

CELLDEX THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 03/14/17 for the Period Ending 03/14/17

Address	53 FRONTAGE ROAD SUITE 220 HAMPTON, NJ 08827
Telephone	908-200-7500
CIK	0000744218
Symbol	CLDX
SIC Code	2835 - In Vitro and In Vivo Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): March 14, 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))
-
-
-

Item 2.02. Results of Operations and Financial Condition.

On March 14, 2017, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter of 2016 and year ended December 31, 2016. 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 March 14, 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: March 14, 2017

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

Celldex Provides Corporate Update and Reports Full Year 2016 Results

Conference Call Scheduled for 4:30 p.m. ET Today

HAMPTON, N.J., March 14, 2017 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the fourth quarter and year-ended December 31, 2016. The Company will host a conference call at 4:30 p.m. ET today to provide an in-depth update on its pipeline and upcoming milestones for 2017.

“Celldex made important progress across our pipeline in the fourth quarter, including successfully completing the integration of Kolltan Pharmaceuticals and its novel RTK antibody programs into our organization and driving a considerable uptick in enrollment in our ongoing study of glembatumumab vedotin in triple negative breast cancer,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “As we look to 2017, we have prioritized completing the glemba studies in breast cancer and checkpoint-refractory metastatic melanoma, the Phase 2 collaborative study of varlilumab with BMS’s Opdivo and our Phase 1 studies of both CDX-0158 and CDX-014. Data from a number of these programs are expected to be available over the next 6 to 12 months.”

“In addition, we will have a change on our leadership team this summer as Chip Catlin, Senior Vice President and Chief Financial Officer, has shared with us his intention to retire in June of this year,” continued Marucci. “Chip’s contribution to Celldex has been significant, and we wish him all the best in his retirement. Sam Martin, our current Vice President of Finance will be promoted to the CFO role concurrent with Chip’s departure. Chip and Sam have worked closely together over the last eight years, and we expect the transition to be seamless.”

Recent Highlights

- **Kolltan Pharmaceuticals acquisition completed** : In late November, Celldex completed the acquisition of Kolltan Pharmaceuticals, Inc., adding a unique platform of antibodies targeting receptor tyrosine kinases (RTKs) to the Company’s pipeline. Clinical and preclinical data suggest these candidates can help overcome tumor resistance mechanisms associated with current tyrosine kinase inhibitors and seen in patients who have failed other cancer therapies.
- **Considerable progress in METRIC enrollment** : Enrollment in the Phase 2b randomized study (METRIC) of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress gpNMB has accelerated consistently over the last several months across the United States, Canada, Australia and the European Union. Assuming the current rate of enrollment continues, Celldex expects enrollment will be completed by the end of September 2017.
- **Third arm added to glembatumumab vedotin Phase 2 study in metastatic melanoma**: Enrollment has initiated in a glembatumumab vedotin plus checkpoint inhibitor (Opdivo[®] or Keytruda[®]) arm in patients who failed prior checkpoint therapy. Enrollment also continues in the glembatumumab vedotin and varlilumab arm, with data from this portion of the study expected in the fall of 2017. Positive data from the single-agent arm of this study in patients who had previously progressed on checkpoint therapy were presented at the European Society for Medical Oncology (ESMO) Congress in October 2016.
- **Continued progress in Phase 2 varlilumab/Opdivo[®] study**: The Phase 2 study of varlilumab and Opdivo continues to enroll patients across multiple indications [colorectal cancer (n=18), ovarian cancer (n=54), head and neck squamous cell carcinoma (n=54), renal cell carcinoma (n=25), glioblastoma (n=20)]. The Company anticipates that data from the Phase 1 study of varlilumab and Opdivo will be presented mid-year 2017. 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 BMS to present data from the study at a future medical meeting. Given the advancement of varlilumab into a broad Phase 2 study with BMS, including in renal cell carcinoma, and efforts to identify areas for cost-containment, Celldex has decided not to advance the varlilumab/Tecentriq[®] and the varlilumab/Sutent[®] combination studies in renal cell carcinoma to Phase 2.
- **Phase 1 study of CDX-0158 (formerly KTN0158) 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 are expected by year-end 2017.
- **CDX-3379 (formerly KTN3379) advancing to Phase 2**: The Company is currently exploring plans for advancement into Phase 2 study.
- **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 expects the Phase 1 dose-escalation portion of the study will complete enrollment by year-end 2017.

Fourth Quarter and Twelve Months 2016 Financial Highlights and 2017 Guidance

Cash position: Cash, cash equivalents and marketable securities as of December 31, 2016 were \$189.8 million compared to \$203.2 million as of September 30, 2016. The decrease was primarily driven by our fourth quarter cash used in operating activities of approximately \$20.3 million. This decrease was partially offset by the receipt of \$4.6 million of cash received, net of transaction expenses paid related to our acquisition of Kolltan and \$3.3 million from sales of our common stock under our Cantor agreement. At December 31, 2016, Celldex had 120.5 million shares outstanding.

Revenues: Total revenue was \$1.9 million in the fourth quarter of 2016 and \$6.8 million for the twelve months ended December 31, 2016, compared to \$1.8 million and \$5.5 million for the comparable periods in 2015. The increase in revenue was primarily due to our clinical trial collaboration with Bristol-Myers Squibb and an increase in grant revenue, partially offset by a decrease in revenue from our research and development agreement with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were \$24.6 million in the fourth quarter of 2016 and \$102.7 million for the twelve months ended December 31, 2016, compared to \$23.9 million and \$100.2 million for the comparable periods in 2015. The increase in R&D expenses for the twelve months ended December 31, 2016 as compared to 2015 was primarily due to higher personnel costs of \$6.3 million, including higher stock-based compensation and

Kolltan-related severance expense of \$1.6 million and \$0.7 million, respectively, offset by lower product development expense of \$5.9 million. This decrease in product development expenses was primarily due to a \$19.9 million decrease in Rintega program costs, partially offset by increases in glebatumumab vedotin and varlilumab program costs of \$4.6 million and \$9.6 million, respectively.

G&A Expenses: General and administrative (G&A) expenses were \$11.9 million in the fourth quarter of 2016 and \$36.0 million for the twelve months ended December 31, 2016, compared to \$11.1 million and \$33.8 million for the comparable periods in 2015. The increase in G&A expenses for the twelve months ended December 31, 2016 as compared to 2015 was primarily due to Kolltan-related severance expense, restructuring expense related to our decision to not occupy our Needham, MA expansion space and higher stock based compensation of \$2.4 million, \$1.2 million and \$0.9 million, respectively, partially offset by lower commercial planning costs of \$2.8 million.

Net loss: Net loss was \$32.3 million, or (\$0.30) per share, for the fourth quarter of 2016 and \$128.5 million, or (\$1.27) per share, for the twelve months ended December 31, 2016, compared to a net loss of \$32.7 million, or (\$0.33) per share, and \$127.2 million, or (\$1.31) per share, for the comparable periods in 2015.

Financial guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 2016 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 elect to pay future Kolltan contingent milestones, if any, in stock rather than cash.

Webcast and Conference Call

Celldex executives will host a conference call at 4:30 p.m. ET today to discuss financial and business results and to provide an update on key 2017 objectives. The conference call and presentation 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 69462587.

A replay of the call will be available approximately two hours after the live call concludes through March 21, 2017. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 69462587. The webcast will also be archived on the Company's website.

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

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 glebatumumab 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 glebatumumab 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)

STATEMENTS OF OPERATIONS DATA	Consolidated Quarter Ended December 31,		Consolidated Year Ended December 31,	
	2016	2015	2016	2015

(Unaudited)**REVENUE**

Product Development and Licensing Agreements	\$	623	\$	389	\$	2,174	\$	1,442
Contracts and Grants		1,251		1,401		4,612		4,038
Total Revenue		1,874		1,790		6,786		5,480
OPERATING EXPENSE								
Research and Development		24,558		23,900		102,726		100,171
General and Administrative		11,933		11,075		35,979		33,837
Amortization of Acquired Intangible Assets		235		253		997		1,013
Total Operating Expense		36,726		35,228		139,702		135,021
Operating Loss		(34,852)		(33,438)		(132,916)		(129,541)
Investment and Other Income, Net		2,545		754		4,386		2,344
Net Loss	\$	(32,307)	\$	(32,684)	\$	(128,530)	\$	(127,197)
Basic and Diluted Net Loss per Common Share	\$	(0.30)	\$	(0.33)	\$	(1.27)	\$	(1.31)
Weighted Average Common Shares Outstanding		107,876		98,633		101,529		97,051

CONDENSED BALANCE SHEETS	Consolidated	
	December 31,	December 31,
	2016	2015
ASSETS		
Cash, Cash Equivalents and Marketable Securities	\$ 189,776	\$ 289,889
Other Current Assets	5,793	5,047
Property and Equipment, net	13,192	11,461
Intangible and Other Assets, net	174,597	31,187
Total Assets	\$ 383,358	\$ 337,584
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	\$ 35,223	\$ 30,240
Long-Term Liabilities	82,704	17,239
Stockholders' Equity	265,431	290,105
Total Liabilities and Stockholders' Equity	\$ 383,358	\$ 337,584

Company Contact

Sarah Cavanaugh
Vice President of Investor Relations & Corp Communications
Celldex Therapeutics, Inc.
(781) 433-3161
scavanaugh@celldex.com

Charles Liles
Associate Director of Investor Relations & Corp Communications

Celldex Therapeutics, Inc.
(781) 433-3107
cliles@celldex.com