorable safety profile; effects of multiple dose administration were consistent with observations in single dose studies. Barzolvolimab resulted in rapid, marked and durable responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment.
    - Mean reduction from baseline in urticaria activity (UAS7) of 66.6% in all patients in the 1.5 mg/kg dose group (n=8) at week 12 and 75.1% in all patients in the 3 mg/kg dose group (n=9) at week 8 (reflects only one dose), demonstrating clinically meaningful symptom improvements for patients.
    - Complete response (UAS7=0) of 57.1% in the 1.5 mg/kg dose group at week 12 and 44.4% at week 8 (reflects only one dose) in the 3 mg/kg dose group which is a key therapeutic goal.
    - 75% well-controlled disease by Urticaria Control Test (UCT) in the 1.5 mg/kg dose group at week 12 and 83.3% in the 3 mg/kg dose group at week 8 (reflects only one dose).
    - Tryptase suppression paralleled symptom improvement, demonstrating the impact of mast cell depletion on CSU disease activity.

- Celldex has completed enrollment in the barzolvolimab Phase 1b open label study in chronic inducible urticaria. The Company plans to present data from the 1.5 mg/kg cold urticaria cohort and long-term follow up from the 3 mg/kg symptomatic dermographism and cold urticaria cohorts in December. Patient follow up continues in the cholinergic cohort and is planned for presentation in mid-2023.

- Celldex continues to enroll 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.

- 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. The Company is finalizing clinical study design and

completing the chronic toxicology study which will support study initiation in the United States.

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 is currently completing CMC and IND-enabling activities and is expected to enter the clinic in 2023.

CDX-527 – Bispecific PD-L1 & CD27

CDX-527 utilizes the Company's proprietary highly active anti-PD-L1 and CD27 human antibodies to couple CD27 co-stimulation with blockade of the PD-L1/PD-1 pathway.

- The standard of care in ovarian cancer continues to evolve, making drug development in this indication more challenging. With multiple clinical trials actively recruiting in ovarian cancer, enrollment to the expansion cohort in patients with checkpoint naïve ovarian cancer (n=8) did not meet the Company's internal timelines and a review of the results to date also did not meet internal hurdles for proceeding. Given the evolving environment and Celldex's pipeline and resource priorities, the Company has decided to discontinue the program.

Third Quarter 2022 Financial Highlights and 2022 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2022 were $323.5 million compared to $356.8 million as of June 30, 2022. The decrease was primarily driven by third quarter cash used in operating activities of $35.2 million, which includes the $15.0 million payment to Shareholder Representative Services (SRS), the representative of the former stockholders of Kolltan Pharmaceuticals, Inc., pursuant to our settlement agreement. At September 30, 2022, Celldex had 47.1 million shares outstanding.

Revenues: Total revenue was $0.4 million in the third quarter of 2022 and $0.7 million for the nine months ended September 30, 2022, compared to $0.2 million and $4.3 million for the comparable periods in 2021. The decrease in revenue for the nine months ended September 30, 2022 compared to the nine months ended September 30, 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 $21.6 million in the third quarter of 2022 and $59.4 million for the nine months ended September 30, 2022, compared to $13.6 million and $38.6 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 $6.5 million in the third quarter of 2022 and $20.6 million for the nine months ended September 30, 2022, compared to $5.8 million and $14.2 million for the comparable periods in 2021. The increase in G&A expenses was primarily due to higher legal costs related 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 nine months ended September 30, 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 $26.8 million, or ($0.57) per share, for the third quarter of 2022, and $85.8 million, or ($1.83) per share, for the nine months ended September 30, 2022, compared to a net loss of $20.5 million, or ($0.45) per share, for the third quarter of 2021 and $50.4 million, or ($1.21) per share, for the nine months ended September 30, 2021. The litigation settlement related loss had a ($0.32) impact on net loss per share for the nine months ended September 30, 2022. The gain on fair value remeasurement of contingent consideration had a $0.15 impact on net loss per share for the nine months ended September 30, 2022.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 30, 2022 are sufficient to meet estimated working capital requirements and fund planned operations through 2025.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	
Revenues:				
Product development and licensing agreements	$ -	$ -	$ 30	$ 29
Contracts and grants	407	153	714	4,288
Total revenues	407	153	744	4,317
Operating expenses:				
Research and development	21,572	13,557	59,359	38,633
General and administrative	6,531	5,821	20,596	14,247
Intangible asset impairment	-	3,500	-	3,500
Gain on fair value remeasurement of contingent consideration	-	(1,901)	(6,862)	(1,160)
Litigation settlement loss	-	-	15,000	-
Total operating expenses	28,103	20,977	88,093	55,220
Operating loss	(27,696)	(20,824)	(87,349)	(50,903)

Investment and other income, net	912	145	1,511	313
Net loss before income tax benefit	$ (26,784)	$ (20,679)	$ (85,838)	$ (50,590)
Income tax benefit	-	227	-	227
Net loss	$ (26,784)	$ (20,452)	$ (85,838)	$ (50,363)
Basic and diluted net loss per common share	$ (0.57)	$ (0.45)	$ (1.83)	$ (1.21)
Shares used in calculating basic and diluted net loss per share	46,916	45,453	46,806	41,582

Condensed Consolidated Balance Sheet Data	**September 30, 2022 (Unaudited)**	**December 31, 2021**
Assets		
Cash, cash equivalents and marketable securities	$ 323,471	$ 408,250
Other current assets	11,128	2,589
Property and equipment, net	3,753	3,551
Intangible and other assets, net	30,874	30,264
Total assets	$ 369,226	$ 444,654
Liabilities and stockholders' equity		
Current liabilities	$ 16,287	$ 16,528
Long-term liabilities	7,523	8,650
Stockholders' equity	345,416	419,476
Total liabilities and stockholders' equity	$ 369,226	$ 444,654