

CELLDEX THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Address	53 FRONTAGE ROAD SUITE 220 HAMPTON, NJ 08827
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): May 9, 2017

Celldex Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction of Incorporation)

000-15006
(Commission File Number)

13-3191702
(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 May 9, 2017, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first 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 May 9, 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: May 9, 2017

By: /s/ Avery W. Catlin
Avery W. Catlin
Senior Vice President and
Chief Financial Officer

Celldex Reports First Quarter 2017 Results

HAMPTON, N.J., May 09, 2017 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the first quarter ended March 31, 2017.

“In the first quarter of 2017, Celldex made considerable progress across our pipeline,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We continue to expect enrollment completion in our ongoing study of glembatumumab vedotin in triple negative breast cancer by the end of September, and we recently completed enrollment in the Phase 2 glembatumumab vedotin plus varlilumab combination cohort in checkpoint-refractory metastatic melanoma. Glemba’s target, gpNMB, is highly expressed in melanoma and triple negative breast cancer, among others, and is associated with more aggressive disease. We believe taking an antibody-drug conjugate approach to targeting gpNMB generates a potent cytotoxic effect within the tumor and its environment and may ultimately result in improved outcomes for patients.”

“We also look forward to presenting data from two programs in oral sessions at ASCO in June—the Phase 2 single-agent study of glembatumumab vedotin in metastatic melanoma and the Phase 1 combination study of varlilumab and Opdivo.”

Recent Highlights

- **Continued progress in METRIC enrollment:** Celldex continues to expect that enrollment will be completed by the end of September 2017. METRIC is a Phase 2b randomized study of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress gpNMB.
- **Single-agent glembatumumab vedotin Phase 2 study in checkpoint-refractory metastatic melanoma accepted for oral presentation at ASCO:** Updated data from the single-agent cohort of the Phase 2 study will be presented in an oral presentation at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in June. Enrollment recently completed in the glembatumumab vedotin and varlilumab arm, with data from this portion of the study expected in the fall of 2017. 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.
- **Phase 1 varlilumab/Opdivo[®] study accepted for oral presentation at ASCO:** Updated data from the Phase 1 portion of the varlilumab and Opdivo study will be presented in an oral presentation at the 2017 ASCO Annual Meeting in June. The Phase 2 portion of the combination study includes cohorts in colorectal cancer, ovarian cancer, head and neck squamous cell carcinoma, renal cell carcinoma and glioblastoma, and is currently enrolling patients. 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. Data from the Phase 1 single-agent study of varlilumab in solid tumors were recently published in the *Journal of Clinical Oncology*.
- **Phase 1 study of CDX-0158 continues to enroll patients:** 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. Data from the study continue to be expected by year-end 2017.
- **CDX-3379 advancing to Phase 2:** The Company is currently finalizing plans for advancement into a Phase 2 study in combination with cetuximab in patients with cetuximab-resistant advanced head and neck squamous cell carcinoma.
- **Enrollment ongoing in Phase 1 study of CDX-014:** The 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. Celldex continues to expect the Phase 1 dose-escalation portion of the study will complete enrollment by year-end 2017.

First Quarter 2017 Financial Highlights and Updated 2017 Guidance

Cash position: Cash, cash equivalents and marketable securities as of March 31, 2017 were \$167.0 million compared to \$189.8 million as of December 31, 2016. The decrease was primarily driven by our first quarter cash used in operating activities of approximately \$35.3 million which included a payment of \$4.7 million in accrued amounts to a vendor of Kolltan. This obligation was assumed in the Kolltan acquisition. This decrease was partially offset by the receipt of \$12.8 million from sales of our common stock under our Cantor agreement. At March 31, 2017, Celldex had 124.2 million shares outstanding.

Revenues: Total revenue was \$1.5 million in the first quarter of 2017, compared to \$1.3 million for the comparable period in 2016. The increase in revenue was primarily due to our clinical trial collaboration with Bristol-Myers Squibb and our research and development agreement with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were \$25.8 million in the first quarter of 2017, compared to \$27.4 million for the comparable period in 2016. The decrease in R&D expenses was primarily due to a decrease in Rintega product development expenses of \$7.3 million, partially offset by increases in glembatumumab vedotin, CDX-0158 and CDX-3379 product development expenses of \$1.8 million, \$0.8 million and \$0.7 million, respectively, and increases in personnel and facility costs related to the Kolltan acquisition.

G&A Expenses: General and administrative (G&A) expenses were \$7.2 million in the first quarter of 2017, compared to \$9.3 million for the comparable period in 2016. The decrease in G&A expenses was primarily due to a decrease in Rintega commercial planning costs of \$2.0 million.

Loss on Fair Value Remeasurement of Contingent Consideration: In connection with the Kolltan Acquisition, we agreed to pay Kolltan’s stockholders milestone payments of up to \$172.5 million in the event that certain specified preclinical and clinical development milestones related to Kolltan’s development programs and/or our development programs and certain commercial milestones related to Kolltan’s drug candidates are achieved. These milestone payments may be made in cash, in shares of our common stock or a combination of both, subject to NASDAQ listing requirements and provisions of the merger agreement. The range of estimated milestone payments is from zero, if no milestones are achieved, to \$172.5 million if all milestones are met. We record the fair value of these obligations to pay additional milestone payments using various estimates, including probabilities of success, discount rates and amount of time until the conditions of the milestone payments are met. The \$3.4 million loss on fair value remeasurement of contingent consideration relates to an increase in the estimate of the fair

value of the contingent consideration primarily due to changes in discount rates and the passage of time.

Net loss: Net loss was \$34.3 million, or (\$0.28) per share, for the first quarter of 2017, compared to a net loss of \$34.7 million, or (\$0.35) per share, for the comparable period in 2016.

Financial guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2017 combined with the anticipated proceeds from future sales of our common stock under our Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2018; however, this guidance assumes we are able to and elect to pay future Kolltan contingent milestones, if any, in stock rather than cash.

Opdivo® is a registered trademark of Bristol-Myers Squibb. *Keytruda*® is a registered trademark of Merck Sharp & Dohme Corp.

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 integrate the business and programs of Kolltan with our business and programs; 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; 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)

CONSOLIDATED STATEMENT OF OPERATIONS DATA

	Quarter Ended March 31,	
	2017	2016
	(Unaudited)	
OPERATING REVENUE		
Product Development and Licensing Agreements	\$ 556	\$ 453
Contracts and Grants	978	850
Total Revenue	1,534	1,303
OPERATING EXPENSE		
Research and Development	25,793	27,447
General and Administrative	7,229	9,307
Loss on Fair Value Remeasurement of Contingent Consideration	3,400	-
Amortization of Acquired Intangible Assets	224	253
Total Operating Expense	36,646	37,007
Operating Loss	(35,112)	(35,704)

Investment and Other Income, Net	851	1,031
Net Loss	\$ (34,261)	\$ (34,673)
Basic and Diluted Net Loss per Common Share	\$ (0.28)	\$ (0.35)
Weighted Average Common Shares Outstanding	122,648	98,689

**CONDENSED CONSOLIDATED
BALANCE SHEETS DATA**

	March 31,	December 31,
	2017	2016
	(Unaudited)	
ASSETS		
Cash, Cash Equivalents and Marketable Securities	\$ 167,023	\$ 189,776
Other Current Assets	6,440	5,793
Property and Equipment, net	12,411	13,192
Intangible and Other Assets, net	174,174	174,597
Total Assets	<u>\$ 360,048</u>	<u>\$ 383,358</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	\$ 27,024	\$ 35,223
Long-Term Liabilities	85,188	82,704
Stockholders' Equity	247,836	265,431
Total Liabilities and Stockholders' Equity	<u>\$ 360,048</u>	<u>\$ 383,358</u>

Company Contact

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