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CELLDEX THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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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 7, 2017

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. [ ]

Item 2.02. Results of Operations and Financial Condition.

On November 7, 2017, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter of 2017. 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 7, 2017.

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 7, 2017

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

EXHIBIT 99.1

Celldex Reports Third Quarter 2017 Results

HAMPTON, N.J., Nov. 07, 2017 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the third quarter ended September 30, 2017.

"In late August, we completed enrollment in our Phase 2 METRIC study of glembatumumab vedotin in triple negative breast cancer," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "We believe glemba holds considerable promise as a potential new targeted therapy for patients with this devastating disease and continue to look forward to topline data from this study in the second quarter of 2018. In early October, Dr. Margo Heath-Chiozzi joined Celldex to lead our global regulatory strategy. With nine product approvals under her leadership, Dr. Heath-Chiozzi brings an exceptional command of the regulatory environment and will play an important role in defining potential approval paths for glemba and our earlier pipeline.

We look forward to a busy end of year as we prepare for the glemba data read out and advance multiple earlier stage studies, including the initiation of two new studies by year-end—a Phase 2 study of CDX-3379 in recurrent head and neck squamous cell cancer and a Phase 1 study of CDX-1140 in solid tumors."

Recent Highlights

- **METRIC enrollment completed:** Enrollment in METRIC was closed in late August with 327 patients on study. Patients were randomized 2 to 1 to either glembatumumab vedotin or to capecitabine, also known by the tradename Xeloda ®, as a comparator. The primary endpoint of the study is progression-free survival (PFS), which is defined as the time from randomization to the earlier of disease progression or death due to any cause. The study calls for 203 progression events for evaluation of the primary endpoint, which will be assessed based on an independent, central reading of patient scans. The sum of the data, including the secondary endpoints of response rate, overall survival, duration of response and safety, will be important in assessing clinical benefit. The Company projects that topline primary endpoint data should be available in the second quarter of 2018, but it could occur earlier or later based on the rate of events in the study.

- **Data from the Phase 2 glembatumumab vedotin and varlilumab combination cohort in checkpoint-refractory metastatic melanoma were accepted for presentation at the Society for Immunotherapy of Cancer's (SITC) 32nd Annual Meeting in November 2017; additional cohorts added to the study:** The cohort enrolled 34 evaluable patients with unresectable stage IV melanoma. All patients had been heavily pre-treated (median prior therapies=3; range 1-8) and had progressed during or after checkpoint inhibitor (CPI) therapy (median prior CPI therapies=2; range 1-4). Almost all patients had received ipilimumab (n=26; 76%) and/or anti-PD-1/anti-PD-L1 (n=34; 100%) therapy. Nine patients presented with BRAF mutation, and eleven had prior treatment with BRAF or BRAF/MEK targeted agents.

  One of 31 patients eligible for response evaluation experienced a confirmed partial response (3%), and an additional two patients also experienced single timepoint partial responses. 52% of patients experienced stable disease (minimum of six or more weeks). A 19% disease control rate (patients without progression for greater than three months) was demonstrated. Median PFS for all patients was 2.6 months (95% CI: 1.4, 2.8), and median overall survival (OS) for all patients was 6.4 months (95% CI: 3.2, 8.3). The safety profile was consistent with prior studies of glembatumumab vedotin, and there was no evidence of additive toxicity associated with the combination.

  Biological effects of varlilumab were consistent with prior observations and did not appear to be impacted by the addition of an antibody-drug conjugate (ADC). Modest clinical benefit in the combination could be due to multiple factors, including potential lack of sensitivity to immunotherapy in patients with checkpoint refractory disease, many of whom progressed so rapidly that they experienced a very short duration of varlilumab treatment (median 2 doses); a possible dearth of antigen presenting cells in tumors; and the potential for immune checkpoint molecules to remain unblocked without checkpoint inhibitor therapy. Planned future cohorts are designed to address some of these potential factors. No significant correlation between rash and outcome was observed but will continue to be monitored in future cohorts. The data from this study will be presented in a poster session on November 10 th, at which time the poster will be posted on the Celldex website.

  Enrollment continues in the glembatumumab vedotin plus checkpoint inhibitor (Opdivo ® or Keytruda ®) arm in patients who failed prior checkpoint therapy, a population with limited treatment options. In September 2017, Celldex amended the study protocol to add a fourth cohort evaluating glembatumumab vedotin in combination with CDX-301 to assess the safety, tolerability and biologic activity of the combination. CDX-301 promotes the production and maturation of dendritic cells. Following completion of this cohort and evaluation of available data, the protocol amendment also allows for the exploration of additional cohorts.

- **Data from the Phase 2 study of glembatumumab vedotin in patients with locally recurrent or metastatic uveal melanoma were presented at the 9th World Congress of Melanoma in October 2017 by the National Cancer Institute (NCI):** Two (6%) objective responses were observed in 31 patients to date, and 35% of patients experienced stable disease greater than 100 days (median 5.5 months). The disease control rate (response rate + stable disease) for all patients on study was noteworthy at 61%. Median PFS was 3.2 months, and median OS was 11.8 months. For patients who experienced either a partial response or stable disease, median PFS was 5.5 months, and median OS has not yet been reached. The NCI is conducting exploratory immune correlates to provide insight into target saturation, antigen release and potential combination strategies. This single-arm, open-label study is sponsored under a Cooperative Research and Development Agreement, or CRADA, with the NCI.

- **Phase 2 varlilumab/Opdivo study continues to enroll patients:** The study includes cohorts in colorectal cancer, ovarian cancer, head and neck squamous cell carcinoma, renal cell carcinoma and glioblastoma. The Company plans to complete enrollment across all cohorts in the Phase 2 portion of the study in the first quarter of 2018 and will work with Bristol-Myers Squibb to present data from the study at a future medical meeting.

- **CDX-3379 advancing to Phase 2:** CDX-3379 is a human immunoglobulin G1 lambda (IgG1λ) monoclonal antibody that selectively binds and inhibits ErbB3 activity. ErbB3 is associated with the development of targeted therapeutic resistance in numerous cancers, including but not limited to epidermal growth factor receptor (EGFR) inhibitors in lung and head and neck cancers. By year-end, Celldex plans to initiate an open-label Phase 2 study of CDX-3379 given in combination with Erbitux ® (cetuximab), an EGFR inhibitor, in approximately 30 patients with recurrent/metastatic head and neck squamous

cell cancer whose disease is resistant to Erbitux. The primary objective of the study is objective response rate. Secondary objectives include assessments of clinical benefit response (CBR), duration of response (DOR), PFS and OS, and safety and pharmacokinetics associated with the combination.

- **Phase 1 study of CDX-0158 nearing completion:** This dose escalation study in patients with advanced refractory gastrointestinal stromal tumors (GIST) and other KIT-positive tumors is designed to determine the maximum tolerated dose, recommend a dose for further study and characterize the safety profile of CDX-0158. A total of 28 patients have been treated with doses up to 15 mg/kg with one patient currently continuing on treatment. Importantly, no evidence of myelosuppression (an effect commonly associated with KIT inhibition) was observed in this study. Approximately two-thirds of the patients on study had infusion reactions that were manageable with pre-medication and longer infusion times. The biomarker data showed evidence of dose-related KIT engagement, and two patients experienced partial metabolic responses on fluorodeoxyglucose (FDG)-PET scan; however, these PET responses were not associated with tumor shrinkage. Given the infusion reactions, modifications have been introduced into the Fc portion of the CDX-0158 antibody to prevent these interactions and increase the half-life of the antibody. This second-generation version, called CDX-0159, has demonstrated equivalent KIT inhibition to CDX-0158 in preclinical studies, but unlike CDX-0158, CDX-0159 does not induce KIT activation when Fc receptors are used to cross-link the antibodies. CDX-0159 is being fully developed in-house with the intention of replacing CDX-0158 in clinical development. We expect manufacturing and IND-enabling efforts for CDX-0159 will be completed in 2018.

- **Enrollment ongoing in Phase 1 study of CDX-014:** This study in advanced renal cell carcinoma (clear cell and papillary) is designed to determine the maximum tolerated dose and to recommend a dose level for further study. We anticipate expanding the Phase 1 study to obtain broader experience in other tumor types with high TIM-1 expression and to explore alternate dosing regimens.

- **Phase 1 study of CDX-1140 to open to enrollment by year-end; preclinical data presented at SITC:** CDX-1140 is a fully human antibody targeted to CD40, a key activator of immune response which is found on dendritic cells, macrophages and B cells and is also expressed on many cancer cells. This study, which is expected to enroll up to approximately 105 patients with recurrent, locally advanced or metastatic cancers, is designed to determine the maximum tolerated dose during a dose-escalation phase and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability and biologic effects of selected dose(s) of CDX-1140 in specific tumor types. The Company believes that the potential for CDX-1140 will be best defined in combination studies with other immunotherapies or conventional cancer treatments.

  Preclinical data, including the IND-enabling toxicology study of CDX-1140, were accepted for presentation at the SITC Annual Meeting on November 11 th , at which time the poster will be posted on the Celldex website. Potent CD40 agonist antibodies have shown encouraging results in early clinical studies; however, systemic toxicity associated with broad CD40 activation has limited their dosing. CDX-1140 has unique properties relative to other CD40 agonist antibodies: potent agonist activity is independent of Fc receptor interaction, contributing to more consistent, controlled immune activation; CD40L binding is not blocked, leading to potential synergistic effects of agonist activity near activated T cells in lymph nodes and tumors; and the antibody does not promote cytokine production in whole blood assays. CDX-1140 has shown direct anti-tumor activity in preclinical models of lymphoma. This toxicology study of CDX-1140 clearly demonstrates strong immune activation effects and low systemic toxicity. The No Observable Adverse Effect Level (NOAEL) for CDX-1140 was determined to be 10 mg/kg in this study. The data support the design of the Phase 1 study of CDX-1140 to rapidly identify the dose for characterizing single-agent and combination activity.

Third Quarter and First Nine Months 2017 Financial Highlights and Updated 2017 Guidance

Cash position: Cash, cash equivalents and marketable securities as of September 30, 2017 were $140.5 million compared to $154.0 million as of June 30, 2017. The decrease was primarily driven by third quarter cash used in operating activities of $24.4 million. This decrease was partially offset by the receipt of $11.2 million from sales of common stock under the Cantor agreement. At September 30, 2017, Celldex had 132.1 million shares outstanding.

Revenues: Total revenue was $3.9 million in the third quarter of 2017 and $9.3 million for the nine months ended September 30, 2017, compared to $2.2 million and $4.9 million for the comparable periods in 2016. The increase in revenue was primarily due to the manufacturing service agreements with the International AIDS Vaccine Initiative and Frontier Biotechnologies, Inc.

R&D Expenses: Research and development (R&D) expenses were $21.9 million in the third quarter of 2017 and $72.7 million for the nine months ended September 30, 2017, compared to $25.0 million and $78.2 million for the comparable periods in 2016.

The $3.1 million decrease in third quarter R&D expenses was primarily due to decreases in varlilumab contract manufacturing and clinical trials expenses of $1.7 million and $1.0 million, respectively.

The $5.5 million decrease in year-to-date R&D expenses was primarily due to decreases in varlilumab and Rintega contract manufacturing expenses of $6.8 million and $2.5 million, respectively, partially offset by an increase in glembatumumab vedotin contract manufacturing expenses of $2.6 million and increases in personnel and facility costs related to the Kolltan acquisition.

G&A Expenses: General and administrative (G&A) expenses were $5.3 million in the third quarter of 2017 and $19.1 million for the nine months ended September 30, 2017, compared to $7.0 million and $24.0 million for the comparable periods in 2016.

The $1.7 million decrease in third quarter G&A expenses was primarily due to lower commercial planning costs of $0.7 million and lower stock-based compensation of $0.6 million.

The $4.9 million decrease in year-to-date G&A expenses was primarily due to lower commercial planning costs of $3.1 million and lower stock-based compensation of $1.4 million.

In-Process Research and Development Impairment: The Company recorded a non-cash partial impairment charge of $13.0 million on the anti-KIT program IPR&D asset acquired from Kolltan for the three months ended September 30, 2017 due to changes in the anti-KIT program projected development and regulatory timelines.

Gain on Fair Value Remeasurement of Contingent Consideration: Gain on the fair value remeasurement of contingent consideration related to the Kolltan

acquisition was $4.6 million in the third quarter of 2017 and $0.2 million for the nine months ended September 30, 2017, primarily due to a reduction in fair value attributed to the milestones related to the Company's anti-KIT program and partially offset by losses related to changes in discount rates and the passage of time.

Net loss: Net loss was $26.4 million, or ($0.20) per share, for the third quarter of 2017 and $89.2 million, or ($0.71) per share, for the nine months ended September 30, 2017, compared to a net loss of $29.6 million, or ($0.29) per share, and $96.2 million, or ($0.97) per share, for the comparable periods in 2016.

Financial guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 30, 2017, combined with the $11.3 million in net proceeds from sales of common stock under the Cantor agreement during October 2017, are sufficient to meet estimated working capital requirements and fund planned operations through 2018; however, this guidance assumes Celldex elects to pay future Kolltan contingent milestones, if any, in stock rather than cash.

Xeloda ® is a registered trademark of Genentech, Inc. Opdivo ® is a registered trademark of Bristol-Myers Squibb. Keytruda ® is a registered trademark of Merck Sharp & Dohme Corp. Erbitux ® is a registered trademark of Eli Lilly & Co.

About Celldex Therapeutics, Inc.

Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline includes antibodies, antibody-drug conjugates and other protein-based therapeutics derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. 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 glembatumumab vedotin and other Company drug candidates; our ability to obtain additional 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; our ability to realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently; 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 and commercial grade 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; our ability to maintain and derive benefit from the Fast Track designation for glembatumumab vedotin which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; 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; 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.

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

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS DATA	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
	2017	**2016**	**2017**	**2016**
	(Unaudited)		**(Unaudited)**	
REVENUES:				
Product Development and Licensing Agreements	$ 1,238	$ 493	$ 2,488	$ 1,551
Contracts and Grants	2,686	1,727	6,799	3,362
Total Revenue	3,924	2,220	9,287	4,913
OPERATING EXPENSES:				
Research and Development	21,915	25,009	72,707	78,168
General and Administrative	5,346	6,950	19,109	24,049
In-Process Research and Development Impairment	13,000	-	13,000	-
Gain on Fair Value Remeasurement				

of Contingent Consideration	(4,600)	-	(200)	-
Amortization of Acquired Intangible Assets	224	254	672	760
Total Operating Expense	35,885	32,213	105,288	102,977
Operating Loss	(31,961)	(29,993)	(96,001)	(98,064)
Investment and Other Income, Net	398	395	1,611	1,841
Net Loss Before Income Tax Benefit	(31,563)	(29,598)	(94,390)	(96,223)
Income Tax Benefit	5,200	-	5,200	-
Net Loss	$ (26,363)	$ (29,598)	$ (89,190)	$ (96,223)
Basic and Diluted Net Loss per Common Share	$ (0.20)	$ (0.29)	$ (0.71)	$ (0.97)
Shares Used in Calculating Basic and Diluted Net Loss per Share	129,640	100,672	125,856	99,398

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	**September 30, 2017 (Unaudited)**	**December 31, 2016**
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 140,530	$ 189,776
Other Current Assets	6,787	5,793
Property and Equipment, net	11,308	13,192
Intangible and Other Assets, net	160,793	174,597
Total Assets	$ 319,418	$ 383,358
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 24,915	$ 35,223
Long-Term Liabilities	75,351	82,704
Stockholders' Equity	219,152	265,431
Total Liabilities and Stockholders' Equity	$ 319,418	$ 383,358

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