

May 2, 2013

# **Celldex Reports First Quarter 2013 Financial Results**

NEEDHAM, Mass., May 2, 2013 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported financial results for the first quarter ended March 31, 2013. Celldex reported a net loss of \$17.3 million, or \$0.23 per share, for the first quarter of 2013 compared to a net loss of \$13.5 million, or \$0.27 per share, for the first quarter of 2012. At March 31, 2013, Celldex reported cash, cash equivalents and marketable securities of \$182.4 million, which the Company believes will be sufficient to meet estimated working capital requirements and fund planned program development through 2015.

"This year will be significant for Celldex as we continue to advance multiple clinical programs, including registration studies in both brain and breast cancer," said Anthony S. Marucci, President and Chief Executive Officer of Celldex Therapeutics. "We are well on track to initiate the accelerated approval study of CDX-011 in triple negative breast cancers that overexpress GPNMB later this year and remain pleased with the pace of enrollment in both our Phase 3 study in frontline glioblastoma and our Phase 2 study in refractory glioblastoma. In addition, by year-end we expect data from three clinical studies—our Phase 2 study of rindopepimut in refractory glioblastoma, our pilot study of CDX-1135 in dense deposit disease and our ongoing Phase 1 study of CDX-1127 in both solid tumors and hematologic malignancies. Importantly, these programs and others in our pipeline are well-financed given the successful completion of our \$114.1 million capital raise in the first quarter."

# First Quarter and Recent Pipeline Highlights:

### The Company

- Continued to open clinical sites to support enrollment in the <u>Phase 3 ACT IV study and the Phase 2 ReACT study</u> of rindopepimut in glioblastoma.
- Advanced plans for the initiation of a randomized, accelerated approval study of CDX-011 in patients with triple negative breast cancers that over-express GPNMB.
- Continued to enroll patients in the dose-escalation portion of the lymphoma and leukemia arm of the <a href="Phase 1 portion">Phase 1 portion</a> of the CDX-1127. The Company is currently planning the initiation of expansion studies in the solid tumor arm.
- Presented results from an <u>in vitro study of CDX-1127</u> that further confirmed the mechanism of action for CDX-1127 and provided additional support for continued clinical development of the candidate in a poster session at the AACR Annual Meeting in April.
- Presented final results from a <u>Phase 1 multi-dose study of CDX-301</u> (rhuFlt3L) in healthy volunteers that demonstrated that CDX-301 was well-tolerated and effectively mobilized hematopoietic cell populations in an oral presentation at the 2013 BMT Tandem Meetings in February.
- Raised net proceeds of \$114.1 million in the first quarter of 2013 to support operations and clinical development activities through 2015.

## **Key 2013 Objectives**

- Complete global recruitment in the ACT IV registration study of rindopepimut in front line glioblastoma and in the ReACT study of rindopepimut in combination with Avastin in patients with recurrent/refractory EGFRvIII-positive glioblastoma. Announce results from the ReACT study by year-end.
- Initiate a randomized, accelerated approval study of CDX-011 in patients with triple negative breast cancers that overexpress GPNMB in the second half of 2013.
- Complete enrollment of the Phase 1 dose-escalation and expansion studies of CDX-1127 in patients with selected malignant solid tumors or hematologic cancers and determine next steps for this program. Report data from this study in the second half of 2013.
- Initiate a pilot study of CDX-1135 in dense deposit disease, an orphan renal disease in children and young adults, with data expected in the second half of 2013.
- Initiate a pilot clinical study of CDX-301 in hematopoietic stem cell transplant in the second half of 2013.
- Initiate a Phase 2 study of CDX-1401 in combination with CDX-301 sponsored by the Cancer Immunotherapy Trials Network of the National Cancer Institute.

## **Further Financial Highlights**

The net loss of \$17.3 million for the first quarter of 2013 represents an increased loss of approximately \$3.8 million when compared to the net loss for the same period in 2012 and is primarily due to higher research and development (R&D) and general and administrative (G&A) expenses in 2013 related to the rindopepimut program.

Revenues for the first quarter of 2013 were consistent with revenues recorded in the first quarter of 2012.

In the first quarter of 2013, R&D expense increased by \$3.3 million compared to 2012 and was primarily a result of increased clinical trial costs of \$2.3 million and contract manufacturing costs of \$0.5 million primarily due to our late-stage rindopepimut program.

G&A expense in the first quarter of 2013 increased by \$0.8 million from \$2.3 million in 2012 due primarily to higher personnel-related expenses and rindopepimut-related commercial planning costs in 2013.

During the quarter ended March 31, 2013, the increase in cash, cash equivalents and marketable securities of \$98.4 million from December 31, 2012 primarily reflects the issuance of 16.2 million shares of common stock during the quarter through our Cantor ATM facility and an underwritten public offering that raised aggregate net proceeds to Celldex of \$114.1 million, partially offset by our first quarter operations-related cash burn of approximately \$16.1 million.

As of March 31, 2013, Celldex had approximately 80.9 million shares outstanding.

#### **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 <a href="http://www.celldextherapeutics.com">http://www.celldextherapeutics.com</a>.

Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: This release contains "forwardlooking 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 ability to successfully complete research and further development and commercialization of rindopepimut, CDX-011 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; our ability to adapt our 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 STATEMENT
OF OPERATIONS DATA

Quarter Ended March 31,

	2013	2012
	(Unaudited)	
OPERATING REVENUE		
Product Development and Licensing Agreements	\$ 30	\$ 35
Contracts and Grants	50	54
Product Royalties	2,334	2,344
Total Revenue	2,414	2,433
OPERATING EXPENSE		
Research and Development	14,090	10,769
Royalty	2,334	2,344
General and Administrative	3,138	2,317
Amortization of Acquired Intangible Assets	253	291
Total Operating Expense	19,815	15,721
Operating Loss	(17,401)	(13,288)
Investment and Other Income, Net	379	205
Interest Expense	(310)	(433)
Net Loss	\$ (17,332)	\$ (13,516)
Basic and Diluted Net Loss per		
Common Share	\$ (0.23)	\$ (0.27)
Weighted Average Common		
Shares Outstanding	74,027	50,145

#### CONDENSED CONSOLIDATED

BALANCE SHEETS DATA	March 31,	December 31,
	2013	2012
	(Unaudited)	
ASSETS		
Cash, Cash Equivalents and Marketable Securities	\$ 182,377	\$ 83,962
Other Current Assets	2,076	1,152
Property and Equipment, net	7,131	7,205
Intangible and Other Assets, net	32,781	33,222
Total Assets	\$ 224,365	\$ 125,541
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	\$ 18,330	\$ 17,685
Long-Term Liabilities	11,094	12,082
Stockholders' Equity	194,941	95,774
Total Liabilities and Stockholders' Equity	\$ 224,365	\$ 125,541

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News Provided by Acquire Media

Source: Celldex Therapeutics, Inc.