

**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) **March 3, 2014**

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**Celldex Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-15006**  
(Commission File Number)

**13-3191702**  
(IRS Employer Identification No.)

**Perryville III Building, 53 Frontage Road, Suite 200**  
**Hampton, New Jersey**  
(Address of principal executive offices)

**08827**  
(Zip Code)

Registrant's telephone number, including area code: **(908) 200-7500**

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(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))
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## **Item 2.02. Results of Operations and Financial Condition.**

On March 3, 2014, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal 2013. 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.

This Current Report on Form 8-K, including exhibit 99.1, 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 rindopepimut (CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab (CDX-1127), CDX-1401, CDX-301 and other products. 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 rindopepimut, 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; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage and successfully complete 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; 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 from time to time in the Company's filings with the Securities and Exchange Commission, including the Company's Form 10-K for the fiscal year ended December 31, 2012, and its Forms 10-Q and 8-K.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautions not to place undue reliance on any forward-looking statements, which speak only as of the date of this Current Report on Form 8-K. 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.

## **Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

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99.1 Press Release of Celldex Therapeutics, Inc., dated March 3, 2014.

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**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.**

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(Registrant)

/s/ **AVERY W. CATLIN**

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**March 3, 2014**

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(Date)

Avery W. Catlin  
*Senior Vice President and  
Chief Financial Officer*

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## Exhibit Index

99.1 Press Release of Celldex Therapeutics, Inc., dated March 3, 2014.

## Celldex Reports Fiscal 2013 Business/Financial Results and Outlines 2014 Strategy

- Management to Host Conference Call Today, Monday, March 3, at 8:30 a.m. Eastern Time -

HAMPTON, N.J., March 3, 2014 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported business and financial highlights for the fourth quarter and year ended December 31, 2013 and outlined the Company's major clinical development goals for 2014.

"This past year was transformational for Celldex as we continued to make strides in cultivating one of the most robust, well-staged pipelines in immuno-oncology," said Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics. "We enter 2014 with five candidates in the clinic, including rindopepimut and glembatumumab vedotin in registration studies. By year-end, we anticipate the initiation of four new Celldex-sponsored clinical trials and several investigator-sponsored studies, including multiple combination regimens. These combination studies are designed to address what we believe is the next great opportunity for the immuno-oncology field—further unlocking the power of the immune system to deliver the greatest benefit to the largest population of patients possible. With last year's successful financing of the Company and current cash projected to fund our planned activities through 2016, we look forward to what we believe will be an exceptionally productive year."

### 2013 Program Updates:

#### ***Rindopepimut ("rindo"; CDX-110) in EGFRvIII(v3)-Positive Glioblastoma (GBM):***

- Celldex continues to actively enroll newly diagnosed patients with GBM in ACT IV, the Phase 3 registration study. More than 200 sites are currently open to enrollment across 24 countries. The Company continues to anticipate completion of enrollment in mid-2014.
- Celldex announced the presentation of four- and five-year survival data from the Phase 2 rindopepimut clinical program in frontline GBM (3 studies; pooled n=105) in November. Survival data suggests a substantial and continuing survival benefit in comparison to a matched historical control dataset, at the median and at all other time points evaluated. Eighteen percent (18%) of patients from the Phase 2 frontline rindopepimut program were alive at four years and 14% were alive at five years. No patients in the matched historical control dataset survived beyond three years.
- In November, positive interim data from the ReACT study in recurrent GBM were presented in an oral session at the Annual Meeting of the Society for Neuro-Oncology. The data demonstrated promising signs of clinical activity in advanced patient populations, including patients both naive and refractory to Avastin<sup>®</sup>. Enrollment in ReACT is expected to be completed in late 2014 with data anticipated by year-end 2014.

#### ***Glembatumumab vedotin ("glemba"; CDX-011) targeting gpNMB in multiple cancers:***

In December, Celldex initiated a randomized, accelerated approval study (METRIC) of glembatumumab vedotin in patients with metastatic triple negative breast cancer that overexpresses the tumor associated marker gpNMB. The METRIC study is expected to include up to 100 sites in the United States, Canada and Australia. The glembatumumab vedotin program will expand into additional indications in 2014 (outlined below).

#### ***Varlilumab ("varli"; CDX-1127) an immune modulating mAb targeting CD27 in solid tumors and hematologic malignancies:***

In November, Celldex presented interim data from the Phase 1 dose-escalation study of varlilumab at the Society for Immunotherapy of Cancer Meeting. The data established an excellent safety profile, clear biologic activity and promising signs of clinical activity in an advanced, refractory patient population, including activation of helper and effector lymphocytes as well as decreasing regulatory T cells (Tregs). The Company also presented preclinical data on combination studies of varlilumab, including with chemotherapy or checkpoint inhibitors. Expansion cohorts have been enrolling in metastatic melanoma and renal cell carcinoma with initial data anticipated in mid-2014. Expansion cohorts are planned in hematologic indications as appropriate. New studies of varlilumab in combination with various agents will be initiated in 2014 (outlined below).

#### ***CDX-1401 an antibody-based dendritic cell targeted vaccine targeting tumors expressing the NY-ESO-1 oncoprotein:***

The Phase 1 study of CDX-1401 was completed in 2013, including longer-term patient follow up. CDX-1401 was well-tolerated and elicited robust antibody and T cell responses in patients with advanced cancer that had progressed after any available curative and/or salvage therapies. Some patients had evidence of clinical benefit with significant stable disease and measurable tumor shrinkage, despite their advanced stage of metastatic disease. Of note, long-term patient follow up suggested that treatment with CDX-1401 may predispose patients to better outcomes on subsequent therapy with checkpoint inhibitors. In particular, of six melanoma patients that went on to receive Yervoy<sup>®</sup> four had significant clinical benefit (1 immune-related partial response, 2 RECIST partial responses, and 1 complete response). In addition, two non-small cell lung cancer patients who received investigational checkpoint blockade within two months of discontinuing CDX-1401 were also reported to experience partial responses. These observations will be explored more fully in clinical studies that Celldex plans to initiate in 2014 (outlined below).

***CDX-301 (Flt3L) a potent hematopoietic cytokine that stimulates the expansion and differentiation of hematopoietic stem cells and dendritic cells:***

In December, positive results were presented from a preclinical combination study of CDX-301 and Mozobil<sup>®</sup> demonstrating that the combination of these agents significantly increased hematopoietic stem cell mobilization and resulted in improved transplantation of mobilized cells at the American Society of Hematology Annual Meeting. Based on these data, Celldex plans to initiate a pilot study of CDX-301 alone and in combination with Mozobil in hematopoietic transplant. In addition, an investigator-sponsored study of intratumoral CDX-301 plus Hiltonol in combination with radiation therapy in patients with advanced, low-grade B-cell lymphoma was also initiated in December. In 2014, Celldex expects CDX-301 to enter combination studies to explore its potential for improving hematopoietic stem cell transplantation and potentiating immune activation (outlined below).

***CDX-1135 targeting C3 activation in Dense Deposit Disease (DDD):***

In July, Celldex initiated a pilot study of CDX-1135 to explore a potential opportunity in treating patients with the ultra-orphan indication, DDD. As previously disclosed, enrollment in the pilot study has been extremely difficult due to the overall rareness of patients with DDD (300-500 in the U.S.) further compounded by the need to enroll patients at a very specific point in their disease course. The study sought to enroll patients—particularly children—with enough kidney deterioration to be able to demonstrate clinical benefit/improvement but not so much disease burden that the kidneys were beyond salvaging. While Celldex has been tracking a number of patients for potential enrollment, some patients progressed too quickly and others never progressed at all. To date, only one patient has been enrolled. While this patient demonstrated initial evidence of clinical improvement, the effect was not sustained. The results from this one patient combined with our experience using this agent in the compassionate use setting have not provided the conclusive results necessary for a feasible approval path in this disease. Due to these challenges, Celldex has decided to close the study in DDD and focus resources on our growing immuno-oncology pipeline at this time.

***2014 Clinical Development Goals:***

***Rindopepimut:***

- Complete accrual of ACT IV, the Phase 3 registration study for patients with frontline GBM
- Complete accrual of ReACT, the Phase 2 study for patients with recurrent GBM (both Group 1 and 2C); report data in late 2014

***Glembatumumab vedotin:***

- Continue accrual of METRIC, the accelerated approval study for patients with triple negative breast cancer
- Initiate a Phase 2 study for patients with metastatic melanoma
- Initiate a Phase 2 study for patients with squamous cell lung cancer

***Varlilumab:***

- Complete the Phase 1 solid tumor expansion cohorts and hematologic dose-escalation cohorts; data anticipated in mid-2014. Initiate expansion cohorts in lymphocytic malignancies as appropriate
- Initiate a Phase 1/2 study of varlilumab and Yervoy (and potentially other checkpoint inhibitors) plus CDX-1401 in NY-ESO+ patients with metastatic melanoma
- Initiate a Phase 1/2 study of varlilumab plus Tafinlar<sup>®</sup> and Mekinist<sup>™</sup> (followed sequentially by a checkpoint inhibitor) for patients with B-raf mutated metastatic melanoma

***CDX-1401:***

- Support a Phase 2 study of CDX-1401 and CDX-301 for patients with metastatic melanoma (NCI sponsored)

***CDX-301:***

- Initiate a pilot study of CDX-301 alone and in combination with Mozobil in hematopoietic stem cell transplantation
- Support a Phase 1/2 study of intratumoral injection of CDX-301 and Hiltonol<sup>®</sup> in combination with low-dose radiotherapy for patients with low-grade B-cell lymphomas (investigator sponsored)

***Fourth Quarter and Year-to-Date 2013 Financial Highlights and 2014 Guidance***

Cash position: Cash, cash equivalents and marketable securities as of December 31, 2013 were \$303.0 million compared to \$136.6 million as of September 30, 2013. The increase was primarily driven by net proceeds to Celldex of \$181.5 million from an underwritten financing and net proceeds from the exercise of stock options of \$2.5 million; partially offset by \$2.1 million spent on leasehold improvements to our new headquarters facility in Hampton, New Jersey and our fourth quarter net cash burn of \$15.5 million. As of December 31, 2013, Celldex had 89.2 million shares outstanding.

Revenues: Total revenue was \$0.6 million in the fourth quarter of 2013 and \$4.1 million for the twelve months ended December 31, 2013, compared to \$3.6 million and \$11.2 million for the comparable periods in 2012. The decrease in revenue was primarily due to the decrease in Rotarix<sup>®</sup> royalty revenue with a corresponding reduction in royalty expense.

**R&D Expenses:** Research and development (R&D) expenses were \$17.8 million in the fourth quarter of 2013 and \$67.4 million for the twelve months ended December 31, 2013, compared to \$13.7 million and \$47.4 million for the comparable periods in 2012. The increase in Celldex's R&D investment was primarily due to the continued progression of our late-stage rindopepimut clinical development program as well as the planning and initiation of the glebatumumab vedotin METRIC study and the expansion of the varlilumab study.

**G&A Expenses:** General and administrative (G&A) expenses were \$4.7 million in the fourth quarter of 2013 and \$14.8 million for the twelve months ended December 31, 2013 compared to \$2.6 million and \$10.0 million for the comparable periods in 2012. The increase in G&A expenses was primarily attributable to higher personnel-related expenses, professional services and rindopepimut-related commercial planning costs in 2013.

**Net loss:** Net loss was \$22.1 million, or (\$0.27) per share, for the fourth quarter of 2013 and \$81.6 million, or (\$1.02) per share, for the twelve months ended December 31, 2013, compared to net loss of \$16.8 million, or (\$0.27) per share, and \$59.1 million, or (\$1.02) per share, for the comparable periods in 2012.

**Financial guidance:** Celldex expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through 2016.

### ***Webcast and Conference Call***

Celldex will host a conference call and live webcast at 8:30 a.m. ET on Monday, March 3, 2014, to discuss Celldex's fourth quarter and twelve month 2013 financial results and to provide an update on anticipated research and development and business objectives for 2014. The conference call and presentation will be webcast live over the Internet and can be accessed by logging on to the Events Calendar under the "News & Events" section of the Celldex Therapeutics website at [www.celldextherapeutics.com](http://www.celldextherapeutics.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 39634623.

A replay of the call will be available approximately two hours after the live call concludes through March 10, 2014. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 39634623. The webcast will also be archived on the Company's website.

*Avastin<sup>®</sup> is a registered trademark of Genentech; Yervoy<sup>®</sup> is a registered trademark of Bristol-Myers Squibb; Tafinlar<sup>®</sup>, Mekinist<sup>™</sup> and Rotarix<sup>®</sup> are registered trademarks of GlaxoSmithKline; Mozobil<sup>®</sup> is a registered trademark of Genzyme Corporation; Hiltonol<sup>®</sup> is a registered trademark of Oncovir.*

### **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](http://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 rindopepimut (CDX-110), glebatumumab vedotin ("glemba"; CDX-011), varlilumab (CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2014. 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 rindopepimut, glebatumumab 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; 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.

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.

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

<b>CONSOLIDATED STATEMENTS OF OPERATIONS DATA</b>	<b>Quarter Ended</b>		<b>Year Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
	<b>(Unaudited)</b>			
<b>REVENUE</b>				
Product Development and Licensing Agreements	\$ 43	\$ 43	\$ 160	\$ 146
Contracts and Grants	577	53	1,617	281
Product Royalties	--	3,551	2,334	10,775
<b>Total Revenue</b>	<b>620</b>	<b>3,647</b>	<b>4,111</b>	<b>11,202</b>
<b>OPERATING EXPENSE</b>				
Research and Development	17,804	13,748	67,401	47,398
Royalty	--	3,551	2,334	10,775
General and Administrative	4,677	2,644	14,805	10,016
Amortization of Acquired Intangible Assets	253	254	1,013	1,090
<b>Total Operating Expense</b>	<b>22,734</b>	<b>20,197</b>	<b>85,553</b>	<b>69,279</b>
Operating Loss	(22,114)	(16,550)	(81,442)	(58,077)
Investment and Other Income, Net	137	94	819	530
Interest Expense	(85)	(351)	(927)	(1,576)
<b>Net Loss</b>	<b>\$ (22,062)</b>	<b>\$ (16,807)</b>	<b>\$ (81,550)</b>	<b>\$ (59,123)</b>
<b>Basic and Diluted Net Loss per Common Share</b>	<b>\$ (0.27)</b>	<b>\$ (0.27)</b>	<b>\$ (1.02)</b>	<b>\$ (1.02)</b>
<b>Weighted Average Common Shares Outstanding</b>	<b>83,042</b>	<b>62,544</b>	<b>79,777</b>	<b>57,713</b>

**CONDENSED CONSOLIDATED**

<b>BALANCE SHEETS</b>	<b>December 31,</b>	<b>December 31,</b>
	<b>2013</b>	<b>2012</b>
<b>ASSETS</b>		
Cash, Cash Equivalents and Marketable Securities	\$ 302,983	\$ 83,962
Other Current Assets	2,206	1,152
Property and Equipment, net	9,973	7,205
Intangible and Other Assets, net	31,933	33,222
<b>Total Assets</b>	<b>\$ 347,095</b>	<b>\$ 125,541</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities	\$ 20,350	\$ 17,685
Long-Term Liabilities	6,950	12,082
Stockholders' Equity	319,795	95,774
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 347,095</b>	<b>\$ 125,541</b>

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