



August 6, 2014

Celldex Reports Second Quarter 2014 Results

Management to Host Conference Call Today, Wednesday, August 6, at 4:30 p.m. Eastern Time

HAMPTON, N.J., Aug. 6, 2014 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported business and financial highlights for the second quarter ended June 30, 2014.

"Celldex has made tremendous progress advancing our pipeline this year—most notably, we will complete patient screening in the coming weeks for our Phase 3 ACT IV study of rindopepimut in newly-diagnosed glioblastoma, an aggressive form of brain cancer," said Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics. "The ACT IV study will include 700 patients with EGFR v_{III} positive glioblastoma from more than 200 clinical trial sites across 22 countries—the most comprehensive study conducted by a biotech company to date in this orphan disease. We are extremely proud of our team and very grateful to the patients, families and physicians who are participating in this study.

In the second quarter, we also accomplished a number of additional, significant milestones—advancing our accelerated approval study of glebatumumab vedotin in triple negative breast cancer, publishing positive data from the CDX-1401 program, presenting positive data from our Phase 1 varlilumab program at ASCO and announcing a clinical trial collaboration with BMS for the varlilumab program. This momentum is expected to continue in the second half of 2014 as we initiate multiple new studies across our pipeline and present data from our Phase 2 ReACT study in recurrent glioblastoma at year-end."

Program Updates:

Rindopepimut ("rindo"; CDX-110) in EGFR v_{III} (v3)-Positive Glioblastoma (GBM):

- | Celldex will close screening in the next several weeks for ACT IV, the Phase 3 registration study of newly diagnosed patients with GBM. Patients whose tissues screen positive for EGFR v_{III} are randomized into the study after completion of surgery and standard chemoradiation, which can occur up to three months after screening. To date, 4,034 patients have been screened and, consistent with prior studies, 30.2% have been EGFR v_{III} positive. 614 patients have been enrolled in ACT IV to date, and, as expected, 263 of these patients were enrolled in the last 8 months. In total, 700 patients will be enrolled into ACT IV to reach the required 374 patients with minimal residual disease (assessed by central review) needed for analysis of the primary overall survival (OS) endpoint. All patients, including patients with disease that exceed this threshold, will be included in a secondary analysis of OS as well as analyses of progression-free survival, safety and tolerability, and quality of life.
- | In the Phase 2 ReACT study in patients with recurrent GBM, Celldex has completed enrollment of both Group 1 (n=70 Avastin®-naïve patients) and the first 23 patients of Group 2C (n=up to 73 Avastin-refractory patients). Group 2C is designed as a two-stage cohort; evidence of anti-tumor activity in the first 23 patients will trigger full completion of enrollment to this arm of the study. Updated data from the study will be presented by year-end 2014.

Glebatumumab vedotin ("glemba"; CDX-011) targeting gpNMB in multiple cancers:

- | In December 2013, Celldex initiated a randomized, accelerated approval study (METRIC) of glebatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress the tumor associated marker gpNMB. To date, 73 sites are open to enrollment across the United States, Canada and Australia. In total, the study is expected to include approximately 100 sites.
- | Celldex continues to advance plans to expand the study of glebatumumab vedotin into other cancers in which gpNMB is expressed.
 - | The protocol for the Phase 2 study in metastatic melanoma has been finalized and the study will be initiated later this year.
 - | Assay optimization and validation for the Phase 2 study in squamous cell lung cancer is expected to be completed by year-end and the study will commence soon thereafter.
 - | Celldex and the National Cancer Institute have entered into a Cooperative Research and Development Agreement (CRADA) under which NCI will sponsor two studies of glebatumumab vedotin—one in uveal

melanoma and one in pediatric osteosarcoma. Celldex will provide support for these studies.

Varlilumab ("varli"; CDX-1127), an immune modulating mAb targeting CD27 in solid tumors and hematologic malignancies:

- | In May, Celldex announced that it had entered into a clinical trial collaboration with Bristol-Myers Squibb Company (BMS) to evaluate the safety, tolerability and preliminary efficacy of Opdivo® (nivolumab), BMS's investigational PD-1 immune checkpoint inhibitor, and varlilumab. Multiple tumor types will be explored in the study, which could potentially include non-small cell lung cancer (NSCLC), metastatic melanoma, ovarian, colorectal (CRC) and squamous cell head and neck cancers. The study will be conducted by Celldex and Celldex and BMS will share development costs. The study is expected to begin in the fourth quarter.
- | In June, Celldex presented data from the Phase 1 varlilumab program in two separate Poster Highlight Sessions at the 2014 American Society of Clinical Oncology (ASCO) Annual Meeting. Results presented included data from the lymphoid malignancies dose-escalation arm and solid tumor expansion cohorts in metastatic melanoma and renal cell carcinoma. Varlilumab was very well tolerated and demonstrated clear biologic activity and promising signs of clinical activity in advanced, treatment-refractory patient populations, which continue to support the rationale for combination studies with other immune activating therapies.
- | Celldex has finalized the protocol for a Phase 1/2 study of varlilumab and Yervoy plus CDX-1401 in NY-ESO+ patients with metastatic melanoma and this study will begin by year-end.
- | In May, Celldex announced that it had agreed to collaborate with Oncothyreon Inc. on a combined clinical trial of ONT-10, a therapeutic vaccine targeting the tumor-associated antigen MUC1, and varlilumab. This study will be conducted and funded by Oncothyreon.
- | Multiple efforts are underway to finalize designs and plans for additional Phase 2 studies of varlilumab and the Company will provide updates on these studies as they get closer to initiation.

CDX-1401, an antibody-based dendritic cell targeted vaccine targeting tumors expressing the NY-ESO-1 oncoprotein:

- | In April, final data from the Phase 1 study of CDX-1401 in solid tumors, including long-term patient follow-up, was published in *Science Translational Medicine* (Vol 6 Issue 232). The data demonstrated robust antibody and T cell responses and evidence of clinical benefit in patients with very advanced cancers and suggested that CDX-1401 may predispose patients to better outcomes on subsequent therapy with checkpoint inhibitors. This data directly supports the initiation of the Phase 1/2 study of varlilumab and Yervoy plus CDX-1401 in NY-ESO+ patients with metastatic melanoma.
- | Celldex continues to provide support for the National Cancer Institute sponsored Phase 2 study of CDX-1401 and CDX-301 for patients with metastatic melanoma, which is currently open to enrollment.

CDX-301 (Flt3L), a potent hematopoietic cytokine that stimulates the expansion and differentiation of hematopoietic stem cells and dendritic cells:

- | Celldex continues to advance plans to initiate combination studies of CDX-301 in 2014 to explore its potential for improving hematopoietic stem cell transplantation and potentiating immune activation. A pilot study of CDX-301 alone and in combination with Mozobil® in hematopoietic stem cell transplantation will be initiated in the third quarter.
- | In addition, the investigator sponsored Phase 1/2 study of intratumoral injection of CDX-301 and Hiltonol® in combination with low-dose radiotherapy for patients with low-grade B-cell lymphomas has initiated and the first patients have been dosed.

Second Quarter and First Six Months 2014 Financial Highlights and 2014 Guidance

Cash position: Cash, cash equivalents and marketable securities as of June 30, 2014 were \$252.4 million compared to \$274.2 million as of March 31, 2014. The decrease was primarily driven by our second quarter net cash burn of \$21.8 million, offset in part by a one-time payment of \$5 million from BMS. As of June 30, 2014 Celldex had 89.4 million shares outstanding.

Revenues: Total revenue was \$0.6 million in the second quarter of 2014 and \$1.0 million for the six months ended June 30, 2014, compared to \$0.1 million and \$2.5 million for the comparable periods in 2013. The increase in the second quarter of 2014 was primarily due to our clinical trial collaboration with BMS and our research and development agreement with Rockefeller. The decrease in the six months ended June 30, 2014 was primarily due to the decrease in Rotarix® 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.

R&D Expenses: Research and development (R&D) expenses were \$24.1 million in the second quarter of 2014 and \$51.2

million for the six months ended June 30, 2014, compared to \$15.1 million and \$29.2 million for the comparable periods in 2013. The increase in Celldex's R&D investment was primarily due to the continued progression of our late-stage clinical development programs, rindopepimut and glembatumumab vedotin, and the continued expansion of the varlilumab program.

G&A Expenses: General and administrative (G&A) expenses were \$4.8 million in the second quarter of 2014 and \$9.4 million for the six months ended June 30, 2014, compared to \$3.4 million and \$6.5 million for the comparable periods in 2013. The increase in G&A expenses was primarily attributable to higher personnel-related expenses and rindopepimut and glembatumumab vedotin commercial planning costs in 2014.

Net loss: Net loss was \$28.3 million, or (\$0.32) per share, for the second quarter of 2014 and \$58.2 million, or (\$0.65) per share, for the six months ended June 30, 2014, compared to a net loss of \$19.0 million, or (\$0.24) per share and \$36.3 million, or (\$0.47) per share for the comparable periods in 2013.

Financial guidance: Celldex expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through 2016.

Webcast and Conference Call

Celldex will host a conference call and live webcast at 4:30 p.m. ET on Wednesday, August 6, 2014, to review the second quarter 2014 financial results and to provide an update on key research and development and business objectives for the remainder of 2014. The conference call and presentation will be webcast live over the Internet and can be accessed by logging on to the Events Calendar under the "News & Events" section of the Celldex Therapeutics website at www.celldextherapeutics.com. The call can also be accessed by dialing (866) 743-9666 (within the United States) or (760) 298-5103 (outside the United States). The passcode is 75485305.

A replay of the call will be available approximately two hours after the live call concludes through August 13, 2014. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 75485305. The webcast will also be archived on the Company's website.

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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 www.celldex.com.

Forward Looking Statement

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 ("rindo"; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2014. 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, glembatumumab vedotin 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; the uncertainties inherent in clinical testing and accruing patients for clinical trials; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage and successfully complete multiple clinical trials and the research and development efforts for our multiple products at varying stages of development; the availability, cost, delivery and quality of clinical and commercial grade materials produced by our own manufacturing facility or supplied by contract manufacturers, who may be our sole source of supply; 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.

--table follows--

CELLEX THERAPEUTICS, INC.
(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Quarter		Six Months	
	Ended June 30,		Ended June 30,	
	2014	2013	2014	2013
	(Unaudited)		(Unaudited)	
REVENUE				
Product Development and Licensing Agreements	\$ 200	\$ 47	\$ 235	\$ 77
Contracts and Grants	392	50	773	100
Product Royalties	--	--	--	2,334
Total Revenue	592	97	1,008	2,511
OPERATING EXPENSE				
Research and Development	24,100	15,090	51,169	29,180
Royalty	--	--	--	2,334
General and Administrative	4,787	3,411	9,369	6,549
Amortization of Acquired Intangible Assets	254	254	507	507
Total Operating Expense	29,141	18,755	61,045	38,570
Operating Loss	(28,549)	(18,658)	(60,037)	(36,059)
Investment and Other Income, Net	275	161	1,860	540
Interest Expense	--	(519)	--	(829)
Net Loss	\$ (28,274)	\$ (19,016)	\$ (58,177)	\$ (36,348)
Basic and Diluted Net Loss per Common Share	\$ (0.32)	\$ (0.24)	\$ (0.65)	\$ (0.47)
Weighted Average Common Shares Outstanding	89,361	80,899	89,316	77,482

**CONDENSED CONSOLIDATED
BALANCE SHEETS**

	June 30,	December 31,
	2014	2013
	(Unaudited)	
ASSETS		
Cash, Cash Equivalents and Marketable Securities	\$ 252,369	\$ 302,983
Other Current Assets	3,228	2,206

Property and Equipment, net	10,601	9,973
Intangible and Other Assets, net	<u>31,394</u>	<u>31,933</u>
Total Assets	<u>\$ 297,592</u>	<u>\$ 347,095</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current Liabilities	\$ 21,202	\$ 20,350
Long-Term Liabilities	11,075	6,950
Stockholders' Equity	<u>265,315</u>	<u>319,795</u>
Total Liabilities and Stockholders' Equity	<u>\$ 297,592</u>	<u>\$ 347,095</u>

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Source: Celldex Therapeutics, Inc.

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