# 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): November 2, 2011

#### 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

(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 November 2, 2011, Celldex Therapeutics, Inc. issued a press release announcing its financial results for the third quarter of 2011. 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 November 2, 2011.

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# 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: November 2, 2011 By: /s/ Avery W. Catlin

Avery W. Catlin Senior Vice President and Chief Financial Officer 99.1 Press Release of Celldex Therapeutics, Inc., dated November 2, 2011.

### **Celldex Reports Third Quarter 2011 Financial Results**

- Company Preparing for Initiation of Rindopepimut Pivotal Phase 3 Study by Year-End -

NEEDHAM, Mass.--(BUSINESS WIRE)--November 2, 2011--Celldex Therapeutics, Inc. (NASDAQ: CLDX) today reported financial results for the third quarter and nine months ended September 30, 2011. Celldex reported a net loss of \$11.8 million, or \$0.27 per share, for the third quarter of 2011 compared to a net loss of \$9.1 million, or \$0.28 per share, for the third quarter of 2010. For the nine months ended September 30, 2011, Celldex reported a net loss of \$32.1 million, or \$0.85 per share, compared to a net loss of \$25.2 million, or \$0.79 per share, for the nine months ended September 30, 2010.

"After discussions with FDA and EMA, we are on track to initiate our Phase 3 study of rindopepimut in EGFRvIII-expressing glioblastoma in December," said Anthony S. Marucci, President and Chief Executive Officer of Celldex. "The initiation of the pivotal rindopepimut program will be a major accomplishment for Celldex and our shareholders, while most importantly moving this promising candidate one step closer towards potential registration for the patients who suffer from this fatal disease. We will also initiate an additional Phase 2 clinical study of rindopepimut in combination with Avastin<sup>®</sup> by year end."

"Further, we will set the stage for a series of additional significant events in other programs. First, we will complete enrollment in our Phase 2b study of CDX-011 in breast cancer by the end of this year, which should drive data availability in this important indication in mid-2012. We will also begin a Phase 1 study of CDX-1127 in patients with solid tumors and hematological cancers and a Phase 1 study of CDX-301, an immune and stem cell growth factor, in healthy subjects," concluded Marucci.

#### **Recent Highlights and Upcoming Milestone Events:**

• Concluded study design discussions with FDA and EMA and finalized the clinical protocol for the ACT IV Phase 3 randomized, KLH-controlled, double-blind study of rindopepimut.

- Continued brisk enrollment of the 120 patient, randomized Phase 2b study of CDX-011 in patients with glycoprotein NMB (GPNMB)-expressing advanced, refractory breast cancer, including triple negative disease. This study is on track to fully accrue by year-end 2011.
- Announced orphan drug designation in the European Union for rindopepimut which provides 10 years of market exclusivity from product launch in the EU, fee reductions, as well as access to the central authorization procedure. The EMA's Orphan Medicinal Product Designation is designed to promote the development of drugs that may provide significant benefit to patients suffering from rare, life-threatening diseases. The Company previously was awarded orphan drug status in the U.S. which provides 7 years of market exclusivity from product launch in the U.S. as well as Fast Track designation.
- The Company expects to present final median overall survival data from the rindopepimut Phase 2 multi-center ACT III study at the Annual Meeting of the Society for Neuro-Oncology to be held November 17-20, 2011 in Orange County, CA.
- Celldex expects to initiate four new clinical trials by year-end 2011:
  - Phase 3 randomized, KLH-controlled, double-blind study of rindopepimut in patients with newly-diagnosed, gross total resected glioblastoma (GB) that express EGFRvIII. The primary endpoint of the study will be overall survival. The ACT IV study is expected to enroll up to 374 patients at over 150 clinical sites internationally.
  - Phase 2 randomized study of rindopepimut in combination with Avastin in recurrent or refractory glioblastoma patients (the ReACT study). The ReACT study is expected to enroll up to 95 patients in the U.S. and will evaluate objective response rates (ORR), progression free survival (PFS) and overall survival (OS) endpoints in this patient population.
  - Phase 1 study of CDX-1127, Celldex's first therapeutic antibody program, in patients with solid tumors or hematologic cancers. CDX-1127 is a fully human monoclonal antibody targeting CD27.
  - Phase 1 trial of CDX-301, an immune and stem cell growth factor, in healthy subjects in collaboration with Rockefeller University. Celldex's first priority is to develop this molecule for hematopoietic stem cell transplant, where it has demonstrated improvement of immune cell reconstitution in preclinical *in vivo* models.

#### Third Quarter and Year-to-Date Financial Highlights:

Revenues for the third quarter of 2011 were relatively consistent with revenues for the third quarter of 2010 as increased product royalty revenue related to Rotarix® in 2011 was offset by \$1.3 million in Pfizer non-cash deferred revenue related to rindopepimut recognized in 2010. Revenues for the first nine months of 2011 decreased by \$2.2 million when compared to the first nine months of 2010 due primarily to \$3.9 million in Pfizer non-cash deferred revenue related to rindopepimut recognized in 2010, offset in part by increased product royalty revenue of \$2.0 million recorded in 2011. Celldex's retained interests in Rotarix® net royalties, which were not sold to Paul Royalty Fund, are recorded as product royalty revenue and a corresponding amount that is payable to Cincinnati Children's Hospital (CCH) is recorded as royalty expense.

Total operating expenses for the third quarter were \$13.8 million compared to \$11.3 million for the third quarter of 2010. For the first nine months of 2011, total operating expenses were \$37.8 million compared to \$36.6 million in the first nine months of 2010. The increases in total operating expenses between periods were primarily driven by increased clinical trials costs for rindopepimut and CDX-011 studies, including preparations for the initiation of the ACT IV study. The increase was also due to higher costs related to R&D personnel, primarily in clinical operations, higher preclinical costs associated with CDX-1127 and CDX-301, as well as increased expenses resulting from higher license/milestone payments to licensors and an increase of \$2.0 million in Rotarix®-related royalty fees payable to Cincinnati Children's Hospital (CCH) in 2011. These increases were partly offset by decreases in G&A expenses and for the nine-month periods, a decrease in amortization expenses for acquired intangible assets in 2011 compared to 2010. As a result of renovations in our Fall River facility completed in late 2010, we have increased our capacity to produce cGMP grade antibody products for our clinical programs.

The \$3.4 million decrease in investment, other income and interest expense, net in 2011 is primarily due to other income of \$3.0 million recorded for the TopoTarget sublicense income payment received in 2010.

At September 30, 2011, Celldex reported cash, cash equivalents and marketable securities of \$62.8 million, a decrease of \$8.4 million from June 30, 2011. The decrease was due primarily to operational expenses during the third quarter. Celldex believes that current cash, cash equivalents and marketable securities as of September 30, 2011 and interest income on invested funds are sufficient to meet estimated working capital requirements and fund planned operations into 2013. As of September 30, 2011, Celldex had approximately 44.1 million shares outstanding.

### **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 http://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 (formerly TP10), 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 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 plan to initiate in 2011; our ability to adapt APC Targeting Technology  $^{TM}$  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 limited cash reserves and our ability to obtain additional capital on acceptable terms, or at all; 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 risks detailed 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, 2010, and its Forms 10-Q and 8-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 share and per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA		Quarter Ended September 30,				Nine Months Ended September 30,			
		2011		2010		2011		2010	
REVENUE Product Development and		(Unaı	udited)			(Una	udited)		
Licensing Agreements	\$	40	\$	1,371	\$	65	\$	4,117	
Contracts and Grants		5		-		5		220	
Product Royalties		2,318		1,037		6,761		4,735	
Total Revenue		2,363		2,408		6,831		9,072	
OPERATING EXPENSE									
Research and Development		8,594		7,215		22,615		20,908	
Royalty		2,318		1,218		6,761		5,277	
General and Administrative		2,273		2,421		6,899		7,848	
Gain on Sale of Assets		-		(50)		(50)		(50)	
Amortization of Acquired Intangible Assets		656		483		1,622		2,660	
Total Operating Expense		13,841		11,287		37,847		36,643	
Operating Loss		(11,478)		(8,879)		(31,016)		(27,571)	
Investment and Other Income, Net		144		124		307		3,379	
Interest Expense		(438)		(332)		(1,358)		(1,002)	
Net Loss	\$	(11,772)	\$	(9,087)	\$	(32,067)	\$	(25,194)	
Basic and Diluted Net Loss per Common Share	\$	(0.27)	\$	(0.28)	\$	(0.85)	\$	(0.79)	
Weighted Average Common	*	(3127)	Ψ	(5.20)	Ψ	(0.03)	<u> </u>	(0.75)	
Shares Outstanding		44,136		31,922		37,926		31,812	

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BALANCE SHEETS	September 30, 2011 (Unaudited)			December 31,		
				2010		
ASSETS						
Cash, Cash Equivalents and Marketable Securities	\$	62,774	\$	61,098		
Other Current Assets		1,608		1,849		
Property and Equipment, net		9,539		10,832		
Intangible and Other Assets, net		34,527		36,164		
Total Assets	\$	108,448	\$	109,943		
LIABILITIES AND STOCKHOLDERS' EQUITY						
Current Liabilities	\$	10,778	\$	20,208		
Long-Term Liabilities		16,996		14,480		
Stockholders' Equity		80,674		75,255		
Total Liabilities and Stockholders' Equity	\$	108,448	\$	109,943		

# CONTACT:

Celldex Therapeutics, Inc.

Anthony S. Marucci, 781-433-0771

President and CEO

or

Avery W. Catlin, 781-433-0771

Chief Financial Officer

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

or

**BMC Communications** 

Brad Miles, 212-477-9007 x17

brad@bmccommunications.com