**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

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# FORM 8-K

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event Reported): February 25, 2016

## 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 200, 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 February 25, 2016, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter of 2015 and year ended December 31, 2015. 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 February 25, 2016.

**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: February 25, 2016

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

**EXHIBIT 99.1**

**Celldex Reports Fourth Quarter and Year-End 2015 Results**

Conference Call Scheduled for 8:00 a.m. ET Today

HAMPTON, N.J., Feb. 25, 2016 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the fourth quarter and year ended December 31, 2015.

“2015 was a year of considerable progress for Celldex and our growing pipeline,” said Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics. “Most importantly, we completed the Phase 2 ReACT Study of RINTEGA in recurrent GBM, confirming a highly statistically significant long-term overall survival benefit. RINTEGA continues to tell a very consistent, impressive story across multiple, clinically relevant endpoints in both the recurrent and newly diagnosed setting, supporting our belief that RINTEGA will be an important treatment option for all patients with EGFRvIII-positive glioblastoma. With this in mind, we look forward to completing the Phase 3 ACT IV trial in the newly diagnosed setting and are confident we are preparing appropriately for potential commercialization.”

“In addition to the strides made in the RINTEGA program, we continued to execute across the entire pipeline in 2015, initiating four new combination studies for the varlilumab program and continuing to enroll patients to ongoing studies of glembatumumab vedotin in both triple negative breast cancer and metastatic melanoma. We also have multiple studies advancing across our earlier-stage product candidates and recently received notice that our IND is now active for CDX-014, our ADC targeting TIM-1. We look forward to initiating the first Phase 1/2 study in renal cell carcinoma for this candidate this year. We are also finalizing preparations with Bristol-Myers Squibb to advance the varlilumab combination study with nivolumab into a broad Phase 2 program. With data reporting from multiple studies across our pipeline in 2016 and into early 2017, we believe the next twelve to eighteen months have the potential to be transformational for the Company,” concluded Marucci.

**Program Updates:**

***RINTEGA® (“rindopepimut”; “rindo”; CDX-110), an EGFRvIII(v3)-specific therapeutic vaccine for glioblastoma (GBM)***

- The ACT IV study is a randomized, double-blind, placebo controlled study of RINTEGA plus GM-CSF added to standard of care temozolomide in patients with newly diagnosed, surgically resected, EGFRvIII-positive glioblastoma. 745 patients were enrolled into ACT IV to reach the required 374 patients with minimal residual disease (assessed by central review) needed for analysis of the primary overall survival endpoint. All patients, including those with disease that exceed this threshold, will be included in a secondary analysis of overall survival as well as analyses of progression-free survival, safety and tolerability, and quality of life. The study design includes interim analyses conducted by an independent Data Safety and Monitoring Board (DSMB) for superiority and futility at 50% and 75% of events (deaths). The first interim analysis occurred in June 2015, and the DSMB recommended continuation of the study as planned. The required number of events to perform the second interim analysis were reached in late 2015, and the analysis will occur in March 2016. Final data from ACT IV are expected by the end of 2016, although our expectations regarding the timing for the final data read out may change based on event rates.

- As previously reported, mature survival data from the Phase 2 ReACT study in patients with recurrent glioblastoma were presented in a podium presentation at the 20th Annual Scientific Meeting of the Society for Neuro-Oncology (SNO) by David A. Reardon, M.D., Clinical Director, Center for Neuro-Oncology, Dana-Farber Cancer Institute and Associate Professor of Medicine, Harvard Medical School, and the lead investigator of the ReACT study. Patients on the RINTEGA arm experienced a statistically significant overall survival (OS) benefit [hazard ratio = 0.53 (0.32, 0.88); p=0.0137], and an impressive, long-term survival benefit was observed. At two years, the survival rate for RINTEGA patients was 25% versus 0% for control patients in the intent to treat (ITT) population, with five patients extending beyond two years. The primary endpoint of the study, progression-free survival at six months (PFS6), was met, and a clear advantage was demonstrated across multiple, clinically important endpoints including long-term progression-free survival, objective response rate (ORR) and need for steroids. 33% of patients on the RINTEGA arm who were receiving steroids at baseline were able to stop steroids for six months or longer compared to none on the control arm.

- As part of an ongoing initiative to expand RINTEGA’s potential product profile, Celldex intends to initiate additional studies of RINTEGA in 2016 including:

    - A study designed to evaluate RINTEGA when administered earlier in the treatment regimen in newly diagnosed glioblastoma. Patients will receive RINTEGA administered after surgery but prior to and concurrently with chemoradiation. In clinical trials conducted to date in the front-line setting, RINTEGA has been administered after surgery but upon completion of chemoradiation. This study is expected to initiate in the second half of 2016.

    - A study designed to evaluate the role alternative immune modifiers could play in combination with RINTEGA. Previous studies of RINTEGA have utilized GM-CSF. This new study will utilize imiquimod. Imiquimod is a topically administered immune response modifier that has broad commercial availability and could potentially serve as a second source of adjuvant if needed, especially outside the United States where GM-CSF is currently available through specialty distribution channels. The study is expected to initiate in March.

***Glembatumumab vedotin ("glemba"; CDX-011), an antibody-drug conjugate targeting gpNMB in multiple cancers***

- Enrollment continues in the Company's Phase 2b randomized study (METRIC) of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress gpNMB, a molecule associated with poor outcomes for triple negative breast cancer patients and the target of glembatumumab vedotin. Enrollment is open across the United States, Canada and Australia. The Company plans to open enrollment in up to 50 sites in the EU beginning in the first quarter of 2016, and enrollment is expected to be completed in the second half of 2016.

- Patient enrollment continues in the Phase 2 study of glembatumumab vedotin in metastatic melanoma and is expected to be completed in the first half of 2016 with data presented at an appropriate medical meeting in the second half of 2016.

- Celldex continues to advance plans to expand the study of glembatumumab vedotin in other cancers in which gpNMB is expressed.
  - A Phase 2 study in squamous cell lung cancer is expected to commence in Q2 2016.
  - Celldex and the National Cancer Institute (NCI) have entered into a Cooperative Research and Development Agreement (CRADA) under which the NCI is sponsoring two studies of glembatumumab vedotin—one in uveal melanoma and one in pediatric osteosarcoma. Both studies are currently open to enrollment.

***Varlilumab ("varli"; CDX-1127), a fully human monoclonal agonist antibody that binds and activates CD27, a critical co-stimulatory molecule in the immune activation cascade***

- The Phase 1/2 study of varlilumab and nivolumab (Opdivo®) in adult patients with multiple solid tumors has completed enrollment to the dose escalation Phase 1 portion of the study. Celldex and Bristol-Myers Squibb have decided to advance this combination into Phase 2. While a maximum tolerated dose was not reached in Phase 1, a 3 mg/kg varlilumab dose has been identified for study in Phase 2. We anticipate the Phase 2 portion of the study will open to enrollment in the second quarter of 2016 and will include cohorts in advanced non-small cell lung cancer, colorectal cancer, ovarian cancer, head and neck squamous cell carcinoma, renal cell carcinoma and glioblastoma. This study is being conducted by Celldex under a clinical trial collaboration with Bristol-Myers Squibb. The companies are sharing development costs.

- The Phase 1/2 study of varlilumab and atezolizumab (anti-PDL1) is currently enrolling patients with multiple solid tumors in the dose escalation Phase 1 portion of the study. The Phase 2 portion of the study will be conducted in renal cell carcinoma. This study is being conducted by Celldex under a clinical trial collaboration with Roche. Roche is providing study drug, and Celldex is responsible for conducting and funding the study.

- Additional combination studies of varlilumab continue to enroll patients including:
  - A Phase 1/2 safety and tolerability study examining the combination of varlilumab and sunitinib (Sutent®) in patients with metastatic clear cell renal cell carcinoma (CC-RCC).
  - A Phase 1/2 safety and tolerability study examining the combination of varlilumab and ipilimumab in patients with Stage III or IV metastatic melanoma. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive Celldex's CDX-1401.

- Celldex presented a preclinical poster on the contribution of varlilumab's immune stimulating properties versus regulatory T cell (Treg) depletion in multiple tumor models in November at the 2015 Society for the Immunotherapy of Cancer (SITC) Annual Meeting. Results suggested that cancers may respond to CD27 immune modulation by independent mechanisms, such as immune co-stimulation and regulatory T cell (Treg) depletion. Varlilumab has the unique ability to act through both of these mechanisms.

***CDX-1401, an antibody-based NY-ESO-1-specific therapeutic vaccine for multiple solid tumors***

- As discussed above, a Phase 1/2 study examining the combination of varlilumab and ipilimumab continues to enroll patients with Stage III or IV metastatic melanoma. In the Phase 2 portion of the study, patients with tumors that express NY-ESO-1 will also receive CDX-1401, an off-the-shelf antibody-based dendritic cell targeted vaccine.

- Celldex continues to support several external collaborations, including an NCI sponsored Phase 2 study of CDX-1401 and CDX-301 for patients with metastatic melanoma, which recently completed enrollment. Based on results to date, plans for additional studies are being considered by NCI. Additionally, Roswell Park Cancer Center is conducting an investigator sponsored study evaluating CDX-1401, poly-ICLC (Hiltonol®) and the IDO1 inhibitor epacadostat (INCB24360) in patients in remission with ovarian, fallopian tube or primary peritoneal cancer. Patients' tumors must have expressed NY-ESO-1 or the LAGE-1 antigen to be eligible for the study. Celldex is providing CDX-1401 and poly-ICLC in support of this study.

***CDX-301 (recombinant human Flt3L), a potent hematopoietic cytokine that uniquely expands dendritic cells and hematopoietic stem cells***

- A pilot study of CDX-301 alone and in combination with plerixafor (Mozobil®) in hematopoietic stem cell transplantation (HSCT) is currently enrolling patients and sibling-matched donors. The Company presented early data from the non-plerixafor treated arm in this study in February at the annual meeting of the American Society for Blood and Marrow Transplantation. Three donor/patient pairs showed that CDX-301 given as a single agent was well tolerated and effective at mobilizing hematopoietic stem cells in healthy donors. The stem cell graft contained notable increases in naïve lymphocytes and plasmacytoid dendritic cells consistent with preclinical data suggesting a possible better outcome. Recipients experienced successful engraftment in an expected time frame. Additional subjects are being accrued to assess the potential synergy of combining CDX-301 with plerixafor in this setting.

- CDX-301's potential activity is also being explored in a Phase 1/2 study of CDX-301 and poly-ICLC in combination with low-dose radiotherapy in patients with low-grade B-cell lymphomas conducted by the Icahn School of Medicine at Mount Sinai.

***Fourth Quarter and Twelve Months 2015 Financial Highlights and 2016 Guidance***

**Cash position:** Cash, cash equivalents and marketable securities as of December 31, 2015 were $289.9 million compared to $304.6 million as of September 30, 2015. The decrease was primarily driven by our fourth quarter cash used in operating activities of approximately $22.9 million, partly offset by the receipt of $9.2 million from the sale of New Jersey tax benefits. As of December 31, 2015 Celldex had 98.7 million shares outstanding.

**Revenues:** Total revenue was $1.8 million in the fourth quarter of 2015 and $5.5 million for the twelve months ended December 31, 2015, compared to $1.5 million and $3.6 million for the comparable periods in 2014. 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 $23.9 million in the fourth quarter of 2015 and $100.2 million for the twelve months ended December 31, 2015, compared to $27.0 million and $104.4 million for the comparable periods in 2014. R&D expenses include stock-based compensation expense of $2.0 million and $6.2 million in the three- and twelve-month periods ended December 31, 2015 compared to $1.1 million and $3.5 million for the comparable periods in 2014.

**G&A Expenses:** General and administrative (G&A) expenses were $11.1 million in the fourth quarter of 2015 and $33.8 million for the twelve months ended December 31, 2015, compared to $6.2 million and $20.6 million for the comparable periods in 2014. The increase in G&A expenses was primarily attributable to higher personnel-related expenses as we prepare for potential commercialization and a $6.5 million increase in RINTEGA and glembatumumab vedotin commercial planning costs in 2015 as compared to 2014. G&A expenses include stock-based compensation expense of $2.1 million and $6.6 million in the three- and twelve-month periods ended December 31, 2015 compared to $1.0 million and $3.4 million for the comparable periods in 2014.

**Net loss:** Net loss was $32.7 million, or ($0.33) per share, for the fourth quarter of 2015 and $127.2 million, or ($1.31) per share, for the twelve months ended December 31, 2015, compared to a net loss of $31.8 million, or ($0.36) per share, and $118.1 million, or ($1.32) per share, for the comparable periods in 2014.

**Financial guidance:** Celldex expects that its cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements through 2017; however, this could be impacted by our clinical data results from the RINTEGA program and their potential impact on our pace of commercial manufacturing and the rate of expansion of our commercial operations.

***Webcast and Conference Call***

Celldex executives will host a conference call at 8:00 a.m. ET today to discuss 2015 financial and business results and to provide an update on key 2016 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 50465153.

A replay of the call will be available approximately two hours after the live call concludes through March 3, 2016. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 50465153. The webcast will also be archived on the Company's website.



**About Celldex Therapeutics, Inc.**

Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline is built from a proprietary portfolio of antibodies and immunomodulators used alone and in strategic combinations to create novel, disease-specific therapies that induce, enhance or suppress the body's immune response. 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, including those related to the Company's strategic focus and the future development and commercialization (by Celldex and others) of RINTEGA® (“rindopepimut”; “rindo”; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab (“varli”; CDX-1127), CDX-1401, CDX-301, CDX-014 and other products and our goals for 2016. 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 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 Rintega, glembatumumab vedotin and other 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 Breakthrough Therapy Designation for RINTEGA, 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,** | |
|---|---|---|---|---|
| | **2015** | **2014** | **2015** | **2014** |
| | **(Unaudited)** | | | |
| **REVENUE** | | | | |
| Product Development and Licensing Agreements | $ 389 | $ 320 | $ 1,442 | $ 838 |
| Contracts and Grants | 1,401 | 1,157 | 4,038 | 2,748 |
| Total Revenue | 1,790 | 1,477 | 5,480 | 3,586 |
| **OPERATING EXPENSE** | | | | |
| Research and Development | 23,900 | 27,026 | 100,171 | 104,381 |
| General and Administrative | 11,075 | 6,249 | 33,837 | 20,622 |
| Amortization of Acquired Intangible Assets | 253 | 253 | 1,013 | 1,013 |
| Total Operating Expense | 35,228 | 33,528 | 135,021 | 126,016 |
| Operating Loss | (33,438) | (32,051) | (129,541) | (122,430) |
| Investment and Other Income, Net | 754 | 230 | 2,344 | 4,350 |
| Interest Expense | - | - | - | - |
| Net Loss | $(32,684) | $ (31,821) | $ (127,197) | $ (118,080) |
| Basic and Diluted Net Loss per Common Share | $ (0.33) | $ (0.36) | $ (1.31) | $ (1.32) |

| | | | | |
|---|---|---|---|---|
| Weighted Average Common Shares Outstanding | 98,633 | 89,559 | 97,051 | 89,399 |

| CONDENSED BALANCE SHEETS | December 31, 2015 | Consolidated December 31, 2014 |
|---|---|---|
| **ASSETS** | | |
| Cash, Cash Equivalents and Marketable Securities | $ 289,889 | $ 201,043 |
| Other Current Assets | 5,047 | 3,942 |
| Property and Equipment, net | 11,461 | 10,535 |
| Intangible and Other Assets, net | 31,187 | 32,494 |
| Total Assets | $ 337,584 | $ 248,014 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current Liabilities | $ 30,240 | $ 24,491 |
| Long-Term Liabilities | 17,239 | 11,863 |
| Stockholders' Equity | 290,105 | 211,660 |
| Total Liabilities and Stockholders' Equity | $ 337,584 | $ 248,014 |

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