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): **July 9, 2021**

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))

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. ☐

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

Item 8.01. Other Events.

On July 9, 2021, Celldex Therapeutics, Inc. (the "Company") announced updated data from the Company's ongoing, open label Phase 1b clinical trial of CDX-0159 in patients with antihistamine refractory cold urticaria and symptomatic dermographism.

Interim data from the Company's ongoing Phase 1b study in inducible urticaria were released as a late-breaking electronic Poster Discussion Session (ePDS) at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2021 on July 9, 2021. The Phase 1b open label clinical trial is designed to evaluate the safety of a single dose of CDX-0159 in patients with cold urticaria or symptomatic dermographism who are refractory to antihistamines. The data update at EAACI included the cold urticaria and symptomatic dermographism cohorts, the two most common forms of chronic inducible urticaria. The study was recently amended to also add a cohort of patients with cholinergic urticaria. In the study, patients' symptoms are induced via provocation testing that resembles real life triggering situations. CDX-0159 is administered intravenously (3.0 mg/kg) as add on treatment to H1-antihistamines and patients are followed for 12 weeks after dosing. Secondary and exploratory objectives include pharmacokinetic and pharmacodynamic assessments, including changes from baseline provocation thresholds, measurement of tryptase and stem cell factor levels, clinical activity outcomes (impact on urticaria symptoms, disease control, clinical response), quality of life assessments and measurement of tissue mast cells through skin biopsies.

As of the data cut-off on June 11, 2021, 20 patients had received a single intravenous infusion of CDX-0159 at 3 mg/kg, including 11 patients with cold urticaria and 9 patients with symptomatic dermographism. Patients had high disease activity as assessed by provocation threshold testing. In patients with cold urticaria and symptomatic dermographism baseline critical temperature thresholds were 18.9°C/66°F (range: 5-27°C/41-80.6°F) and FricTest® thresholds were 3.8 (range: 3-4) of 4. Safety results were reported for all 20 patients; activity results were reported for the 19 patients who received a full dose of CDX-0159. 14 of 19 patients completed the 12-week study observation period and five were ongoing (range of 2-8 weeks) as of June 11, 2021.

- All 19/19 (100%) patients experienced a clinical response as assessed by provocation threshold testing; 18/19 (95%) experienced a complete response and 1/19 (5%) experienced a partial response.
    - 10/10 (100%) patients with cold urticaria experienced a complete response.
    - 8/9 (89%) patients with symptomatic dermographism experienced a complete response and 1/9 (11%) experienced a partial response.
    - Complete responses were observed in all 3 patients (1 cold urticaria; 2 symptomatic dermographism) with prior Xolair® (omalizumab) experience, including two who were Xolair refractory.
- Rapid onset of responses after dosing and sustained durability were observed.
    - Most patients with cold urticaria and symptomatic dermographism experienced a complete response by week 1 and by week 4, respectively.
    - The median duration of response for patients was 77+ days for cold urticaria and 57+ days for symptomatic dermographism.
- Improvements in disease activity as reported by physician's and patient's global assessment of disease severity were consistent with the complete responses as measured by provocation testing.
- A single 3 mg/kg dose of CDX-0159 resulted in rapid, marked and durable suppression of serum tryptase and depletion of skin mast cells (87% depletion) as measured through biopsy.
    - The kinetics of serum tryptase and skin mast cell depletion mirrored clinical activity.
    - This confirmed that serum tryptase level is a robust pharmacodynamic biomarker for assessing mast cell burden and clinical activity in inducible urticaria and potentially in other diseases with mast cell driven involvement.
- CDX-0159 was generally well tolerated. The most common adverse events were hair color changes, mild infusion reactions, and transient changes in taste perception.
    - Hair color changes (generally small areas of hair color lightening) and taste disorders (generally partial changes of ability to taste salt) are consistent with inhibiting KIT signaling in other cell types and are expected to be fully reversible.

    - As previously reported, a single severe infusion reaction of brief loss of consciousness was observed in a patient with a history of fainting. The patient rapidly recovered. Importantly, no evidence of mast cell activation as measured by serum tryptase monitoring was observed.
    - There was no evidence of clinically significant decreases in hematology parameters—an important finding for a KIT inhibitor.
- One patient with symptomatic dermographism enrolled in the study also had a diagnosis of prurigo nodularis. After a single dose of CDX-0159, this patient experienced both a complete response of symptomatic dermographism and notable improvement of the prurigo nodularis.

The subcutaneous formulation of CDX-0159 is planned to enter the clinic in the third quarter of 2021. The Company plans to initiate a study in prurigo nodularis in the fourth quarter of 2021. Celldex remains on track to initiate the Phase 2 studies in both spontaneous and inducible urticaria in the first half of 2022. Initial results from the cholinergic cohort are planned for presentation at a scientific congress in the first quarter of 2022. Treatment results from the Phase 1b study in chronic spontaneous urticaria are planned for presentation at a scientific congress in early summer of 2022. The Company plans to expand development into a fourth indication by year end 2022.

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: July 12, 2021

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