

November 8, 2013

# Celldex Reports Third Quarter 2013 Financial Results

PHILLIPSBURG, N.J., Nov. 8, 2013 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported financial results for the third quarter ended September 30, 2013. Celldex reported a net loss of \$23.1 million, or \$0.29 per share, for the third quarter of 2013 compared to a net loss of \$15.0 million, or \$0.25 per share, for the third quarter of 2012. For the nine months ended September 30, 2013, Celldex reported a net loss of \$59.5 million, or \$0.76 per share, compared to a net loss of \$42.3 million, or \$0.75 per share, for the nine months ended September 30, 2012. At September 30, 2013, Celldex reported \$136.6 million in cash, cash equivalents and marketable securities.

"As we approach year-end, Celldex is well positioned to achieve a number of milestones that will play an important role in advancing our pipeline into 2014 and beyond," said Anthony Marucci, President and Chief Executive Officer. "We remain on track to initiate our accelerated approval study of CDX-011 in triple negative breast cancer and we continue to make excellent progress advancing our Phase 3 study of rindopepimut in frontline glioblastoma. We also recently announced the initiation of an expansion cohort for our ReACT study in refractory glioblastoma and will present data from ReACT in an oral session at the Society for Neuro-Oncology meeting in late November. In addition, we are presenting data from the Phase 1 CDX-1127 study at the Society for Immunotherapy of Cancer Meeting this weekend."

### **Program Updates:**

#### Rindopepimut in EGFRv III(v3)—Positive Glioblastoma (GBM):

- Celldex continues to actively enroll newly diagnosed patients with GBM in the Phase 3 ACT IV registration study.
- In August, the Company announced that it had completed enrollment of Group 2 (Avastin<sup>®</sup> refractory patients) in the ReACT study and that, based on early evidence of anti-tumor activity, an expansion cohort of up to 75 patients would be added to better characterize the potential activity of rindopepimut in this refractory patient population. Enrollment is ongoing in this expansion cohort and in Group 1 (Avastin naive patients). Celldex will report data from the ReACT study in an oral presentation at the Society for Neuro-Oncology (SNO) Annual Meeting on Sunday, November 24, 2013.
- Celldex will host a conference call on Monday, November 25, 2013 at 8:30 am ET to provide a program update and discuss the data presented at SNO.

## Glembatumumab vedotin ("glemba"; CDX-011) in Breast Cancers that Over-express GPNMB

Celldex continues to advance plans for the METRIC study, a randomized, accelerated approval study of glemba in patients with triple negative breast cancers that over-express GPNMB. The study is expected to initiate by year-end 2013 and will be conducted in approximately 100 sites, primarily in the United States with additional sites in Canada and Australia.

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

- Enrollment continues in the Phase 1 dose-escalation study of CDX-1127. Celldex will present data from this study in poster sessions at the Society for Immunotherapy of Cancer Meeting (SITC) on Saturday, November 9, 2013. The Company will also present preclinical data on combination studies of CDX-1127, including chemotherapies and checkpoint inhibitors, in a poster session at SITC on Friday, November 8, 2013.
- Celldex hosted a conference call on Thursday, November 7, 2013 to provide a program update and discuss the data to be presented at SITC. The results from the Phase 1 dose-escalation study suggest an excellent safety profile and demonstrate clear biologic activity and promising signs of clinical activity in an advanced, refractory patient population. Based on the data, after completing the dose-escalation study and its corresponding expansion cohorts, the Company intends to initiate additional studies of CDX-1127.

The Company's pilot study of CDX-1135 (a soluble form of human complement receptor type 1) in DDD is ongoing. DDD is an ultra-rare, progressive kidney disease that ultimately results in kidney failure in the majority of affected individuals. The Company anticipates presenting a program update on our year-end conference call in February 2014.

### Other programs

- Celldex continues to advance plans to initiate a pilot clinical study of CDX-301 (Flt3L) in hematopoietic stem cell transplant (HSTC) that will build upon ongoing work with Mozobil (plerixafor) and anticipates this study will begin in early 2014.
- The Company is planning a collaborative Phase 2 study of CDX-1401 in combination with CDX-301 in malignant melanoma. This study will be conducted under a cooperative research and development agreement (CRADA) with the Cancer Immunotherapy Trials Network (CITN) and the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute.

## **Further Financial Highlights**

Third Quarter and First Nine Months 2013 Results

Total revenue in the third quarter of 2013 was \$1.0 million, compared to \$3.1 million in the third quarter of 2012. Total revenue for the nine months ended September 30, 2013 was \$3.5 million, compared to \$7.6 million for the nine months ended September 30, 2012. The decrease in revenue was primarily due to the decrease in Rotarix<sup>®</sup> royalty revenue with a corresponding reduction in royalty expense. 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>. Included in revenue for the third quarter of 2013 was \$0.9 million recognized from a new services contract with Rockefeller University for the development and manufacture of two anti-HIV antibodies.

Research and development (R&D) expenses in the third quarter of 2013 were \$20.4 million, compared to \$11.8 million in the second quarter of 2012. R&D expenses for the nine months ended September 30, 2013 were \$49.6 million, compared to \$33.7 million for the nine months ended September 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 planning for the METRIC study and the expansion of the CDX-1127 study. Clinical trial expenses in 2013 increased by \$3.1 million and \$7.1 million when compared to 2012 for the three- and nine-month periods, respectively. In addition, during 2013, we have substantially expanded our manufacturing activities with our commercial suppliers to support our pivotal studies in rindopepimut and glemba. External contract manufacturing expenses increased by \$3.3 million and \$5.0 million for the three- and nine-month periods, respectively, in 2013 versus 2012.

General and administrative (G&A) expenses in the third quarter of 2013 were \$3.6 million, compared to \$2.8 million in the third quarter of 2012. G&A expenses for the nine months ended September 30, 2013 were \$10.1 million, compared to \$7.4 million for the nine months ended September 30, 2012. The increase in G&A expenses was primarily attributable to higher personnel-related expenses, professional services and rindopepimut-related commercial planning costs in 2013.

At September 30, 2013, Celldex reported cash, cash equivalents and marketable securities of \$136.6 million. The decrease of \$18.4 million from June 30, 2013 includes \$0.9 million spent on leasehold improvements to our future headquarters facility in New Jersey and our third quarter net cash burn of \$17.5 million.

As of September 30, 2013, Celldex had 81.1 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 <a href="https://www.celldex.com">www.celldex.com</a>.

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), Glembatumumab vedotin ("glemba"; 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, glemba 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 STATEMENTS	Quarter Ended September 30,		Nine Months Ended September 30,	
OF OPERATIONS DATA				
	2013	2012	2013	2012
	(Unau	lited) (Unaudited)		ted)
REVENUE				
Product Development and				
Licensing Agreements	\$ 40	\$ 28	\$ 117	\$ 103
Contracts and Grants	940	79	1,040	228
Product Royalties		3,006	2,334	7,224
Total Revenue	980	3,113	3,491	7,555
OPERATING EXPENSE				
Research and Development	20,417	11,769	49,597	33,650
Royalty		3,006	2,334	7,224
General and Administrative	3,578	2,835	10,128	7,372
Amortization of Acquired Intangible Assets	254	254	760	836
Total Operating Expense	24,249	17,864	62,819	49,082
Operating Loss	(23,269)	(14,751)	(59,328)	(41,527)
Investment and Other Income, Net	142	105	682	436
Interest Expense	(13)	(381)	(842)	(1,225)
Net Loss	\$ (23,140)	\$ (15,027)	\$ (59,488)	\$ (42,316)
Basic and Diluted Net Loss per Common Share	\$ (0.29)	\$ (0.25)	\$ (0.76)	\$ (0.75)

#### **CONDENSED CONSOLIDATED**

BALANCE SHEETS	September 30, December 31,		
	2013	2012	
	(Unaudited)		
ASSETS			
Cash, Cash Equivalents and Marketable Securities	\$ 136,588	\$ 83,962	
Other Current Assets	3,358	1,152	
Property and Equipment, net	8,814	7,205	
Intangible and Other Assets, net	32,195	33,222	
Total Assets	\$ 180,955	\$ 125,541	
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current Liabilities	\$ 16,795	\$ 17,685	
Long-Term Liabilities	7,415	12,082	
Stockholders' Equity	156,745	95,774	
Total Liabilities and Stockholders' Equity	\$ 180,955	\$ 125,541	

CONTACT: Sarah Cavanaugh

Vice President of Investor Relations &

Corp Communications

Celldex Therapeutics, Inc.

(781) 433-3161

scavanaugh@celldex.com

Source: Celldex Therapeutics, Inc.

News Provided by Acquire Media