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): May 6, 2021

Celldex Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-15006**	**13-3191702**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

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))

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 2.02. Results of Operations and Financial Condition.

On May 6, 2021, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter of 2021. 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 May 6, 2021.

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: May 6, 2021

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

EXHIBIT 99.1

Celldex Reports First Quarter 2021 Financial Results and Provides Corporate Update

HAMPTON, N.J., May 06, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the first quarter ended March 31, 2021 and provided a corporate update.

“We are very encouraged by the recently reported positive interim results from our ongoing Phase 1b study of CDX-0159 in chronic inducible urticaria. These data demonstrated an 80% complete response rate and a well-tolerated safety profile, which we believe is a significant accomplishment in this complex disease setting with limited treatment options,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “Based on these exciting results, we recently amended the protocol to add a third cohort in cholinergic urticaria, a debilitating disease affecting mainly young adults, where passive or active sweating induces hives and can severely impair their quality of life. We are nearing completion of patient dosing across both the cold induced and symptomatic dermographism cohorts from this study and look forward to presenting updated results from these cohorts this summer.”

Mr. Marucci continued, “We are also making progress advancing our bispecific platform, presenting promising preclinical data at AACR that supports the development of clinical bispecific candidates that co-target ILT4 and PD-(L)1. We look forward to continuing these efforts while also exploring important targets controlling inflammation and auto-immune pathways.”

Recent Pipeline Highlights

CDX-0159 - KIT Inhibitor Program

CDX-0159 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.

- Celldex initiated a Phase 1b open label study designed to evaluate the safety of a single dose (3.0 mg/kg) of CDX-0159 administered intravenously in December of 2020. Up to 20 patients with cold contact urticaria (ColdU; n=10) or symptomatic dermographism (SD; n=10) who are refractory to antihistamines are being enrolled. Patients' symptoms are induced via provocation testing that resembles real life triggering situations. 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. The study is being conducted by Dr. Marcus Maurer, Professor of Dermatology and Allergy at Charité - Universitätsmedizin in Berlin.

  Interim data from this study were reported in late March. Fifteen out of 20 planned patients with antihistamine refractory CIndU had received a single intravenous infusion of CDX-0159 at 3 mg/kg, including nine patients with ColdU and six patients with SD. Safety results were reported for all 15 patients; activity results were reported for all patients assessed for at least 15 days/2 weeks after treatment (n=10; 7 ColdU and 3 SD). Patients had high disease activity as assessed by provocation threshold testing.

  - Eight of 10 patients, including all patients with ColdU, (7 ColdU; 1 SD) experienced a complete response (CR) as assessed by provocation threshold testing. One patient experienced a partial response (PR). All patients will continue to be assessed for response through week 12. CDX-0159 was generally well tolerated.
  - Enrollment is nearing completion in the ColdU and SD cohorts. Based on these compelling results, the study has been expanded to also include 10 patients with cholinergic urticaria and patient screening is expected to begin this month.
  - Updated results from additional patients with cold induced urticaria and symptomatic dermographism and long term follow up that continues to characterize magnitude and duration of treatment effect and their link to changes in tryptase levels are expected this summer.

- Celldex initiated dosing in a Phase 1b multi-center study of CDX-0159 in chronic spontaneous urticaria (CSU) in October. This study is a randomized, double-blind, placebo-controlled clinical trial designed to assess the safety of multiple ascending doses of CDX-0159 in up to 40 patients with CSU who remain symptomatic despite treatment with antihistamines. Secondary and exploratory objectives include pharmacokinetic and pharmacodynamic assessments, including measurement of tryptase and stem cell factor levels and clinical activity outcomes (impact on urticaria symptoms, disease control, clinical response) as well as quality of life assessments. Results from the study are expected by the end of 2021.

- CDX-0159 development is being expanded into prurigo nodularis (PN), a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Initiation of this study is planned for the fourth quarter of 2021.

- Manufacturing activities are also progressing as planned to support the introduction of the CDX-0159 subcutaneous formulation into the clinical program in the third quarter of 2021.

CDX-1140 - CD40 Agonist Program

CDX-1140 is a potent CD40 human agonist antibody developed by Celldex that the Company believes has the potential to successfully balance systemic doses for good tissue and tumor penetration with an acceptable safety profile.

- In the Phase 1 study of CDX-1140 in patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas, both the monotherapy and combination with CDX-301 portions of the trial are complete. Expansion cohorts are actively recruiting including:

  - CDX-1140 with KEYTRUDA® (pembrolizumab) in patients with squamous cell head and neck cancer and non small cell lung cancer who have progressed on checkpoint therapy; and,
  - CDX-1140 with standard of care chemotherapy in first line metastatic pancreatic cancer.

  Updated data from this program are expected to be presented later this year.

CDX-527 - Bispecific Antibody Program

CDX-527 is the first candidate developed by Celldex from its bispecific platform which 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.

- In August 2020, Celldex initiated a Phase 1 dose-escalation study in up to ~40 patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy to be followed by tumor-specific expansion cohorts. The study is designed to determine the MTD during a dose-escalation phase and to recommend a dose level for further study in the subsequent expansion phase. The expansion is designed to further evaluate the tolerability, and biologic and anti-tumor effects of selected dose level(s) of CDX-527 in specific tumor types. Initial data from the Phase 1 study focused on pharmacokinetic and pharmacodynamic properties have been accepted for presentation at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting to be held June 4th-8th.

Preclinical Programs

- In April 2021, Celldex presented promising data from the Company's growing bispecific platform at the American Association of Cancer Research (AACR) Annual Meeting. The Company described the discovery and characterization of ILT4 inhibitory monoclonal antibodies (mAbs) for engineering bispecific antibodies (bsAbs) that revert myeloid cell suppression by antagonizing ILT4 and activate T-cell responses through PD-(L)1 inhibition. Based on the results, Celldex is developing clinical bispecific candidates that co-target ILT4 and PD-(L)1. Celldex is also exploring important targets controlling inflammation and auto-immune pathways.

- In direct support of our bispecific platform, Celldex has entered into a research and collaboration agreement with Biosion, Inc., a global biotechnology company focused on the discovery and clinical development of innovative biologicals for unmet medical needs, to construct and develop bispecific antibodies that combine undisclosed components from both Celldex and Biosion discoveries.

While Celldex's clinical development programs have not been significantly, negatively impacted by COVID-19 to date, the Company continues to carefully monitor the evolving situation closely across all development programs and work to minimize potential impact/disruptions.

First Quarter 2021 Financial Highlights and 2021 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2021 were $176.1 million compared to $194.4 million as of December 31, 2020. The decrease was primarily driven by first quarter cash used in operating activities of $18.1 million. At March 31, 2021, Celldex had 39.6 million shares outstanding.

Revenues: Total revenue was $0.7 million in the first quarter of 2021 compared to $2.7 million for the comparable period in 2020. The decrease in revenue was primarily due to the $1.8 million milestone payment received from Rockefeller University in the first quarter of 2020 related to Celldex's manufacturing and development services agreement.

R&D Expenses: Research and development (R&D) expenses were $12.7 million in the first quarter of 2021 compared to $11.7 million for the comparable period in 2020. The increase in R&D expenses was primarily due to an increase in contract research and clinical trial expenses.

G&A Expenses: General and administrative (G&A) expenses were $4.1 million in the first quarter of 2021 compared to $3.7 million for the comparable period in 2020. The increase in G&A expenses was primarily due to higher stock-based compensation expense.

Changes in Fair Value Remeasurement of Contingent Consideration: During the quarter ended March 31, 2021, the Company recorded a $0.5 million loss on fair value remeasurement of contingent consideration primarily due to changes in discount rates and the passage of time.

Net Loss: Net loss was $16.5 million, or ($0.42) per share, for the first quarter of 2021 compared to a net loss of $12.6 million, or ($0.73) per share, for the comparable period in 2020.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2021 are sufficient to meet estimated working capital requirements and fund planned operations through 2023.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA.

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; the effects of the outbreak of COVID-19 on our business and results of operations; 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 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.

Company Contact
Sarah Cavanaugh
Senior Vice President, Corporate Affairs & Administration
(508) 864-8337
scavanaugh@celldex.com

Patrick Till
Senior Director, Investor Relations & Corporate Communications
(484) 788-8560
ptill@celldex.com

CELLDEX THERAPEUTICS, INC.
(In thousands, except per share amounts)

Consolidated Statements of Operations Data	**Three Months Ended March 31,**	
	2021	**2020**
	(Unaudited)	
Revenues:		
Product development and licensing agreements	$ 3	$ 2,286
Contracts and grants	682	442

Total revenues	685	2,728
Operating expenses:		
Research and development	12,720	11,695
General and administrative	4,121	3,666
Loss on fair value remeasurement of contingent consideration	483	234
Total operating expenses	17,324	15,595
Operating loss	(16,639)	(12,867)
Investment and other income, net	101	242
Net loss	$ (16,538)	$ (12,625)
Basic and diluted net loss per common share	$ (0.42)	$ (0.73)
Shares used in calculating basic and diluted net loss per share	39,614	17,406

Condensed Consolidated Balance Sheet Data	**March 31, 2021 (Unaudited)**	**December 31, 2020**
Assets		
Cash, cash equivalents and marketable securities	$ 176,083	$ 194,422
Other current assets	5,416	3,421
Property and equipment, net	3,747	3,815
Intangible and other assets, net	33,819	34,180
Total assets	$ 219,065	$ 235,838
Liabilities and stockholders' equity		
Current liabilities	$ 16,977	$ 14,206
Long-term liabilities	7,922	12,275
Stockholders' equity	194,166	209,357
Total liabilities and stockholders' equity	$ 219,065	$ 235,838