Celldex Therapeutics, Inc.
Form 8-K
February 04, 2013

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): **February 4, 2013**

CELLDEX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-15006**	**13-3191702**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

Recent Developments

Certain Recent Balance Sheet Data

While full financial information for the year ended December 31, 2012 is not yet available, Celldex Therapeutics, Inc. (the Company) is providing the following unaudited preliminary information for the year ended December 31, 2012 as an update. The Company had cash, cash equivalents and short-term investments of approximately $84.0 million at December 31, 2012. The preliminary financial data included in this report has been prepared by, and is the responsibility of, the Company s management. PricewaterhouseCoopers LLP has not audited, reviewed, compiled or performed any procedures with respect to the foregoing preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

The foregoing selected, unaudited preliminary financial information is based upon the Company s progress to date and does not present all necessary information for an understanding of the Company s financial condition as of December 31, 2012 or its results of operations for the three months and year ended December 31, 2012. The preparation and audit of the Company s consolidated financial statements for the year ended December 31, 2012 is ongoing and could result in material changes to the financial results set forth above.

Recent Sale of Common Stock

Pursuant to a controlled equity offering sales agreement dated as of January 6, 2011, as amended (the Cantor Agreement) by and between the Company and Cantor Fitzgerald & Co. (Cantor), the Company may issue and sell an amount of shares of its common stock having an aggregate offering price of up to $44.0 million from time to time into the open market at prevailing prices through Cantor, acting as agent. The Company agreed to pay Cantor a commission of 3% of the gross proceeds from each sale and to reimburse Cantor for certain expenses incurred in connection with entering into the Cantor Agreement. The Cantor Agreement terminates upon the sale, under the Cantor Agreement, of an amount of shares of the Company s common stock having an aggregate offering price of $44.0 million or upon ten day notice by either Cantor or the Company.

Since September 30, 2012, the Company issued 5,954,798 shares of its common stock under the Cantor Agreement, raising aggregate net proceeds of approximately $38.0 million. As of February 1, 2013, an additional amount of shares of common stock having an aggregate offering price of up to $4.4 million were available for sale under the Cantor Agreement.

CDX-011 Developments

In December 2012, we had our end of Phase 2b meeting with the United States Federal Drug Administration, or FDA, for our CDX-011 program, which we have characterized as positive. Based on this meeting, we intend to initiate a CDX-011 study suitable for accelerated

approval in the second half of 2013. We are currently finalizing the clinical trial design and will update investors on our plans for the accelerated approval trial on our year-end 2012 call in early March 2013. Also in December 2012, we announced final results, as shown below, from the EMERGE study which suggested that CDX-011 induces significant response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with high glycoprotein NMB, referred to as GPNMB, expression (expression in greater than 25% of tumor cells) and in patients with triple negative breast cancer. The overall survival and progression free survival of patients treated with CDX-011 was also observed to be greatest in patients with triple

negative breast cancer who also highly express GPNMB and all patients with high GPNMB expression.

EMERGE: Overall Response Rate and Disease Control Data

	All Patients		Triple Negative		On target effect clearly demonstrated in targeted patient populations: High GPNMB Expression		On target effect clearly demonstrated in targeted patient populations: Triple Negative and High GPNMB Expression	
	CDX-011 (n=81)	IC (n=36)	CDX-011 (n=27)	IC (n=9)	CDX-011 (n=25)	IC (n=8)	CDX-011 (n=12)	IC (n=4)
Response	16%	14%	19%	0%	32%	13%	33%	0%
Disease Control Rate	57%	53%	67%	33%	64%	38%	75%	25%

Responses per RECIST 1.1; IC = Investigator s Choice; CDX-011 arm includes 15 patients who crossed over to receive CDX-011 treatment after progression on IC. Analysis of best response excludes patients who discontinued from study without evaluable post-baseline radiographic imaging (n=15 for CDX-011 arm; n=5 for IC arm).

EMERGE: Overall Survival (OS) and Progression Free Survival (PFS) Data

	All Patients		Triple Negative		On target effect clearly demonstrated in targeted patient populations: High GPNMB Expression		On target effect clearly demonstrated in targeted patient populations: Triple Negative and High GPNMB Expression	
	CDX-011	IC	CDX-011	IC	CDX-011	IC	CDX-011	IC
Median OS (months)	7.5	7.4	6.9	6.5	10.0	5.7	10.0	5.5
	p=0.24		p=0.30		p=0.18		p=0.003	
Median PFS (months)	2.1	2.0	2.3	1.6	2.7	1.5	3.0	1.5
	p=0.38		p=0.43		p=0.14		p=0.008	

Analyses include all treated patients. Patients who initially received Investigator s Choice (IC) and subsequently crossed over to receive CDX-011 (n=15) are included in the PFS analysis for each treatment. These patients, with a median OS of 12.5 months, are assigned to the IC arm only for OS analysis. Median OS for the remaining IC patients who did not cross over is 5.4 months.

When cross over patients are removed, median OS in patients with high GPNMB expression is 10.0 months for CDX-011 vs 5.2 months for IC (p=0.05) and median OS in triple negative patients with high GPNMB expression is 10.0 months for CDX-011 vs 5.2 months for IC (p=0.009).

Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: *This report contains forward-looking statements, including statements relating to Celldex s unaudited preliminary financial information. These statements are subject to significant risks and uncertainties, actual results could differ materially from those projected and Celldex cautions stockholders not to place undue reliance on the forward-looking statements contained in this report. These risks and uncertainties include, without limitation, risks and uncertainties related to the ongoing process of preparing and auditing the financial statements of Celldex and risks and uncertainties related to Celldex and its business which can be found in the Risk Factors section of Celldex s Form 10-K, filed with the SEC on March 8, 2012. Celldex undertakes no duty or obligation to update any forward-looking statements contained in this report as a result of new information, future events or changes in Celldex s expectations.*

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 4, 2013	By:	/s/ Avery W. Catlin Avery W. Catlin Title: Senior Vice President and Chief Financial Officer