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): February 28, 2022

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 2.02. Results of Operations and Financial Condition.

On February 28, 2022, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended 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 February 28, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 28, 2022

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

EXHIBIT 99.1

Celldex Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

- *CSU Phase 1b multi-dose data expected in July*
- *CDX-0159 subcutaneous formulation study results fully support transition to SubQ dosing; Phase 2 studies in CSU and CIndU to initiate Q2 2022*
- *Expanded development of CDX-0159 into Eosinophilic Esophagitis (EoE)*
- *Well capitalized with $408.3 million in cash, cash equivalents, and marketable securities expected to fund activities through 2025*
- *Conference call today Monday February 28th, 4:30pm ET*

HAMPTON, N.J., Feb. 28, 2022 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the fourth quarter and year ended December 31, 2021 and provided a corporate update.

“Celldex made significant progress over the past year in advancing our pipeline, as marked by successful clinical results from our Phase 1b study with CDX-0159 demonstrating a 95% complete response rate in chronic inducible urticaria, and we remain excited to report data from our chronic spontaneous urticaria Phase 1b study early this summer,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “In July 2021, we raised $287 million in gross proceeds from a public offering which provides us with a very strong foundation to further develop our scientific and clinical programs. After successfully completing key readiness activities, including the development of a CDX-0159 subcutaneous formulation, we remain on track to initiate our Phase 2 urticaria programs in the second quarter of 2022.”

Mr. Marucci continued, “With encouraging results and multiple ongoing studies across all our programs, we are focused on executing our development plan and are well positioned for a transformational year.”

Program 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 is currently completing enrollment in the Phase 1b multi-center, randomized, double-blind, placebo-controlled study of CDX-0159 in chronic spontaneous urticaria (CSU). This study is designed to assess the safety and treatment effects of multiple ascending doses of CDX-0159 in up to 40 patients with chronic spontaneous urticaria who remain symptomatic despite treatment with antihistamines. Data from this study (0.5, 1.5 and 3 mg/kg cohorts) are planned to be submitted for a late breaking presentation at EAACI 2022.

- Celldex remains on track to initiate Phase 2 studies in chronic spontaneous urticaria and chronic inducible urticaria (cold urticaria and symptomatic dermographism) in the second quarter of 2022. In the fourth quarter of 2021 and first quarter of this year, Celldex successfully advanced important activities to support the initiation of these studies.

    - A randomized, double-blind, placebo-controlled, Phase 1 study designed to evaluate the safety of single ascending doses of the subcutaneous formulation of CDX-0159 has been conducted in healthy volunteers. Subcutaneous administration of CDX-0159 demonstrated a well tolerated safety profile; no injection site reactions were reported. Multiple dose levels have been identified that possess promising pharmacokinetic and pharmacodynamic properties. Importantly, subcutaneous delivery of CDX-0159 resulted in dose-dependent, rapid and sustained decreases in serum tryptase compared with placebo and achieved sufficient exposure to produce tryptase suppression levels comparable with the levels that generated impressive clinical activity observed in the Phase 1 chronic inducible urticaria IV study. Celldex anticipates the upcoming Phase 2 multi-dose studies in urticaria will evaluate 75mg and 150mg administered q4weeks and 300mg administered q8weeks. The planned doses support a 0.5 to 2 ml injection volume, allowing for a single injection as CDX-0159 advances towards potential commercialization.

    - The in-life dosing portion of the six month chronic toxicology study has also been completed; a subset of the animals will continue to be followed beyond clearance of the CDX-0159 antibody to study completion. As expected and consistent with other KIT-targeting agents, impact on spermatogenesis was observed which is anticipated to be fully reversible upon clearance of the antibody. There were no other clinically adverse findings reported in the study. Celldex believes these data strongly support the Company’s planned Phase 2 programs in urticaria later this year and future indications.

- Celldex believes there is broad development opportunity for CDX-0159 and continues to assess potential opportunities for CDX-0159 in other diseases where mast cells play an important role, such as dermatologic, respiratory, allergic, gastrointestinal and ophthalmic conditions. In 2022, Celldex plans to expand development into eosinophilic esophagitis (EoE), the most common type of eosinophilic gastrointestinal disease. Several studies have suggested that mast cells may be an important driver in the disease, demonstrating that the number and activation state of mast cells are greatly increased

in EoE biopsies and that mast cell signatures correlate with markers of inflammation, fibrosis, pain and disease severity. Given the lack of effective therapies for EoE and CDX-0159's potential as a mast cell depleting agent, Celldex believes EoE is an important indication for future study and plans to initiate a Phase 2 trial in the fourth quarter of 2022.

- In December 2021, Celldex announced the first patient was dosed in the Phase 1b multi-center, randomized, double-blind, placebo-controlled study of CDX-0159 in patients with prurigo nodularis (PN), a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. This study is designed to assess the safety and treatment effects across multiple dose levels of CDX-0159 in up to 30 patients with PN.

- In 2021, Celldex presented interim data from the CDX-0159 single dose (3 mg/kg) Phase 1b open label study in inducible urticaria (cold contact and symptomatic dermographism) across multiple medical meetings. CDX-0159 demonstrated a compelling 95% complete response rate to provocation testing; responses occurred rapidly after dosing and were durable. Clinical benefit was also supported across patient reported outcomes measuring symptom control and quality of life. Rapid, marked and durable suppression of serum tryptase and depletion of skin mast cells (87% depletion) as measured through biopsy were also observed. CDX-0159 was generally well tolerated. In March and June 2021, respectively, we added a third cohort (single dose, 3 mg/kg) in patients with cholinergic urticaria (n=10) and a fourth cohort at a lower dose (single dose, 1.5 mg/kg) in cold urticaria. Enrollment to these cohorts is ongoing.

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, the monotherapy cohort, the combination cohort with CDX-301 and the safety run-in combination cohort with gemcitabine/nab-paclitaxel have been completed. Expansion cohorts 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 are ongoing.

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 the Phase 1 dose-escalation study of CDX-527 in patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy, enrollment to the dose escalation portion of the study has been completed and an expansion cohort in ovarian cancer is currently enrolling patients.

Corporate Highlights

- In July 2021, Celldex closed an underwritten public offering of common stock, including the full exercise of the underwriters' option to purchase additional shares, for gross proceeds of $287.5 million. Celldex believes that the proceeds from this offering, together with current reserves, provide the cash runway to fund key clinical, regulatory and operational activities through 2025.

- In September 2021, Marc Rothenberg, MD, PhD was appointed to the Celldex Scientific Advisory Board. Dr. Rothenberg is currently Director of the Allergy and Immunology Division and Director of the Cincinnati Center for Eosinophilic Disorders at Cincinnati Children's Hospital Medical Center. His clinical and research interests have focused on developing innovative therapies for allergic inflammatory diseases, with a focus on eosinophilic gastrointestinal disorders (EGIDs).

Fourth Quarter and Twelve Months 2021 Financial Highlights and 2022 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2021 were $408.3 million compared to $423.1 million as of September 30, 2021. The decrease was primarily driven by cash used in operating activities of $14.5 million. At December 31, 2021, Celldex had 46.7 million shares outstanding.

Revenues: Total revenue was $0.3 million in the fourth quarter of 2021 and $4.7 million for the year ended December 31, 2021, compared to $3.8 million and $7.4 million for the comparable periods in 2020. The decrease in revenue was primarily due to a decrease in revenue from product development and licensing agreements as a result of 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 and a decrease in services performed under our contract manufacturing and research and development agreements with Rockefeller University and Gilead Sciences.

R&D Expenses: Research and development (R&D) expenses were $14.7 million in the fourth quarter of 2021 and $53.3 million for the year ended December 31, 2021, compared to $10.4 million and $42.5 million for the comparable periods in 2020. The increase in R&D expenses was primarily due to an increase in clinical trial, contract research, and personnel expenses.

G&A Expenses: General and administrative (G&A) expenses were $6.2 million in the fourth quarter of 2021 and $20.5 million for the year ended December 31, 2021, compared to $3.6 million and $14.5 million for the comparable periods in 2020. The

increase in G&A expenses was primarily due to higher stock-based compensation and legal expenses.

Intangible Asset Impairment: The Company recorded a non-cash impairment charge of $3.5 million related to the TAM program IPR&D asset in the third quarter of 2021 as a result of a lack of interest in the program from third parties. The Company recorded a non-cash impairment charge of $14.5 million related to the TAM 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 during the second quarter of 2020 due to the discontinuation of the CDX-3379 program.

Changes in Fair Value Remeasurement of Contingent Consideration: During the year ended December 31, 2021, the Company recorded a $1.4 million gain on fair value remeasurement of contingent consideration primarily due to updated assumptions for the TAM program, partially offset by losses related to changes in discount rates and the passage of time.

Net Loss: Net loss was $20.1 million, or ($0.43) per share, for the fourth quarter of 2021, and $70.5 million, or ($1.64) per share, for the year ended December 31, 2021, compared to a net loss of $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.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 2021 are sufficient to meet estimated working capital requirements and fund planned operations through 2025.

Webcast and Conference Call

Celldex executives will host a conference call at 4:30 p.m. ET today to discuss business and financial results and to provide an update on key 2022 objectives. The conference call will be webcast live over the internet and can be accessed by going to the "Events & Presentations" page under the "Investors & Media" section of the Celldex Therapeutics website at www.celldex.com. The call can also be accessed by dialing (866) 743-9666 (within the United States) or (760) 298-5103 (outside the United States). The passcode is 2177774.

A replay of the call will be available approximately two hours after the live call concludes. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 217774. The webcast will also be archived on the Company's website.

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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, including 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.

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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,**	
	2021	**2020**	**2021**	**2020**
	(Unaudited)			
Revenues:				
Product development and licensing agreements	$ 1	$ 3	$ 31	$ 2,301
Contracts and grants	332	3,783	4,620	5,117
Total revenues	333	3,786	4,651	7,418
Operating expenses:				
Research and development	14,678	10,425	53,311	42,534
General and administrative	6,241	3,623	20,488	14,456
Intangible asset impairment	-	14,500	3,500	18,000
(Gain) loss on fair value remeasurement of contingent consideration	(245)	18	(1,405)	(4,218)
Total operating expenses	20,674	28,566	75,894	70,772
Operating loss	(20,341)	(24,780)	(71,243)	(63,354)
Investment and other income, net	193	1,941	505	2,407
Net loss before income tax benefit	(20,148)	(22,839)	(70,738)	(60,947)
Income tax benefit	-	939	227	1,167
Net loss	$ (20,148)	$ (21,900)	$ (70,511)	$ (59,780)
Basic and diluted net loss per common share	$ (0.43)	$ (0.55)	$ (1.64)	$ (2.02)
Shares used in calculating basic and diluted net loss per share	46,691	39,577	42,870	29,640

Condensed Consolidated Balance Sheet Data	**December 31, 2021**	**December 31, 2020**
Assets		
Cash, cash equivalents and marketable securities	$ 408,250	$ 194,422
Other current assets	2,589	3,421
Property and equipment, net	3,551	3,815
Intangible and other assets, net	30,264	34,180
Total assets	$ 444,654	$ 235,838

Liabilities and stockholders' equity		
Current liabilities	$ 16,528	$ 14,206
Long-term liabilities	8,650	12,275
Stockholders' equity	419,476	209,357
Total liabilities and stockholders' equity	$ 444,654	$ 235,838