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 29, 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 March 29, 2021, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended 2020. 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 March 29, 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: March 29, 2021

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

EXHIBIT 99.1

Celldex Provides Corporate Update and Reports Fourth Quarter and Year End 2020 Results

HAMPTON, N.J., March 29, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the fourth quarter and year ended December 31, 2020.

“Celldex made significant progress across our pipeline in 2020 and today continued this momentum with the announcement of compelling interim results from our ongoing Phase 1b study of CDX-0159 in chronic inducible urticaria where we have observed an 80% complete response rate and a well-tolerated safety profile to date,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “These data support the novel mechanism of CDX-0159 and the potential broad applicability of this compound in mast cell driven diseases. Based on these results, we are expanding the study to also include patients with cholinergic urticaria and look forward to presenting updated results from the cold induced and symptomatic dermographism cohorts this summer. We also anticipate results from the ongoing Phase 1b study in chronic spontaneous urticaria by the end of the year and are on track to initiate a third study in prurigo nodularis in the fourth quarter.”

“In 2020, we also continued to advance our oncology programs, presenting data from our CDX-1140 program supporting this candidate as a best in class CD40 agonist and initiating a Phase 1 study of CDX-527, the first candidate from our bispecific platform, into the clinic. We anticipate data updates from both of these programs later this year and look forward to what promises to be a busy and exciting time for the Company.”

Recent Pipeline Highlights

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.

CDX-0159—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. Results from a Phase 1a dose escalation study of CDX-0159 were featured in a late breaking presentation in June at the EAACI Annual Congress 2020. CDX-0159 demonstrated a favorable safety profile as well as profound and durable reductions of plasma tryptase, indicative of systemic mast cell ablation.

- 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 earlier today. 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. In ColdU and SD pts, baseline critical temperature thresholds were 18.7 +/- 2.7 °C (range: 5-27°C) and FricTest® thresholds were 3.7 +/- 0.3 (range: 3-4) of 4.

  - Eight of 10 patients (7 ColdU; 1 SD) experienced a complete response (CR) as assessed by provocation threshold testing. The remaining two patients (both with SD), had been recently treated and were followed for two weeks. One patient experienced a partial response (PR) thus far and one patient reported symptomatic improvement (decreased itching). All patients will continue to be assessed for response through week 12.
  - Patient global assessment (Pat-GA) and physician global assessment (Phy-GA) results were consistent with provocation testing results.
  - Measurements of serum tryptase levels are available for only the first six patients evaluated for activity, all with ColdU. The mean baseline was 3.3 +/- 0.2 ng/ml and levels on day 15 after treatment were at or below the limit of detection. These patients all experienced complete responses.
  - CDX-0159 was generally well tolerated. Six of 15 patients had mild infusion reactions, generally areas of localized redness and itching, which resolved rapidly. A single severe infusion reaction was observed (brief loss of consciousness, followed by shaking and sweating). The patient was treated with antihistamines and steroids; no epinephrine was administered. The patient rapidly recovered and was hospitalized for observation with no further manifestations of this event. Importantly, there was no evidence of mast cell activation as measured by decreases in serum tryptase levels shortly after the infusion and further at a later time point.
  - Through day 15, three patients had transient, mild decreases in hemoglobin, and no patients had meaningful declines in white blood cells.

- Enrollment is currently being completed in the ColdU and SD cohorts. Based on these compelling results, the study is being expanded to also include 10 patients with cholinergic urticaria and enrollment of these patients is planned to begin in May of 2021.
- 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.

- In February 2021, Celldex announced that development of CDX-0159 will be expanded into prurigo nodularis (PN), a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Mast cells through their interactions with sensory neurons and other immune cells are believed to play an important role in amplifying chronic itch and neuroinflammation. Initiation of this study is planned for the fourth quarter of 2021. Celldex is also exploring additional mast cell driven diseases for potential future development, including mast cell activation syndromes, asthma, allergic conditions and mast cell driven gastrointestinal disorders.

- 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—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 dose-escalation 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 dose escalation portions of the trial are complete with an identified maximum tolerated dose (MTD) and recommended dose of CDX-1140 at 1.5 mg/kg—one of the highest systemic dose levels in the CD40 agonist class. Expansion cohorts are actively recruiting including:

  - CDX-1140 with KEYTRUDA® (pembrolizumab) in patients who have progressed on checkpoint therapy; and,
  - A combination of 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.

- Updated interim data from the ongoing Phase 1 study were presented at the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting & Pre-Conference Programs (SITC 2020) in November 2020. Analysis was focused on patients treated at the MTD and recommended dose of 1.5 mg/kg. 41 patients had been treated at the 1.5 mg/kg dose at the time of data cutoff (n=25 monotherapy; n=16 in combination with CDX-301, a dendritic cell growth factor used as a priming agent to increase the number of dendritic cells in blood and tissue available for CDX-1140 activation). 29 patients had post-treatment scans performed and five patients had not reached their first post-treatment response assessment. In addition, preliminary safety data from the combination cohort with pembrolizumab (n=9; 4 at 0.72 mg/kg and 5 at 1.5 mg/kg CDX-1140) were also presented. CDX-1140 monotherapy and in combination with CDX-301 or pembrolizumab was generally well tolerated with mostly grade 1 or grade 2 drug related adverse events. Activity at 1.5mg/kg dose of CDX-1140 to date included:

  - An ongoing (6+ months) complete response (CR) in a patient with follicular lymphoma treated with CDX-1140 in combination with CDX-301; notable tumor shrinkage and/or necrosis in 6 patients with squamous cell head and neck cancer (SCCHN), including extensive tumor cavitation/necrosis of a large baseline protruding neck mass associated with decreased tumor pain in a patient; and stable disease (n=10) for 11 to 32 weeks.
  - CDX-1140 at 1.5 mg/kg provided good systemic exposure that enhanced the distribution into tissues and tumor and resulted in marked changes in the tumor microenvironment (TME) consistent with a more inflammatory and less immunosuppressive state as demonstrated by gene expression analysis. Interferon signaling and cytotoxicity pathways were most highly upregulated, while immunosuppression via TGFb signaling and metastatic pathways were downregulated, marking the first clear demonstration in patients of biological activity within the TME for a systemically administered agonist anti-CD40 mAb.

CDX-527—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 ~90 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 are expected to be presented later this year.

Fourth Quarter and Twelve Months 2020 Financial Highlights and 2021 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2020 were $194.4 million compared to $199.6 million as of September 30, 2020. The decrease was primarily driven by fourth quarter cash used in operating activities of $5.2 million. At December 31, 2020, Celldex had 39.6 million shares outstanding.

Revenues: Total revenue was $3.8 million in the fourth quarter of 2020 and $7.4 million for the year ended December 31, 2020, compared to $0.9 million and $3.6 million for the comparable periods in 2019. The increase in revenue was primarily due to the $1.8 million milestone payment from Rockefeller University related to our manufacturing and development services agreement and an increase in services performed under our manufacturing and research and development agreements with Rockefeller University and Gilead Sciences, partially offset by a decrease in services performed under our manufacturing and research and development agreement with Duke University.

R&D Expenses: Research and development (R&D) expenses were $10.4 million in the fourth quarter of 2020 and $42.5 million for the year ended December 31, 2020, compared to $10.3 million and $42.7 million for the comparable periods in 2019. The decrease in R&D expenses was primarily due to a decrease in contract research and facility expenses, partially offset by an increase in clinical trials and contract manufacturing expenses.

G&A Expenses: General and administrative (G&A) expenses were $3.6 million in the fourth quarter of 2020 and $14.5 million for the year ended December 31, 2020, compared to $3.2 million and $15.4 million for the comparable periods in 2019. The decrease in G&A expenses was primarily due to a decrease in stock-based compensation and facility expenses.

Intangible Asset Impairment: The Company recorded a non-cash partial impairment charge of $14.5 million related to the TAM program IPR&D asset in the fourth quarter of 2020 as a result of changes in the projected development and regulatory timelines for the program. The Company recorded a non-cash impairment charge of $3.5 million related to the CDX-3379 IPR&D asset in the second quarter of 2020 as a result of the discontinuation of the CDX-3379 program.

Changes in Fair Value Remeasurement of Contingent Consideration: During the year ended December 31, 2020, the Company recorded a $4.2 million gain on the fair value remeasurement of contingent consideration primarily due to updated assumptions for CDX-3379 related milestones due to the discontinuation of the CDX-3379 program partially offset by changes in discount rates and the passage of time.

Net Loss: Net loss was $21.9 million, or ($0.55) per share, for the fourth quarter of 2020 and $59.8 million, or ($2.02) per share, for the year ended December 31, 2020, compared to a net loss of $10.4 million, or ($0.64) per share, for the fourth quarter of 2019 and $50.9 million, or ($3.51) per share, for the year ended December 31, 2019.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 2020 are sufficient to meet estimated working capital requirements and fund planned operations through 2023.

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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.

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

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	**Three Months Ended December 31,**		**Year Ended December 31,**	
	2020	**2019**	**2020**	**2019**
	(Unaudited)			
REVENUES:				
Product Development and Licensing Agreements	$ 3	$ 94	$ 2,301	$ 473
Contracts and Grants	3,783	793	5,117	3,100
Total Revenue	3,786	887	7,418	3,573
OPERATING EXPENSES:				
Research and Development	10,425	10,339	42,534	42,672
General and Administrative	3,623	3,219	14,456	15,426
Intangible Asset Impairment	14,500	-	18,000	-
Other Asset Impairment	-	-	-	1,800
Loss (Gain) on Fair Value Remeasurement of Contingent Consideration	18	318	(4,218)	(1,294)
Total Operating Expense	28,566	13,876	70,772	58,604
Operating Loss	(24,780)	(12,989)	(63,354)	(55,031)
Investment and Other Income, Net	1,941	2,542	2,407	4,153
Net Loss Before Income Tax Benefit	(22,839)	(10,447)	(60,947)	(50,878)
Income Tax Benefit	939	-	1,167	-
Net Loss	$ (21,900)	$ (10,447)	$ (59,780)	$ (50,878)
Basic and Diluted Net Loss per Common Share	$ (0.55)	$ (0.64)	$ (2.02)	$ (3.51)
Shares Used in Calculating Basic and Diluted Net Loss per Share	39,577	16,442	29,640	14,507

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	**December 31, 2020**	**December 31, 2019**

ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 194,422	$ 64,383
Other Current Assets	3,421	2,315
Property and Equipment, net	3,815	4,031
Intangible and Other Assets, net	34,180	52,204
Total Assets	$ 235,838	$ 122,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 14,206	$ 11,643
Long-Term Liabilities	12,275	17,264
Stockholders' Equity	209,357	94,026
Total Liabilities and Stockholders' Equity	$ 235,838	$ 122,933