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): **June 15, 2020**

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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

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.

ATM Offering

Celldex Therapeutics, Inc. (the "Company") reported on its March 31, 2020 balance sheet filed with its Form 10-Q for the quarter ended on that date that it had approximately 17.7 million shares of common stock ("Common Stock") outstanding at March 31, 2020 and approximately $53.7 million of cash, cash equivalents and marketable securities at such date. Since such balance sheet date, the Company has sold approximately 6.0 million more shares of Common Stock under its Controlled Equity Offering ^{SM} Sales Agreement, dated May 19, 2016, with Cantor Fitzgerald & Co., with gross proceeds of approximately $24.6 million. The Company paid a commission equal to 3% of the gross proceeds from the sale of shares of its common stock under the Sales Agreement. On June 15, 2020, the Company filed an amendment and supplement to the Prospectus Supplement dated June 12, 2020 for the Sales Agreement to reduce the remaining amount of common stock being offered thereunder to approximately $18.3 million and suspended sales for 90 days, but the Sales Agreement remains in full force and effect. As of June 12, 2020, the Company had 22,555,303 shares of common stock outstanding.

This Current Report on Form 8-K, including the exhibits hereto, shall not constitute an offer to sell or the solicitation of an offer to buy any securities of the Company, which is being made only by means of a written prospectus meeting the requirements of Section 10 of the Securities Act, nor shall there be any sale of the Company's securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of such jurisdiction.

Business Update

Celldex previously announced results from our Phase 1 randomized, double-blind, placebo-controlled, dose escalation study of KIT inhibitor CDX-0159 in healthy subjects. Data were featured in a late breaking presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2020 held on June 6, 2020. We believe that the data support expansion of the program into mast cell driven diseases, including initially studies in forms of chronic urticaria (CU) given the central role mast cells are known to play in the etiology of CU.

The Phase 1 study is a randomized, double-blind, placebo-controlled, single ascending dose escalation study of CDX-0159 in healthy subjects (n=32; 8 subjects per cohort, 6 CDX-0159; 2 placebo). Subjects received a single intravenous infusion of CDX-0159 at 0.3, 1.0, 3.0, or 9.0 mg/kg or placebo. The objectives of the study included safety and tolerability, pharmacokinetics (PK) and pharmacodynamics (tryptase and stem cell factor) and immunogenicity. CDX-0159 demonstrated a favorable safety profile and profound tryptase suppression, indicative of systemic mast cell ablation.

- Most common adverse events were mild infusion-related reactions, all of which spontaneously resolved without intervention. Mild and asymptomatic decreases in neutrophil and white blood cell count were observed in laboratory testing.

- A single dose of CDX-0159 suppressed plasma tryptase levels in a dose-dependent manner, indicative of systemic mast cell suppression. Tryptase suppression below the level of detection was observed after a single 1.0 mg/kg dose and was maintained for more than 2 months at single doses of both 3.0 and 9.0 mg/kg of CDX-0159.

- Dose dependent increases in plasma stem cell factor mirror decreases in tryptase, consistent with allosteric blockade of stem cell factor to KIT and demonstrate complete target engagement in vivo.

- Long serum half-life and non-immunogenic profile support a convenient dosing schedule.

- Enhanced PK profile and durable tryptase suppression at low doses support re-formulation for sub-cutaneous administration.

- Data support clinical studies with repeat dosing in patients with mast cell driven disorders.

Celldex plans to initiate Phase 1b studies of CDX-0159 in patients with chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU), diseases where mast cell degranulation plays a central role in the onset and progression of the disease, by year end. The prevalence of CSU and CIndU is approximately 0.5-1% of the total population or up to 1 to 3 million patients in the United States alone. CSU presents as itchy hives, angioedema or both for at least six weeks without a specific trigger; multiple episodes can play out over years or even decades. About 50% of patients with CSU achieve symptomatic control with antihistamines or leukotriene receptor antagonists. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine/leukotriene refractory patients. Consequently, there is a need for more effective later line therapies. CIndUs are forms of urticaria that have an attributable cause or trigger associated with them, typically resulting in hives or wheals. Prevalence of CIndU is estimated at 0.5% of the total population and is reported to overlap in up to 36% of CSU patients. Celldex is exploring cold-induced and dermographism (scratch-induced) urticarias. Full results from the CIndU and CSU studies as currently planned would be available in Q1 2021 and 2H 2021, respectively. Celldex is also exploring additional mast cell driven diseases for future development, including mast cell activation, auto-immune, inflammatory, allergic and fibrotic disorders.

We intend to initiate a Phase 1b study of CDX-0159 in 20 patients with CIndU (one cohort of 10 patients with cold contact urticaria and a second cohort of 10 patients with symptomatic dermographism) that are refractory to antihistamines, at a urticaria center of excellence in Germany beginning in fall 2020, with results expected in Q1 2021. The trial design will study a single dose of CDX-0159 at 3mg/kg with 12 weeks of follow-up. The primary endpoint of the trial is safety and tolerability. We also intend to initiate a placebo-controlled, multi-center, dose escalation Phase 1b study of CDX-0159 in patients with CSU (n=40) that are refractory to antihistamines beginning in fall 2020, with results expected in the second half of 2021. The trial design will evaluate CDX-0159 and placebo in four sequential cohorts: 0.5 mg/kg (Q 4 weeks), 1.5 mg/kg (Q 4 weeks), 3.0 mg/kg (Q 8 weeks) and 4.5 mg/kg (Q 8 weeks) for up to 12 weeks with an additional 12 week follow-up period. The primary endpoint of the trial is safety and tolerability. If the results of these studies are supportive, we intend to commence a Phase 2 study of CDX-0159 in patients with CSU that are refractory to antihistamines commencing in 2022.

Celldex also anticipates the following potential upcoming development milestones:

Second Half 2020

- CDX-1140 interim update on expansion cohorts
- CDX-3379 clinical and biomarker data
- CDX-0159 initiate Phase 1b studies in CIndU and CSU (fall)
- CDX-527 initiate Phase 1

First Half 2021

- CDX-0159 Phase 1b CIndU safety and activity data (Q1)
- CDX-1140 clinical and biomarket data from expansion cohorts
- CDX-527 Phase 1 data
- CDX-3379 expanded clinical and biomarker data

Second Half 2021

- Initiate study in third mast cell drive indication (summer)
- CDX-0159 Phase 1b CSU safety and activity data

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: June 15, 2020

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