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): August 5, 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 August 5, 2021, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second 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 August 5, 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: August 5, 2021

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

EXHIBIT 99.1

Celldex Reports Second Quarter 2021 Financial Results and Provides Corporate Update

- Positive data from CDX-0159 Phase 1b Study in Chronic Inducible Urticaria presented at EAACI 2021 -

- Raised $287 million in gross proceeds from a follow-on public offering of common stock, closed in July 2021 -

HAMPTON, N.J., Aug. 05, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the second quarter ended June 30, 2021 and provided a corporate update.

“Last month, Celldex reported positive data from our ongoing Phase 1b study of CDX-0159 in chronic inducible urticaria, where a single dose demonstrated a rapid, profound and durable response,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “These data not only spoke to the potential to bring patients suffering from urticaria an opportunity for fast, lasting and meaningful relief, but also showed that CDX-0159 safely depletes mast cells, a significant scientific and medical achievement that indicates CDX-0159’s potential to help other patients in need across a myriad of diseases with mast cell involvement.”

Mr. Marucci continued, “Importantly, driven by these data, we successfully completed a $287.5 million follow-on offering which will support the expansion of the CDX-0159 program into later stage studies and additional indications, along with the continued development of our bispecific platform, which is exploring important pathways in inflammatory diseases, auto-immune disorders and oncology. We look forward to building on our successes in what promises to be an exciting second half of the year.”

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.

- On July 9, Celldex reported interim data from the CDX-0159 single dose Phase 1b open label study, 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.
- Celldex plans to present additional Phase 1b single dose data from the cold urticaria and symptomatic dermographism cohorts, including quality of life assessments, in the fall of 2021 and data from the cholinergic cohort in the first quarter of 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 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 for presentation at a scientific congress in early summer of 2022.
- Celldex is expanding CDX-0159 development into prurigo nodularis, a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin. Of note, a patient with symptomatic dermographism enrolled in the chronic inducible urticaria study also had a diagnosis of prurigo nodularis. This patient experienced both a complete response of symptomatic dermographism and notable improvement of the prurigo nodularis symptoms on study. 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. Celldex plans to initiate 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 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. An update from this program is expected by end of 2021.

CDX-527 - Bispecific Antibody Program

CDX-527 is the first candidate developed by Celldex from its bispecific platform and 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 expansion cohorts are being planned; additional data is expected in 2022.

Corporate 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.

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.

Second Quarter 2021 Financial Highlights and 2021 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2021 were $164.0 million compared to $176.1 million as of March 31, 2021. The decrease was primarily driven by second quarter cash used in operating activities of $11.9 million. At June 30, 2021, Celldex had 39.6 million shares outstanding. In July 2021, the Company issued 6,845,238 shares of its common stock in an underwritten public offering of common stock resulting in net proceeds to the Company of approximately $270.0 million, after deducting underwriting fees and offering expenses.

Revenues: Total revenue was $3.5 million in the second quarter of 2021 and $4.2 million for the six months ended June 30, 2021, compared to $0.2 million and $3.0 for the comparable periods in 2020. The increase in revenue 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 $12.4 million in the second quarter of 2021 and $25.1 million for the six months ended June 30, 2021, compared to $9.7 million and $21.4 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, partially offset by a decrease in rent expense.

G&A Expenses: General and administrative (G&A) expenses were $4.3 million in the second quarter of 2021 and $8.4 million for the six months ended June 30, 2021, compared to $3.5 million and $7.2 million for the comparable periods in 2020. The increase in G&A expenses was primarily due to higher personnel expenses.

Intangible Asset Impairment: 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 loss on fair value remeasurement of contingent consideration was $0.3 million for the second quarter of 2021 and $0.7 million for the six months ended June 30, 2021, primarily due to changes in discount rates and the passage of time.

Net Loss: Net loss was $13.4 million, or ($0.34) per share, for the second quarter of 2021, and $29.9 million, or ($0.76) per share, for the six months ended June 30, 2021, compared to a net loss of $11.0 million, or ($0.50) per share, for the second quarter of 2020 and $23.7 million, or ($1.20) per share, for the six months ended June 30, 2020.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 30, 2021, along with the approximately $270.0 million in net proceeds raised in our July 2021 underwritten public offering of common stock, are sufficient to meet estimated working capital requirements and fund planned operations through 2025.

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, 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 June 30,**	**Six Months Ended June 30,**

	2021 (Unaudited)	2020	2021 (Unaudited)	2020
Revenues:				
Product development and licensing agreements	$ 26	$ -	$ 29	$ 2,285
Contracts and grants	3,454	236	4,136	680
Total revenues	3,480	236	4,165	2,965
Operating expenses:				
Research and development	12,356	9,705	25,076	21,400
General and administrative	4,306	3,528	8,426	7,194
Intangible asset impairment	-	3,500	-	3,500
Loss (gain) on fair value remeasurement of contingent consideration	258	(5,132)	741	(4,898)
Total operating expenses	16,920	11,601	34,243	27,196
Operating loss	(13,440)	(11,365)	(30,078)	(24,231)
Investment and other income, net	67	106	167	347
Net loss before income tax benefit	(13,373)	(11,259)	(29,911)	(23,884)
Income tax benefit	-	228	-	228
Net loss	$ (13,373)	$ (11,031)	$ (29,911)	$ (23,656)
Basic and diluted net loss per common share	$ (0.34)	$ (0.50)	$ (0.76)	$ (1.20)
Shares used in calculating basic and diluted net loss per share	39,616	22,082	39,615	19,744

Condensed Consolidated Balance Sheet Data

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Cash, cash equivalents and marketable securities	$ 164,037	$ 194,422
Other current assets	3,569	3,421
Property and equipment, net	3,496	3,815
Intangible and other assets, net	33,449	34,180
Total assets	$ 204,551	$ 235,838
Liabilities and stockholders' equity		
Current liabilities	$ 14,488	$ 14,206
Long-term liabilities	7,781	12,275
Stockholders' equity	182,282	209,357
Total liabilities and stockholders' equity	$ 204,551	$ 235,838