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): March 21, 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 8.01 Other Events.

At the 2023 American Academy of Dermatology Annual Meeting held March 17-21, it was inaccurately reported in a session on the treatment landscape in prurigo nodularis (PN) that Celldex Therapeutics, Inc.'s ("Celldex") Phase 1b study and clinical development of barzolvolimab in PN was terminated because of the occurrence of a serious adverse event. While a serious anaphylactic adverse event was reported in a complicated patient with multiple comorbidities, the event was reviewed by the independent Data Review Committee (DRC) and following its evaluation the DRC unanimously recommended that the study and the program should proceed. Enrollment to this study was not terminated early because of the safety event and Celldex plans to continue to develop barzolvolimab for PN.

As previously disclosed, the Phase 1b study in PN was challenging to enroll in the dermatology setting, primarily because of the intravenous route of administration. Since the initiation of the PN study in late 2021, we successfully advanced the subcutaneous formulation of barzolvolimab in our ongoing Phase 2 studies in chronic urticarias. As we recently disclosed in our 2022 Annual Report on Form 10K, given the enrollment challenges and the availability of the subcutaneous formulation, we made the decision to close enrollment at 24 patients in the PN study and believe we will have sufficient data for analysis to inform future development decisions. The study remains blinded. We plan to present data from the ongoing study, including 24 weeks of follow-up, in the fourth quarter at a medical meeting and are planning for the initiation of a Phase 2 subcutaneous study in PN in late 2023 or early 2024.

As is customary in drug development, we do not typically report safety or efficacy data, including adverse event reports, in real time and rather present full or partial study data at peer reviewed medical meetings or in corporate disclosures. As we have previously stated, if we see individual safety events that we believe would meaningfully impact or meaningfully change the barzolvolimab development program then we would disclose such events in the most appropriate manner. No such events have been reported in the program.

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, including, but not limited to, statements about the status and initiation of our clinical trials. 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.

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: March 21, 2023

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