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 5, 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)	(IRS 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)

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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 8.01. Other Events.

On November 6, 2023, Celldex Therapeutics, Inc. (the "Company") announced topline data from the Company's ongoing Phase 2 study of barzolvolimab in patients with chronic spontaneous urticaria ("CSU") refractory to antihistamines, including patients who received prior biologics, which data supports further development of barzolvolimab in Phase 3 CSU studies. Treatment options for patients with CSU are limited and there are no approved therapies for patients who do not respond to omalizumab.

Data from the 208 patients randomized in the study showed that barzolvolimab achieved the primary efficacy endpoint across multiple dose groups, with a statistically significant mean change from baseline to week 12 of UAS7 (urticaria activity score) compared to placebo. Barzolvolimab demonstrated rapid, durable and clinically meaningful responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment. Demographics and baseline disease characteristics were well balanced across treatment groups.

Summary of Clinical Activity Assessments at Week 12

	300 mg q8w (n=51)	150 mg q4w (n=52)	75 mg q4w (n=53)	Placebo (n=51)
UAS7 Changes				
Baseline UAS7 (mean)	31.33	30.75	30.30	30.09
LS Mean change at Week 12	-23.87	-23.02	-17.06	-10.47
LS Mean difference from placebo (Confidence Interval, p value)	-13.41 (CI: -17.47, -9.34) **p<0.0001**	-12.55 (CI:-16.56, -8.55) **p<0.0001**	-6.60 (CI:-10.71, -2.49) p=0.0017	
Clinical Responses				
UAS7=0 (Complete Control)	37.5%	51.1%	22.9%	6.4%
UAS7≤6 (Well-controlled)	62.5%	59.6%	41.7%	12.8%

Approximately 20% of enrolled patients received prior treatment with omalizumab. These patients experienced a similar clinical benefit as the overall treated population within their individual dosing groups.

Barzolvolimab was generally well tolerated with a favorable safety profile. Most adverse events were mild to moderate in severity; through 12 weeks, the most common treatment emergent adverse events in barzolvolimab treated patients were hair color changes (9%), urticaria (9%) and neutropenia (8%). The rate of infections was similar between barzolvolimab-treated patients and placebo with no apparent association between neutropenia and infections. Treatment will continue to 52 weeks. The Company expects to advance CSU into registrational studies in 2024.

In addition, as previously disclosed, the Company entered a Confidential Settlement Agreement and Mutual Release (the "Settlement Agreement") with Shareholder Representatives Services LLC ("SRS") relating to the previously disclosed litigation brought by the Company (the "Litigation") arising under the Agreement and Plan of Merger, dated November 1, 2016 (the "Merger Agreement"), by and among Kolltan Pharmaceuticals, Inc., the Company, Connemara Merger Sub 1 Inc., Connemara Merger Sub 2 LLC and SRS, solely in its capacity as the Stockholders Representative. The Company has determined that the positive topline results from the Company's Phase 2 clinical trial of barzolvolimab in patients with moderate to severe CSU satisfies the requirement of "successful completion" such that the Company is obligated to make the applicable milestone payment under the Settlement Agreement in the amount of $12,500,000, which the Company intends to pay in cash.

On November 5, 2023, the Company also presented positive data from its Phase 1B study of barzolvolimab in prurigo nodularis. The data demonstrated a meaningful reduction in itch (≥4-point decrease in Worst Itch-Numerical Rating Scale) and clear or almost clear skin (Investigator Global Assessment 0/1 of skin lesions) with single dose 3.0 mg/kg barzolvolimab.

The Company also disclosed that data from its Phase 2 study in patients with chronic inducible urticaria who remain symptomatic despite antihistamine therapy is expected in the second half of 2024.

Forward-Looking Statements

This current report on Form 8-K contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through the Company's use of words such as "may," "will," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future. These forward-looking statements are subject to risks and uncertainties that may cause actual future experience and results to differ materially from those discussed in these forward-looking statements. Important factors that might cause such a difference include, but are not limited to, whether results from preclinical studies and early stage clinical trials will be predictive of the results of later preclinical studies and clinical trials; the timing, cost and uncertainty of obtaining regulatory approvals for product candidates; changes in the Company's expected uses of cash and other expenditures, the Company's ability to develop and commercialize products before competitors that are superior to the alternatives developed by such competitors; the validity of the Company's patents and the Company's ability to avoid intellectual property litigation, which can be costly and divert management time and attention; and the other factors listed under "Risk Factors" in the Company's filings with the Securities and Exchange Commission, including Forms 10-K, 10-Q and 8-K. The Company does not undertake any obligation to release publicly any revisions to any such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

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.

Dated: November 6, 2023

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