#### 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): August 10, 2012

#### CELLDEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

0-15006

(Commission File Number)

13-3191702

(IRS Employer Identification No.)

## 119 Fourth Avenue Needham, Massachusetts 02494-2725

(Address of principal executive offices) (Zip Code)

#### (781) 433-0771

(Registrant's telephone number, including area code)

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 August 10, 2012, Celldex Therapeutics, Inc. issued a press release announcing its financial results for the second quarter of 2012. 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, 2012.

[Remainder of page left blank intentionally]

# SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be filed on its behalf by the undersigned hereunto duly authorized.

Celldex Therapeutics, Inc.

Dated: August 10, 2012 By: /s/ Avery W. Catlin

Avery W. Catlin

Senior Vice President and Chief Financial Officer 99.1 Press Release of Celldex Therapeutics, Inc., dated August 10, 2012.

# **Celldex Reports Second Quarter 2012 Financial Results**

#### - Management to Host Conference Call Today at 8:30 AM Eastern Time -

NEEDHAM, Mass.--(BUSINESS WIRE)--August 10, 2012--Celldex Therapeutics, Inc. (NASDAQ: CLDX) today reported financial results for the second quarter ended June 30, 2012. Celldex reported a net loss of \$13.8 million, or \$0.23 per share, for the second quarter of 2012 compared to a net loss of \$10.2 million, or \$0.27 per share, for the second quarter of 2011. For the six months ended June 30, 2012, Celldex reported a net loss of \$27.3 million, or \$0.50 per share, compared to a net loss of \$20.3 million, or \$0.58 per share, for the six months ended June 30, 2011.

Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics commented, "In the second quarter, Celldex has rapidly opened clinical sites for the Phase 3 ACT IV study and the Phase 2 ReACT study of rindopepimut in glioblastoma (GB). Celldex also reported positive topline data from our Phase 2b EMERGE study of CDX-011 in patients with metastatic breast cancer. The results were consistent with previous studies and suggest that CDX-011 has considerable potential, particularly in key patient populations with more difficult to treat disease, including patients with high GPNMB expression levels and patients with triple negative breast cancer. Together these patients account for more than 35% of the total breast cancer population. We believe CDX-011 could play a vital role as a much needed treatment option for these patients and look forward to updating results from the EMERGE study in the fourth quarter."

At June 30, 2012, Celldex reported cash, cash equivalents and marketable securities of \$78.7 million, which the Company believes will be sufficient to meet estimated working capital requirements and fund planned program development into 2014. The decrease of \$13.5 million from March 31, 2012 is due primarily to planned, increased operational expenses during the quarter related to ongoing studies of rindopepimut (CDX-110), including the pivotal ACT IV study in patients with newly diagnosed EGFRvIII-positive GB and the Phase 2 ReACT study in patients with recurrent EGFRvIII-positive GB.

#### **Second Quarter and Recent Highlights**

- Celldex presented positive, topline results from the CDX-011 EMERGE study on May 23, 2012. CDX-011 is a first-in-class, next generation antibody drug conjugate that targets a Celldex proprietary target, glycoprotein NMB (GPNMB). GPNMB is believed to promote breast cancer metastases and its expression is generally associated with a poor prognosis. Preliminary results from the EMERGE study suggest that CDX-011 induces impressive response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with high GPNMB expression (expression in ≥25% of tumor cells) and in patients with triple negative breast cancer.
  - In the high GPNMB expressing patient population (n=25), treatment with CDX-011 resulted in a 32% overall response rate (ORR; includes confirmed and unconfirmed responses), whereas treatment with Investigator's Choice (IC) single-agent chemotherapy (n=8) resulted in a 13% ORR.
  - CDX-011 also demonstrated strong response rates in patients with triple negative breast cancer across all levels of GPNMB expression [CDX-011 ORR of 21% (n=24); IC ORR of 0% (n=9)], where treatment options are extremely limited. In addition, in patients with triple negative breast cancer who also highly express GPNMB, greater activity was observed [CDX-011 ORR of 36% (n=11); IC ORR of 0% (n=3)].
  - In patients with high GPNMB in the CDX-011 arm, a trend of improvement in progression-free survival (PFS) was observed.
  - In patients with both triple negative breast cancer and high GPNMB expression, a statistically significant PFS benefit was observed (p=0.0032).
  - Study data continue to mature and patients continue to be followed. The Company anticipates updating results in the fourth quarter of 2012.
- Celldex continued a major initiative to open clinical sites to support enrollment in the Phase 3 ACT IV study and the Phase 2 ReACT study of rindopepimut in glioblastoma. In total, there are now more than 150 clinical sites around the world that have been selected to participate in the ACT IV study and, to date, 78 of these sites are actively screening patients. The ReACT study is also well positioned, with 25 study sites selected to participate and 17 actively screening to date.
- Celldex was added to the NASDAQ Biotechnology Index® (NBI), effective prior to market open on Monday, May 21, 2012. The NBI includes biotechnology or pharmaceutical companies listed exclusively on the NASDAQ Global Select Market or on the NASDAQ Global Market that meet predetermined eligibility requirements, including a minimum market capitalization of \$200 million and an average daily trading volume of at least 100,000 shares, amongst other criteria.

#### **Anticipated Milestones**

#### Celldex expects to:

- Initiate a Phase 2 pilot study of CDX-1135 (formerly TP10) in dense deposit disease (DDD), an orphan kidney disease in children and young adults, in the second half of 2012. DDD is caused by uncontrolled activation of the alternative pathway of complement. The complement activation leads to progressive kidney damage and failure. CDX-1135 has been shown to inhibit the complement cascade at both the C3 and C5 levels and has shown clear biologic activity in DDD animal models and in earlier human clinical trials. Celldex believes CDX-1135 could have therapeutic applications in DDD and other complement mediated diseases. The study will determine the appropriate dose and regimen for further clinical development of CDX-1135 based on safety, tolerability, biological and therapeutic activity.
- Present results from Phase 1 study of CDX-1401 in solid tumors in the fourth quarter of 2012.
- Present updated overall survival data from the rindopepimut Phase 2 ACT III study in the fourth quarter of 2012.
- Present more mature data from the EMERGE Phase 2b study in the fourth quarter of 2012.
- Complete Phase 1 accrual of the CDX-301 healthy volunteer study in the fourth quarter of 2012. Celldex plans to develop CDX-301 for hematopoietic stem cell transplant.
- Complete Phase 1 accrual of the solid tumor arm of the CDX-1127 study in the fourth quarter of 2012.

### **Financial Highlights**

Second Quarter Results

The net loss of \$13.8 million for the second quarter of 2012 represents an increase of \$3.5 million when compared to the net loss for the same period in 2011, primarily due to increases in research and development (R&D) expenses, partially offset by decreases in amortization expense.

Revenues for the second quarter of 2012 increased when compared to revenues in 2011, primarily because of contracts and grants revenue received related to an APC-based HIV vaccine being funded through a Small Business Innovation Research (SBIR) grant in collaboration with The Rockefeller University.

R&D expenses in the second quarter of 2012 and 2011 were \$11.1 million and \$7.2 million, respectively, an increase of \$3.9 million between years. The increase in R&D expenses between 2012 and 2011 primarily reflect higher costs related to the ACT IV and ReACT rindopepimut clinical trials in 2012, offset by lower contracted research and contract manufacturing expenses.

General and administrative (G&A) expense in the second quarters of 2012 and 2011 was approximately \$2.2 million. G&A expense in 2012 included higher consulting expense, offset by lower insurance costs compared to 2011.

#### Six Month Results

The net loss of \$27.3 million for the first six months of 2012 represents an increased loss of \$7.0 million when compared to the net loss of \$20.3 million for the same period in 2011. The increased loss resulted from higher R&D expenses primarily for clinical trial costs, partially offset by lower amortization expenses in 2012.

Revenues for the first six months of 2012 and 2011 were relatively consistent during both periods. Lower product royalty revenue was offset by contracts and grants revenue in 2012.

R&D expense for the first six months of 2012 was \$21.9 million, an increase of \$7.9 million compared to \$14.0 million in 2011. Increases in costs were primarily related to the ACT IV and ReACT rindopepimut clinical trials in 2012, offset in part by decreases in laboratory supplies and services and contracted research.

G&A expense was \$4.5 million and \$4.6 million in the first six months of 2012 and 2011, respectively. Lower insurance and professional services costs were offset in part by higher consulting and investor relations expenses in 2012 compared to 2011.

The \$0.4 million decrease in amortization expense for the six months ended June 30, 2012 was primarily due to certain intangible assets becoming fully amortized during 2011.

As of June 30, 2012, Celldex had approximately 58.8 million shares outstanding.

# Webcast and Conference Call

Celldex will host a conference call and live webcast at 8:30 a.m. ET on Friday, August 10, 2012, to provide an update on anticipated research and development and business objectives for the remainder of 2012. The conference call 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 <a href="https://www.celldextherapeutics.com">www.celldextherapeutics.com</a>. The call can also be accessed by dialing 800-510-0178 (within the United States) or 617-614-3450 (outside the United States). The passcode for participants is 67901994. A replay of the call will be available approximately two hours after the live call concludes through August 24, 2012. To access the replay, dial 888-286-8010 (within the United States) or 617-801-6888 (outside the United States). The passcode is 83435012. The webcast will also be archived on the Company's website.

#### **About Celldex Therapeutics, Inc.**

Celldex Therapeutics is the first antibody-based combination immunotherapy company. Celldex has a pipeline of drug candidates in development for the treatment of cancer and other difficult-to-treat diseases based on its antibody focused Precision Targeted Immunotherapy (PTI) Platform. The PTI Platform is a complementary portfolio of monoclonal antibodies, antibody-targeted vaccines and immunomodulators used in optimal combinations to create novel disease-specific drug candidates. For more information, please visit www.celldextherapeutics.com.

Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: 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), CDX-011, CDX-1135, CDX-1401, CDX-1127, CDX-301, Belinostat 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 limited cash reserves and our ability to obtain additional capital 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; our ability to adapt APC Targeting Technology<sup>TM</sup> to develop new, safe and effective vaccines against oncology and infectious disease indications; our ability to successfully complete product research and further development of our programs; the uncertainties inherent in clinical testing; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage research and development efforts for multiple products at varying stages of development; 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.

# CELLDEX THERAPEUTICS, INC. (In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA		Quarter Ended June 30,				Six Months Ended June 30,			
		2012		2011		2012		2011	
		(Unaudited)				(Unaudited)			
REVENUE									
Product Development and	_				_		_		
Licensing Agreements	\$	40	\$	11	\$	75	\$	25	
Contracts and Grants		96		-		149		-	
Product Royalties		1,873		1,941		4,218		4,443	
Total Revenue		2,009		1,952		4,442		4,468	
OPERATING EXPENSE									
Research and Development		11,114		7,169		21,881		14,021	
Royalty		1,873		1,941		4,218		4,443	
General and Administrative		2,219		2,240		4,536		4,576	
Amortization of Acquired Intangible Assets		291		483		583		966	
Total Operating Expense		15,497		11,833		31,218		24,006	
Operating Loss		(13,488)		(9,881)		(26,776)		(19,538)	
Investment and Other Income, Net		126		79		331		163	
Interest Expense		(411)		(434)		(844)		(920)	
Net Loss	\$	(13,773)	\$	(10,236)	\$	(27,289)	\$	(20,295)	
Basic and Diluted Net Loss per									
Common Share	\$	(0.23)	\$	(0.27)	\$	(0.50)	\$	(0.58)	
Weighted Average Common		• •				` `		`	
Shares Outstanding		58,733		37,463		54,439		34,770	

CONDENSED CONSOLIDATED

BALANCE SHEETS		June 30,		
	J)	2012 Jnaudited)	2011	
ASSETS				
Cash, Cash Equivalents and Marketable Securities	\$	78,672	\$	53,312
Other Current Assets		1,726		1,372
Property and Equipment, net		7,998		9,093
Intangible and Other Assets, net		33,733		34,217
Total Assets	\$	122,129	\$	97,994
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities	\$	12,579	\$	14,298
Long-Term Liabilities		15,002		14,974
Stockholders' Equity		94,548		68,722
Total Liabilities and Stockholders' Equity	\$	122,129	\$	97,994

# CONTACT:

Celldex Therapeutics, Inc. Sarah Cavanaugh, 781-433-3161 Vice President of IR & Corp Comm scavanaugh@celldextherapeutics.com or

Avery W. Catlin, 781-433-0771 Chief Financial Officer

 $\underline{IR@cell dextherapeutics.com}$ 

For Media:

or

**BMC** Communications

Brad Miles, 646-513-3125

bmiles@bmccommunications.com