November 1, 2012

Celldex Reports Third Quarter 2012 Financial Results

NEEDHAM, Mass.--(BUSINESS WIRE)-- Celldex Therapeutics, Inc. (NASDAQ: CLDX) today reported financial results for the third quarter ended September 30, 2012. Celldex reported a net loss of $15.0 million, or $0.25 per share, for the third quarter of 2012 compared to a net loss of $11.8 million, or $0.27 per share, for the third quarter of 2011. For the nine months ended September 30, 2012, Celldex reported a net loss of $42.3 million, or $0.75 per share, compared to a net loss of $32.1 million, or $0.85 per share, for the nine months ended September 30, 2011.

Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics commented, "In the third quarter, Celldex continued to advance our two lead programs, rapidly opening clinical sites for the Phase 3 ACT IV study and the Phase 2 ReACT study of rindopepimut in glioblastoma and preparing for an end-of-Phase 2 meeting with the Food and Drug Administration to discuss future development of CDX-011 in breast cancer. We look forward to presenting updates from these programs at the Society for Neuro-Oncology Annual Meeting in November and the San Antonio Breast Cancer Symposium in December. Further, by year-end, we anticipate completing accrual in the solid tumor arm of the Phase 1 study of CDX-1127. We will also initiate a Phase 2 pilot study of CDX-1135 in dense deposit disease. These events, coupled with ongoing activity in a number of other programs, will set the stage for a series of future significant milestones in 2013 and beyond."

At September 30, 2012, Celldex reported cash, cash equivalents and marketable securities of $77.6 million, which the Company believes will be sufficient to meet estimated working capital requirements and fund planned program development into 2014. The decrease of $1.1 million from June 30, 2012 is due primarily to planned, increased operational expenses during the quarter related to ongoing studies of rindopepimut (CDX-110), including the pivotal ACT IV study in patients with newly diagnosed EGFRvIII-positive glioblastoma and the Phase 2 ReACT study in patients with recurrent EGFRvIII-positive glioblastoma. The cash outflows for these expenses were offset by the issuance of 2.0 million shares during the quarter through our Cantor ATM facility that raised net proceeds to Celldex of $10.9 million.

Third Quarter and Recent Highlights

- Celldex continued to advance the CDX-011 program, including requesting and preparing for an end-of-Phase 2 meeting with the Food and Drug Administration to discuss future clinical and regulatory development for this program. In May of 2012, Celldex presented positive, topline results from the Phase 2b EMERGE study of CDX-011 in patients with advanced, refractory breast cancer. Preliminary results suggested that CDX-011 induced impressive response rates compared to currently available therapies in patient subsets with advanced, refractory breast cancers with high GPNMB expression (expression in ≥25% of tumor cells) and in patients with triple negative breast cancer. Mature data from the EMERGE study will be presented at the San Antonio Breast Cancer Symposium in December.
- Celldex continued its major initiative to open clinical sites to support enrollment in the Phase 3 ACT IV study and the Phase 2 ReACT study of rindopepimut in glioblastoma. In total, there are now more than 150 clinical sites around the world that have been selected to participate in the ACT IV study and, to date, 105 of these sites are actively screening patients. The ReACT study is also well positioned, with 25 study sites selected to participate and 21 actively screening to date.
- Celldex presented positive results from its Phase 1 study of CDX-1401 in solid tumors at the Society for Immunotherapy of Cancer (SITC) Annual Meeting on October 26, 2012. The study evaluated the safety, immunogenicity and clinical activity of escalating doses of CDX-1401 plus resiquimod and/or Poly ICLC (Hiltonol™) in 45 patients with advanced malignancies that had progressed after any available curative and/or salvage therapies. 60% of patients had confirmed NY-ESO-1 expression in archived tumor sample. Thirteen patients maintained stable disease for up to 13.4 months with a median of 6.7 months. Treatment was well-tolerated and there were no dose limiting toxicities. Humoral responses were elicited in both NY-ESO-1 positive and negative patients. NY-ESO-1-specific T cell responses were absent or low at baseline, but increased post-vaccination in 53% of evaluable patients, including both CD4 and/or CD8 T cell responses. Robust immune responses were observed with CDX-1401 with resiquimod and Poly ICLC alone and in combination. The study has identified a well-tolerated and immunogenic regimen and we expect that a study sponsored by the Cancer Immunotherapy Trials Network will be initiated in 2013.
- Celldex received a new Small Business Innovation Research (SBIR) contract award totaling approximately $200,000 from the National Cancer Institute to develop the combination of two immune modulators, CDX-301 (Flt3L) and CDX-1127 (an antibody that activates CD27) for use during radiotherapy.

- Celldex recently completed patient accrual and treatment in the CDX-301 healthy volunteer study and expects to present preliminary results from this Phase 1 study at the American Society of Hematology (ASH) Annual Meeting in December 2012.

Anticipated Milestones

Celldex expects to:

- Present updated overall survival data from the rindopepimut Phase 2 ACT III, ACT II and ACTIVATE studies at the Society for Neuro-Oncology (SNO) meeting in November 2012.
- Present more mature data from the EMERGE Phase 2b study at the San Antonio Breast Cancer Symposium in December 2012.
- Complete Phase 1 accrual of the solid tumor arm of the CDX-1127 study in the fourth quarter of 2012.
- Initiate a Phase 2 pilot study of CDX-1135 in dense deposit disease (DDD), an orphan kidney disease in children and young adults, by year-end 2012. DDD is caused by uncontrolled activation of the alternative pathway of complement, which leads to progressive kidney damage and failure. CDX-1135 has been shown to inhibit the complement cascade at both the C3 and C5 levels and has shown clear biologic activity in DDD animal models and in earlier human clinical trials.
- Participate in four upcoming financial conferences, the Brean Capital 2012 Life Sciences Summit and the Lazard Capital Markets 9th Annual Healthcare Conference in November and the 2012 dbAccess BioFEST Conference and the Oppenheimer Annual Healthcare Conference in December.

Financial Highlights

Third Quarter Results

The net loss of $15.0 million for the third quarter of 2012 represents an increase of $3.2 million when compared to the net loss of $11.8 million for the same period in 2011, primarily due to increases in research and development (R&D) expenses and general and administrative (G&A) expenses, partially offset by decreases in amortization expense.

Revenues for the third quarter of 2012 increased when compared to revenues in 2011, primarily because of Rotarix® related product royalty revenues and contracts and grants revenue received related to an APC-based HIV vaccine being funded through an SBIR grant in collaboration with The Rockefeller University.

R&D expenses in the third quarter of 2012 and 2011 were $11.8 million and $8.6 million, respectively, an increase of $3.2 million from 2011 to 2012. The increase in R&D expenses between 2012 and 2011 primarily reflect higher costs related to our rindopepimut program, including the ACT IV and ReACT clinical trials, and related consulting expenses in 2012.

G&A expenses in the third quarters of 2012 and 2011 were $2.8 million and $2.3 million, respectively, an increase of $0.5 million from 2011 to 2012. G&A expense in 2012 included higher personnel-related, consulting, and rindopepimut-related commercialization expenses compared to 2011.

Nine Month Results

The net loss of $42.3 million for the first nine months of 2012 represents an increased loss of $10.2 million when compared to the net loss of $32.1 million for the same period in 2011. The increased loss resulted from higher R&D expenses primarily for clinical trial costs and higher G&A expenses, partially offset by lower amortization expenses in 2012.

Revenues for the first nine months of 2012 and 2011 were $7.6 million and $6.8 million, respectively, an increase of $0.8 million from 2011 to 2012. Higher product royalty, contracts and grants revenues were experienced in 2012.

R&D expense for the first nine months of 2012 was $33.7 million, an increase of $11.1 million compared to $22.6 million in 2011. Increases in costs were primarily related to our rindopepimut program, including the ACT IV and ReACT clinical trials, and related consulting expenses in 2012.

G&A expense was $7.4 million and $6.8 million in the first nine months of 2012 and 2011, respectively. Higher personnel-related, consulting and rindopepimut-related commercialization expenses as well as investor relations expenses related to our R&D Day held earlier this year were offset in part by lower insurance and professional services costs in 2012 compared to 2011.

As of September 30, 2012, Celldex had approximately 60.8 million shares outstanding.

About Celldex Therapeutics, Inc.

Celldex Therapeutics is the first antibody-based combination immunotherapy company. Celldex has a pipeline of drug candidates in development for the treatment of cancer and other difficult-to-treat diseases based on its antibody focused Precision Targeted Immunotherapy (PTI) Platform. The PTI Platform is a complementary portfolio of monoclonal antibodies, antibody-targeted vaccines and immunomodulators used in optimal combinations to create novel disease-specific drug candidates. For more information, please visit 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 limited cash reserves and our ability to obtain additional capital 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 APC Targeting Technology™ 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 OF OPERATIONS DATA	Quarter Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(Unaudited)		(Unaudited)	
REVENUE				
Product Development and Licensing Agreements	$ 28	$ 40	$ 103	$ 65
Contracts and Grants	79	5	228	5
Product Royalties	3,006	2,318	7,224	6,761
Total Revenue	3,113	2,363	7,555	6,831
OPERATING EXPENSE				
Research and Development	11,769	8,594	33,650	22,615
Royalty	3,006	2,318	7,224	6,761
General and Administrative	2,835	2,273	7,372	6,849
Amortization of Acquired Intangible Assets	254	656	836	1,622
Total Operating Expense	17,864	13,841	49,082	37,847

Operating Loss	(14,751)	(11,478)	(41,527)	(31,016)
Investment and Other Income, Net	105	144	436	307
Interest Expense	(381)	(438)	(1,225)	(1,358)
Net Loss	$ (15,027)	$ (11,772)	$ (42,316)	$ (32,067)
Basic and Diluted Net Loss per Common Share	$ (0.25)	$ (0.27)	$ (0.75)	$ (0.85)
Weighted Average Common Shares Outstanding	59,467	44,136	56,090	37,926

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2012 (Unaudited)	December 31, 2011
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 77,615	$ 53,312
Other Current Assets	1,195	1,372
Property and Equipment, net	7,566	9,093
Intangible and Other Assets, net	33,461	34,217
Total Assets	$ 119,837	$ 97,994
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 15,131	$ 14,298
Long-Term Liabilities	13,691	14,974
Stockholders' Equity	91,015	68,722
Total Liabilities and Stockholders' Equity	$ 119,837	$ 97,994

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