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): November 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)	(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 November 9, 2021, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third 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 November 9, 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: November 9, 2021

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

EXHIBIT 99.1

Celldex Reports Third Quarter 2021 Financial Results and Provides Corporate Update

HAMPTON, N.J., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the third quarter ended September 30, 2021 and provided a corporate update.

“During the third quarter we reported compelling data from our ongoing Phase 1b study of CDX-0159 in chronic inducible urticaria, including a rapid, profound and durable 95% complete response rate to provocation testing after just a single dose,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “Last month, we added to these positive results, reporting additional patient-reported outcome measures that demonstrated rapid and sustained improvement in urticaria disease control and improvements in quality of life. We were also pleased to recently initiate a Phase 1 study of the subcutaneous formulation of CDX-0159 and recently opened enrollment in the Phase 1b study in prurigo nodularis.”

Mr. Marucci continued, “We continue to make significant progress across our clinical pipeline including our bispecific platform, which is exploring important pathways in inflammatory diseases, auto-immune disorders and oncology. We look forward to updating you on these programs over the coming months.”

Recent 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.

- In July, Celldex reported interim data from the CDX-0159 single dose Phase 1b open label study in inducible urticaria, which were presented in a late-breaking poster discussion session as part of the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2021.
    - All 19 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.
    - Rapid onset of responses after dosing and sustained durability were observed and 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 (11+ weeks) for cold urticaria and 57+ days (8+ weeks) for symptomatic dermographism.
    - 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 which 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.
- In September, Celldex reported symptom control & quality of life measurements data from the CDX-0159 single dose Phase 1b open label study in inducible urticaria, which were presented in an e-poster session as part of the European Academy of Dermatology and Venereology (EADV) 2021 Virtual 30th Congress.
    - A single 3 mg/kg dose of CDX-0159 resulted in a rapid and sustained improvement in urticaria control and greatly reduced disease impact on quality of life, as measured by the Urticaria Control Test (UCT) and Dermatology Life Quality Index (DLQI). These data support and build on the previously reported 95% complete response rate to provocation testing.
- Additional Phase 1b single dose data from the cholinergic cohort of this study are planned to be submitted for presentation at EAACI 2022.
- Celldex continues to enroll patients 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 CSU who remain symptomatic despite treatment with antihistamines. Treatment results from this study are planned to be submitted for presentation at EAACI 2022.
- In September, Celldex initiated and has since completed dosing in 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 in healthy

volunteers. Celldex intends to utilize the subcutaneous formulation in its Phase 2 program in chronic urticarias.

- In September, enrollment opened 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 dosing cohorts of CDX-0159 in up to 40 patients with PN.

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 up to ~260 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.

    - The combination of CDX-1140 with pembrolizumab has completed the safety run-in phase. Expansion cohorts in patients with checkpoint-refractory/resistant squamous cell head and neck cancer and non-small cell lung cancer are enrolling patients. Of the six patients with squamous cell head and neck cancer treated with CDX-1140 at 1.5 mg/kg in combination with pembrolizumab, encouraging preliminary results have been observed including a confirmed partial response and durable stable disease. Of the six evaluable patients with non-small cell lung cancer, four have had stable disease as their best response. Adverse events, such as arthralgia, myalgia, and fatigue, have occurred more frequently in combination with pembrolizumab relative to CDX-1140 monotherapy and the protocol has been amended to allow CDX-1140 dose reduction, if necessary, to help manage these toxicities. Enrollment to the study is ongoing.

    - Emerging data from the safety run-in cohort of CDX-1140 with gemcitabine/nab-paclitaxel in patients with previously untreated metastatic pancreatic adenocarcinoma and external CD40 agonist data recently reported using the same regimen, suggest that simultaneous treatment with chemotherapy and CD40 activation may not be optimal. Alternative strategies for investigating CDX-1140 in pancreatic cancer in other regimens are being explored, including through investigator sponsored studies.

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 June, Celldex reported initial data from the 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, which were presented at the 2021 ASCO Annual Meeting. A good safety profile was observed along with promising pharmacodynamic and pharmacokinetic activity, which are important key hurdles for the development of bispecific antibodies. 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. Enrollment to the dose escalation portion of the study has been completed and an expansion cohort in ovarian cancer is currently enrolling patients.

Recent Operational Highlights

- In July, 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, 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).

To date, the Company has managed delays and disruptions related to the COVID-19 pandemic without significant impact in planned and ongoing preclinical and clinical trials, manufacturing or shipping. The Company continues to carefully monitor the evolving situation closely across all development programs and work to minimize potential impact/disruptions.

Third Quarter 2021 Financial Highlights and 2021 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2021 were $423.1 million compared to $164.0 million as of June 30, 2021. The increase was primarily driven by net proceeds of $269.9 million from our July 2021

underwritten public offering, partially offset by third quarter cash used in operating activities of $16.4 million. At September 30, 2021, Celldex had 46.7 million shares outstanding.

Revenues: Total revenue was $0.2 million in the third quarter of 2021 and $4.3 million for the nine months ended September 30, 2021, compared to $0.7 million and $3.6 million for the comparable periods in 2020. The increase in revenue for the nine months ended September 30, 2021 compared to the nine months ended September 30, 2020 was primarily due to an increase in services performed under our contract manufacturing and research and development agreements with Rockefeller University and Gilead Sciences, partially offset by 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.

R&D Expenses: Research and development (R&D) expenses were $13.6 million in the third quarter of 2021 and $38.6 million for the nine months ended September 30, 2021, compared to $10.7 million and $32.1 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 $5.8 million in the third quarter of 2021 and $14.2 million for the nine months ended September 30, 2021, compared to $3.6 million and $10.8 million for the comparable periods in 2020. The increase in G&A expenses was primarily due to higher personnel 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 $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: The gain on fair value remeasurement of contingent consideration was $1.9 million for the third quarter of 2021 and $1.2 million for the nine months ended September 30, 2021, primarily due to updated assumptions for the TAM program, changes in discount rates and the passage of time.

Net Loss: Net loss was $20.5 million, or ($0.45) per share, for the third quarter of 2021, and $50.4 million, or ($1.21) per share, for the nine months ended September 30, 2021, compared to a net loss of $14.2 million, or ($0.36) per share, for the third quarter of 2020 and $37.9 million, or ($1.44) per share, for the nine months ended September 30, 2020.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 30, 2021 are sufficient to meet estimated working capital requirements and fund planned operations through 2025.

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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 September 30,**		**Nine Months Ended September 30,**	
	2021	**2020**	**2021**	**2020**
	(Unaudited)		**(Unaudited)**	
Revenues:				
Product development and licensing agreements	$ -	$ 12	$ 29	$ 2,297
Contracts and grants	153	656	4,288	1,336
Total revenues	153	668	4,317	3,633
Operating expenses:				
Research and development	13,557	10,708	38,633	32,109
General and administrative	5,821	3,640	14,247	10,833
Intangible asset impairment	3,500	-	3,500	3,500
(Gain) loss on fair value remeasurement of contingent consideration	(1,901)	662	(1,160)	(4,236)
Total operating expenses	20,977	15,010	55,220	42,206
Operating loss	(20,824)	(14,342)	(50,903)	(38,573)
Investment and other income, net	145	118	313	465
Net loss before income tax benefit	(20,679)	(14,224)	(50,590)	(38,108)
Income tax benefit	227	-	227	228
Net loss	$ (20,452)	$ (14,224)	$ (50,363)	$ (37,880)
Basic and diluted net loss per common share	$ (0.45)	$ (0.36)	$ (1.21)	$ (1.44)
Shares used in calculating basic and diluted net loss per share	45,453	39,278	41,582	26,303

Condensed Consolidated Balance Sheet Data	**September 30, 2021**	**December 31, 2020**
	(Unaudited)	
Assets		

Cash, cash equivalents and marketable securities	$ 423,089	$ 194,422
Other current assets	3,466	3,421
Property and equipment, net	3,342	3,815
Intangible and other assets, net	30,304	34,180
Total assets	$ 460,201	$ 235,838
Liabilities and stockholders' equity		
Current liabilities	$ 14,176	$ 14,206
Long-term liabilities	9,313	12,275
Stockholders' equity	436,712	209,357
Total liabilities and stockholders' equity	$ 460,201	$ 235,838