

**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): **August 10, 2015**

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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 August 10, 2015, Celldex Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the second quarter of 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 August 10, 2015.

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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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**August 10, 2015**

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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 August 10, 2015.

## Celldex Reports Second Quarter 2015 Results

Conference Call Scheduled for Monday, August 10 at 4:30 p.m. Eastern Time

HAMPTON, N.J., Aug. 10, 2015 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the second quarter ended June 30, 2015.

"Celldex is acutely aware of the significant unmet need for patients with glioblastoma, and we continue to focus considerable efforts on advancing the RINTEGA® program," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "At ASCO in June, we presented data from the Phase 2 ReACT study, which achieved the primary endpoint of progression-free survival at six months and, most importantly, demonstrated a survival benefit for patients on the RINTEGA arm. We continue to follow these patients and look forward to presenting data on the emerging long-term survival benefit later this year. The Phase 3 ACT IV study continues to progress as planned, and we look forward to the second interim analysis in late 2015/early 2016."

"Our momentum is further supported by ongoing progress in our pipeline. Varlilumab is now in four combination studies, and we anticipate that a fifth study with Roche's anti-PDL1 antibody will start later this year. We look forward to presenting data from a number of these studies in 2016 and believe these data will define an important role for varlilumab in cancer immunotherapy treatment. Glembatumumab vedotin also continues to actively enroll patients in two trials—the METRIC study in triple negative breast cancer and a study in metastatic melanoma. We are completing preparations that support the opening of METRIC study sites in the EU early next year and remain on track to complete enrollment in 2016. As we continue to advance Celldex towards becoming a fully integrated, commercial-stage biotechnology company, we were pleased to announce the promotion of Dr. Rick Wright to the position of Chief Commercial Officer. In this role, Rick will be responsible for developing a global business strategy and building the infrastructure required to support commercialization of RINTEGA and our cancer immunotherapy pipeline," concluded Marucci.

### Program Updates:

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

- In June, the independent Data Safety and Monitoring Board (DSMB) recommended continuation of the Phase 3 ACT IV study of RINTEGA® (rindopepimut) in patients with newly diagnosed glioblastoma as a result of a prespecified interim analysis assessing safety, futility and efficacy at 50% of events (deaths). 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 second interim analysis is expected to occur in late 2015/early 2016.
- Data from the Phase 2 ReACT study in patients with recurrent glioblastoma were presented in an oral session at the 2015 ASCO Annual Meeting 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, and an impressive long-term survival benefit is emerging. 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. The Company anticipates that mature overall survival and long-term survival will be presented by year-end at an upcoming medical meeting.
- Based on discussions to date with the regulatory authorities about the Phase 2 REACT data, the Company continues to believe the most likely scenario for potential RINTEGA approval filings will be upon receiving data from the ACT IV study, at which time the Company expects that it would file for full approval in both the front-line and recurrent setting. Under the RINTEGA program's recently awarded Breakthrough Therapy Designation, the Company is actively engaged with the Center for Biologics Evaluation and Research (CBER) to complete all of the required activities associated with the ability to apply for licensure and considerable progress is being made, particularly in the areas of chemistry manufacturing and controls (CMC) and companion diagnostics readiness. The Company will continue to take all the necessary steps to prepare for filing so this process can be completed as expeditiously as possible when ACT IV data become available.

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

- Patient enrollment has accelerated 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. Approximately 100 sites are open to enrollment across the United States, Canada and Australia. Trial expansion into the European Union (EU) is underway, and the Company plans to open enrollment in up to 50 sites in the EU in early 2016. Based on current projections, enrollment will be completed in the second half of 2016.
- Patient enrollment continues in the Phase 2 study of glembatumumab vedotin in metastatic melanoma. To date, 10 sites are open to enrollment in the United States.

- Celldex continues to advance plans to expand the study of glembatumumab vedotin in other cancers in which gpNMB is expressed.
  - Study design is being finalized for a Phase 2 study in squamous cell lung cancer, and the study is expected to commence in 2H 2015.
  - Celldex and the National Cancer Institute have entered into a Cooperative Research and Development Agreement (CRADA) under which the NCI will sponsor two studies of glembatumumab vedotin—one in uveal melanoma and one in pediatric osteosarcoma. Protocols for the study are currently being developed.

***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 advanced non-small cell lung cancer, metastatic melanoma, colorectal cancer, ovarian cancer, and head and neck squamous cell carcinoma is actively enrolling patients. This study is being conducted by Celldex under a clinical trial collaboration with Bristol-Myers Squibb Company. The companies are sharing development costs.
- In April 2015, Celldex announced that it had entered into a clinical trial collaboration with Roche to evaluate the combination of varlilumab and atezolizumab (anti-PDL1) in a Phase 1/2 study in renal cell carcinoma. Under the terms of this agreement, Roche will provide study drug, and Celldex will be responsible for conducting and funding the study, which is expected to open to enrollment in 2H 2015.
- In the second quarter, the Company announced the initiation of two combination studies of varlilumab, both of which are now enrolling patients. Efforts are underway for additional Phase 2 studies of varlilumab, and the Company will provide updates on these studies as they are initiated. Newly initiated studies in the second quarter include:
  - 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); and,
  - A Phase 1/2 safety and tolerability study examining the combination of varlilumab and ipilimumab (Yervoy®) 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 preclinical data that support varlilumab's expansion into combination studies with PD-1 inhibitors in a poster session at the 2015 AACR Annual Meeting in April. Data demonstrated that the combination of varlilumab and anti-PDL1 induces a potent immune-mediated effect that results in important changes in the tumor microenvironment. Most notably, the combination strategy improved the ratio of effector T cells to regulatory T cells, which was accompanied by a reduction in the expression of PD-1 on both effector and regulatory T cells.
- The Phase 1b study of varlilumab and ONT-10, Oncothyreon's therapeutic vaccine targeting the tumor-associated antigen MUC1, continues to actively enroll patients with advanced breast or ovarian cancer. Celldex is providing study drug, and Oncothyreon is conducting the study.

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

- In the second quarter, Celldex announced the initiation of a Phase 1/2 study examining the combination of varlilumab and ipilimumab (Yervoy®) in patients with Stage III or IV metastatic melanoma. This study is currently open to enrollment. 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 a National Cancer Institute sponsored Phase 2 study of CDX-1401 and CDX-301 for patients with metastatic melanoma, which is open to enrollment.

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

- CDX-301 is being developed as a combination product with other immuno-oncology agents in a number of investigator-sponsored studies.
- A pilot study of CDX-301 alone and in combination with Mozobil® in hematopoietic stem cell transplantation was initiated in September 2014 and is currently enrolling patients and sibling-matched donors.

***Second Quarter and First Six Months 2015 Financial Highlights and 2015 Guidance***

**Cash position:** Cash, cash equivalents and marketable securities as of June 30, 2015 were \$334.0 million compared to \$359.8 million as of March 31, 2015. The decrease was primarily driven by our second quarter net cash burn of \$25.8 million. As of June 30, 2015 Celldex had 98.5 million shares outstanding.

**Revenues:** Total revenue was \$2.2 million in the second quarter of 2015 and \$2.7 million for the six months ended June 30, 2015, compared to \$0.6 million and \$1.0 million for the comparable periods in 2014. The increase in the second quarter of 2015 and the six months ended June 30, 2015 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 \$26.5 million in the second quarter of 2015 and \$51.6 million for the six months ended June 30, 2015, compared to \$24.1 million and \$51.2 million for the comparable periods in 2014.

**G&A Expenses:** General and administrative (G&A) expenses were \$8.2 million in the second quarter of 2015 and \$14.3 million for the six months ended June 30, 2015, compared to \$4.8 million and \$9.4 million for the comparable periods in 2014. The

increase in G&A expenses was primarily attributable to higher commercial personnel-related expenses as we prepare for potential product launch and a \$2.2 million increase year to date in RINTEGA and glembatumumab vedotin commercial planning costs over the \$1.9 million spent in the comparable period in 2014.

**Net loss:** Net loss was \$32.4 million, or (\$0.33) per share, for the second quarter of 2015 and \$62.5 million, or (\$0.65) per share, for the six months ended June 30, 2015, compared to a net loss of \$28.3 million, or (\$0.32) per share and \$58.2 million, or (\$0.65) 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.

*RINTEGA® is a registered trademark of Celldex Therapeutics. Opdivo® and Yervoy® are registered trademarks of Bristol-Myers Squibb. Sutent® is a registered trademark of Pfizer. Mozobil® is a registered trademark of sanofi-aventis U.S. LLC.*

## **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 2015 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](http://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 4299662.

A replay of the call will be available approximately two hours after the live call concludes through August 16, 2015. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 4299662. 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](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 RINTEGA® ("rindopepimut"; "rindo"; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2015. 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.

**CELLEX THERAPEUTICS, INC.**

(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Quarter		Six Months	
	Ended June 30,		Ended June 30,	
	2015	2014	2015	2014
	(Unaudited)		(Unaudited)	
<b>REVENUE</b>				
Product Development and Licensing Agreements	\$ 334	\$ 200	\$ 676	\$ 235
Contracts and Grants	1,844	392	1,988	773
<b>Total Revenue</b>	<b>2,178</b>	<b>592</b>	<b>2,664</b>	<b>1,008</b>
<b>OPERATING EXPENSE</b>				
Research and Development	26,490	24,100	51,615	51,169
General and Administrative	8,184	4,787	14,273	9,369
Amortization of Acquired Intangible Assets	254	254	507	507
<b>Total Operating Expense</b>	<b>34,928</b>	<b>29,141</b>	<b>66,395</b>	<b>61,045</b>
Operating Loss	(32,750)	(28,549)	(63,731)	(60,037)
Investment and Other Income, Net	391	275	1,198	1,860
<b>Net Loss</b>	<b>\$ (32,359)</b>	<b>\$ (28,274)</b>	<b>\$ (62,533)</b>	<b>\$ (58,177)</b>
Basic and Diluted Net Loss per Common Share	\$ (0.33)	\$ (0.32)	\$ (0.65)	\$ (0.65)
Weighted Average Common Shares Outstanding	98,482	89,361	95,477	89,316

#### CONDENSED CONSOLIDATED

BALANCE SHEETS	June 30,	December 31,
	2015	2014
	(Unaudited)	
<b>ASSETS</b>		
Cash, Cash Equivalents and Marketable Securities	\$ 333,992	\$ 201,043
Other Current Assets	5,549	3,942
Property and Equipment, net	11,735	10,535
Intangible and Other Assets, net	31,941	32,494
<b>Total Assets</b>	<b>\$ 383,217</b>	<b>\$ 248,014</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities	\$ 26,691	\$ 24,491
Long-Term Liabilities	10,648	11,863
Stockholders' Equity	345,878	211,660
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 383,217</b>	<b>\$ 248,014</b>

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