



August 6, 2013

## Celldex Reports Second Quarter 2013 Financial Results

PHILLIPSBURG, N.J., Aug. 6, 2013 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported financial results for the second quarter ended June 30, 2013. Celldex reported a net loss of \$19.0 million, or \$0.24 per share, for the second quarter of 2013 compared to a net loss of \$13.8 million, or \$0.23 per share, for the second quarter of 2012. For the six months ended June 30, 2013, Celldex reported a net loss of \$36.3 million, or \$0.47 per share, compared to a net loss of \$27.3 million, or \$0.50 per share, for the six months ended June 30, 2012. At June 30, 2013, Celldex reported \$155.0 million in cash, cash equivalents and marketable securities, which reflects total principal and interest payments of \$10.5 million on our term loan (including its payoff during the second quarter).

"In the second quarter, Celldex continued to advance multiple clinical programs towards key inflection points," said Anthony Marucci, President and Chief Executive Officer. "We completed several important steps in preparation for the initiation of our accelerated approval study of CDX-011 in triple negative breast cancer, including selecting a diagnostic partner. We also remain pleased with the pace of enrollment in our Phase 3 study of rindopepimut in frontline glioblastoma and look forward to presenting data from our Phase 2 study in refractory glioblastoma at the Society for Neuro-Oncology meeting later this year. In addition, we enrolled the first patient in our pilot study of CDX-1135 in dense deposit disease and initiated expansion cohorts in our Phase 1 study of CDX-1127 in metastatic melanoma and renal cell carcinoma. We believe the second half of the year promises to be as productive as the first half and we look forward to continuing to update on our progress."

### Program Updates:

#### ***Rindopepimut in EGFRv3—Positive Glioblastoma (GBM):***

- | Celldex continues to actively enroll newly diagnosed patients with GBM in the Phase 3 ACT IV study with a goal to complete enrollment by the end of 2013.
- | The Company continues to advance the ReACT study in recurrent GBM. The study includes two groups—group 1 is comprised of patients who are Avastin<sup>®</sup> naïve and group 2 is comprised of patients who are Avastin refractory. Celldex anticipates reporting data from the ReACT study at the Society for Neuro-Oncology (SNO) Annual Meeting in November 2013.

#### ***CDX-011 (Glembatumumab vedotin) in Breast Cancers that Over-express GPNMB***

- | Celldex continues to advance plans for the initiation of a randomized, accelerated approval study (the METRIC study) of CDX-011 in patients with triple negative breast cancers that over-express GPNMB and expects to initiate METRIC in the second half of 2013.
- | The study will be conducted in approximately 100 sites, primarily in the United States with additional sites in Canada and Australia.
- | Celldex has selected a partner to develop the diagnostic for the METRIC study.

#### ***CDX-1127 Targeting CD27 in Solid Tumors and Hematologic Malignancies***

- | Celldex has completed enrollment of the solid tumor dose-escalation portion of the ongoing Phase 1 study and recently initiated expansion cohorts in metastatic melanoma and renal cell carcinoma. The study continues to enroll patients in the dose-escalation portion of the lymphoma and leukemia arm and expansion studies are planned when this phase of the study completes. Celldex anticipates presenting data from the solid tumor dose-escalation portion of the study and the corresponding expansion cohorts by the end of 2013. Reporting of data from the hematologic arm is anticipated in 2014.
- | The Company announced the issuance of a seminal patent for CD27 agonists (US Patent No: 8,481,029) which broadly supports the Company's product candidate CDX-1127. The patent includes 18 claims covering various methods of treating cancer using agonistic anti-human CD27 antibodies.
- | Celldex presented results from an *in vitro* study of CDX-1127 at AACR 2013 that further confirmed that CDX-1127 elicits potent activation of T cells by inducing their proliferation and release of important immune modulating cytokines. Most importantly, the data demonstrated that this activation is highly regulated, which limits any safety concerns related to non-specific stimulation of the immune system that similar candidates in this class have faced.

This finding is supported by the favorable safety profile observed to date in the Phase 1 study.

### ***CDX-1135 in Dense Deposit Disease (DDD)***

- ▮ The Company announced that the first patient in the pilot study of CDX-1135 (a soluble form of human complement receptor type 1) in DDD has been dosed. DDD is an ultra-rare, progressive kidney disease that ultimately results in kidney failure in the majority of affected individuals. The study will continue to enroll patients and the Company anticipates presenting preliminary data by the end of 2013.

### ***Other programs***

- ▮ Celldex continues to advance plans to initiate a pilot clinical study of CDX-301 (Flt3L) in hematopoietic stem cell transplant (HSTC) in the second half of 2013.
- ▮ The Company recently finalized a cooperative research and development agreement (CRADA) with the Cancer Immunotherapy Trials Network (CITN) of the National Cancer Institute to initiate a Phase 2 study of CDX-1401 in combination with CDX-301 in malignant melanoma.

### **Further Financial Highlights**

#### *Second Quarter and First Six Months 2013 Results*

Total revenue in the second quarter of 2013 was \$0.1 million, compared to \$2.0 million in the second quarter of 2012. Total revenue for the six months ended June 30, 2013 was \$2.5 million, compared to \$4.4 million for the six months ended June 30, 2012. The decrease in revenue was primarily due to the decrease in Rotarix<sup>®</sup> royalty revenue. Our agreement with GlaxoSmithKline terminated upon the anticipated expiration of the last relevant patent right covered by the GlaxoSmithKline agreement. We do not expect additional royalty revenue or royalty expense related to Rotarix<sup>®</sup>.

Research and development (R&D) expenses in the second quarter of 2013 were \$15.1 million, compared to \$11.1 million in the second quarter of 2012. R&D expenses for the six months ended June 30, 2013 were \$29.2 million, compared to \$21.9 million for the six months ended June 30, 2012. The increase in Celldex's R&D investment was primarily due to the continued progression of our late-stage rindopepimut clinical development program, including ACT IV and ReACT, as well as the initiation of CDX-1135 and expansion of the CDX-1127 study. In addition, during 2013, we continued our manufacturing efforts with our intended commercial suppliers to support our pivotal studies in rindopepimut and CDX-011.

General and administrative (G&A) expenses in the second quarter of 2013 were \$3.4 million, compared to \$2.2 million in the second quarter of 2012. G&A expenses for the six months ended June 30, 2013 were \$6.5 million, compared to \$4.5 million for the six months ended June 30, 2012. The increase in G&A expenses was primarily due to higher personnel-related expenses, professional services and rindopepimut-related commercial planning costs in 2013. During 2013, we have increased our headcount to 124 as we continue to add important positions in the areas of commercial development, marketing, regulatory, and manufacturing.

At June 30, 2013, Celldex reported cash, cash equivalents and marketable securities of \$155.0 million, which the Company believes will be sufficient to meet estimated working capital requirements and fund planned program development through 2015. The decrease of \$27.4 million from March 31, 2013 includes total principal and interest payments on our term loan of \$10.5 million during the second quarter of 2013 and our second quarter net cash burn of approximately \$16.9 million. In May 2013, we paid off our term loan, which would have otherwise matured in December 2014, for a savings of approximately \$0.5 million in interest costs (net of prepayment fees).

As of June 30, 2013, Celldex had approximately 81.0 million shares outstanding.

*Avastin is a registered trademark of Genentech, a member of the Roche Group.*

### **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 <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, 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.

## CELLEX THERAPEUTICS, INC.

(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Quarter		Six Months	
	Ended June 30,		Ended June 30,	
	2013	2012	2013	2012
	(Unaudited)		(Unaudited)	
<b>REVENUE</b>				
Product Development and Licensing Agreements	\$ 47	\$ 40	\$ 77	\$ 75
Contracts and Grants	50	96	100	149
Product Royalties	--	1,873	2,334	4,218
<b>Total Revenue</b>	<b>97</b>	<b>2,009</b>	<b>2,511</b>	<b>4,442</b>
<b>OPERATING EXPENSE</b>				
Research and Development	15,090	11,114	29,180	21,881
Royalty	--	1,873	2,334	4,218
General and Administrative	3,411	2,219	6,549	4,536
Amortization of Acquired Intangible Assets	254	291	507	583
<b>Total Operating Expense</b>	<b>18,755</b>	<b>15,497</b>	<b>38,570</b>	<b>31,218</b>
Operating Loss	(18,658)	(13,488)	(36,059)	(26,776)
Investment and Other Income, Net	161	126	540	331
Interest Expense	(519)	(411)	(829)	(844)
<b>Net Loss</b>	<b>\$ (19,016)</b>	<b>\$ (13,773)</b>	<b>\$ (36,348)</b>	<b>\$ (27,289)</b>
<b>Basic and Diluted Net Loss per Common Share</b>	<b>\$ (0.24)</b>	<b>\$ (0.23)</b>	<b>\$ (0.47)</b>	<b>\$ (0.50)</b>
<b>Weighted Average Common Shares Outstanding</b>	<b>80,899</b>	<b>58,733</b>	<b>77,482</b>	<b>54,439</b>

**CONDENSED CONSOLIDATED  
BALANCE SHEETS**

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	<u>June 30,</u>	<u>December 31,</u>
	<b>2013</b>	<b>2012</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Cash, Cash Equivalents and Marketable Securities	\$ 154,983	\$ 83,962
Other Current Assets	1,447	1,152
Property and Equipment, net	7,338	7,205
Intangible and Other Assets, net	<u>32,465</u>	<u>33,222</u>
Total Assets	<u>\$ 196,233</u>	<u>\$ 125,541</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities	\$ 12,503	\$ 17,685
Long-Term Liabilities	6,636	12,082
Stockholders' Equity	<u>177,094</u>	<u>95,774</u>
Total Liabilities and Stockholders' Equity	<u>\$ 196,233</u>	<u>\$ 125,541</u>

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Source: Celldex Therapeutics, Inc.

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