

March 7, 2013

# **Celldex Reports Fourth Quarter and Fiscal 2012 Financial Results**

# Management to Host Conference Call to Discuss Results and Provide 2013 Outlook Today, Thursday, March 7, at 8:30 a.m. Eastern Time

NEEDHAM, Mass., March 7, 2013 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today reported financial results for the fourth quarter and the year ended December 31, 2012. Celldex reported a net loss of \$16.8 million, or (\$0.27) per share, for the fourth quarter of 2012 compared to net loss of \$12.7 million, or (\$0.29) per share, for the fourth quarter of 2012 compared to net loss of \$12.7 million, or (\$0.29) per share, for the fourth quarter of 2012 compared to net loss of \$12.7 million, or (\$0.29) per share, for the fourth quarter of 2012 compared to net loss of \$12.7 million, or (\$0.29) per share, for the fourth quarter of 2011. For the twelve months ended December 31, 2012, Celldex reported a net loss of \$59.1 million, or (\$1.02) per share, compared to a net loss of \$44.8 million, or (\$1.13) per share, for the twelve months ended December 31, 2011. At December 31, 2012, Celldex reported cash, cash equivalents and marketable securities of \$84.0 million. Following recent financings, as of February 28, 2013, Celldex had cash, cash equivalents and marketable securities of approximately \$189 million.

"Celldex ended 2012 reporting positive data from four clinical programs at major medical meetings, including final results from our Phase 2b study of CDX-011 in metastatic breast cancer," said Anthony Marucci, Chief Executive Officer of Celldex Therapeutics. "Based on the CDX-011 final data package and subsequent discussions with the FDA, we look forward to initiating a randomized trial suitable for accelerated approval in patients with triple negative breast cancer that also over-express GPNMB in the second half of 2013."

Marucci continued, "Importantly, we begin 2013 well-financed with a current cash position that will support operations and clinical development through 2015. To that end, in addition to the CDX-011 accelerated approval study, we will also initiate new clinical studies and expansion studies for four other Celldex programs in 2013. We expect data from three clinical

studies by year end—including from our Phase 2 study of rindopepimut with Avastin<sup>®</sup> in refractory glioblastoma. To close what will already be a very busy year, we also look forward to completing enrollment in the rindopepimut ACT IV registration trial in frontline glioblastoma."

# Fourth Quarter and Recent Highlights

- Presented positive final results from the <u>Phase 2b EMERGE study</u> of CDX-011 in patients with GPNMB-expressing, advanced, heavily pretreated breast cancer at the San Antonio Breast Cancer Symposium in December. Progression free and overall survival benefits were demonstrated in the subgroup of patients with triple negative disease that also over-expressed GPNMB, and strong trends towards benefits were seen in all patients with over-expression of GPNMB.
- Announced impressive <u>three-year survival data</u> across three Phase 2 studies of rindopepimut, in EGFRvIII-positive glioblastoma at the Society for Neuro-Oncology Annual Meeting in November. In addition, Celldex announced a new contemporary historical control data set compiled from the Radiation Therapy Oncology Group (RTOG)'s Phase 3 0525 study that continues to demonstrate that patients with EGFRvIII-positive glioblastoma fare worse than the general glioblastoma patient population. Importantly, the data set provides further confidence in the ACT IV registration study design.
- 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. In total, there are now more than 142 clinical sites around the world that are actively screening patients to participate in the ACT IV study. The ReACT study is also well-positioned, with all 25 study sites actively screening to date.
- Presented positive results from the <u>Phase 1 study of CDX-1401</u> in solid tumors at the Society for Immunotherapy of Cancer Annual Meeting in October 2012. The study identified a well-tolerated and immunogenic regimen.
- Completed enrollment in the <u>Phase 1 portion of the CDX-1127</u> solid tumor arm. CDX-1127 was determined to be welltolerated to date, including at the highest dose level. Celldex continues to enroll patients in the dose escalation portion of the lymphoma and leukemia arm.
- Presented final results from a <u>Phase 1 multi-dose study of CDX-301</u> (rhuFlt3L) in healthy volunteers in an oral presentation at the American Society for Blood and Marrow Transplantation 2013 BMT Tandem Meetings in February

2013. The study demonstrated that CDX-301 was well-tolerated and can effectively mobilize hematopoietic cell populations in healthy volunteers.

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 pivotal, randomized, accelerated approval study of CDX-011 in patients with triple negative breast cancers that over-express GPNMB in the second half.
- Complete enrollment of the Phase 1 dose-escalation and expansion studies of CDX-1127 in patients with hematologic cancers and initiate expansion cohorts in both solid tumors and hematologic malignancies. Report data from this study in the second half.
- Initiate a pilot study of CDX-1135 in dense deposit disease, an orphan renal disease in children and young adults, with data expected by year end.
- Initiate a pilot clinical study of CDX-301 in hematopoietic stem cell transplant in the second half.
- 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.

## Fourth Quarter and Year-to-Date Financial Highlights

The increase in net loss of \$4.1 million between the fourth quarters of 2012 and 2011 is primarily due to higher research and development (R&D) expense as a result of higher clinical trials costs for the rindopepimut Phase 3 and Phase 2 programs. General and administrative (G&A) expense in the fourth quarter of 2012 increased by \$0.3 million from \$2.3 million in 2011 due primarily to higher personnel-related expenses in 2012. The increase in cash, cash equivalents and marketable securities of \$6.3 million from September 30, 2012 primarily reflects the issuance of 3.5 million shares during the quarter through our Cantor ATM facility that raised net proceeds to Celldex of \$20.9 million, partially offset by our fourth quarter operations-related cash burn of approximately \$13.3 million and principal payments on our term loan of \$1.3 million.

The net loss of \$59.1 million for 2012 represents an increased loss of \$14.3 million when compared to the net loss of \$44.8 million for the same period in 2011 and is primarily due to increased R&D expense. R&D expense in 2012 increased by \$15.0 million compared to 2011 and was primarily a result of increased later-stage clinical trials costs of \$14.3 million in 2012 related to the rindopepimut program. G&A expenses increased by \$0.8 million to \$10.0 million in 2012 compared to \$9.2 million in 2011, primarily due to increased personnel-related expenses and rindopepimut-related commercial planning costs in 2012.

As of December 31, 2012, Celldex had approximately 64.4 million shares outstanding. As a result of our financing transactions in January and February 2013, we now have 80.6 million shares outstanding.

#### Webcast and Conference Call

Celldex will host a conference call and live audio webcast at 8:30 a.m. ET on Thursday, March 7, 2013 to discuss Celldex's fourth quarter and twelve month 2012 financial results and to provide an update on anticipated research and development and business objectives for 2013. The conference call and presentation will be webcast live over the Internet and can be accessed by logging on to "Events & Presentations" under the "Investors & Media" section of the Celldex Therapeutics' website at <u>www.celldextherapeutics.com</u>. The call can also be accessed by dialing 888-350-0137 (within the United States) or 970-315-0478 (outside the United States).

A replay of the call will be available approximately two hours after the live call concludes through March 14, 2013. To access the replay, dial 855-859-2056 (within the United States) or 404-537-3406 (outside the United States). The passcode is 13866763. The webcast will also be archived on the Company's website.

#### 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 therapeutics and immunomodulators used in optimal combinations to create novel disease-specific drug candidates. For more information, please visit <u>http://www.celldextherapeutics.com</u>.

**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<sup>TM</sup> to develop new, safe and effective therapeutics for 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.

Avastin<sup>®</sup> is a registered trademark of Genentech, a member of the Roche Group.

#### CELLDEX THERAPEUTICS, INC.

#### (In thousands, except per share amounts)

| CONSOLIDATED STATEMENTS                    | Quarter      | Ended  | Year En      | ded    |
|--|--------------|--------|--------------|--------|
| OF OPERATIONS DATA                         | December 31, |        | December 31, |        |
|  | 2012         | 2011   | 2012         | 2011   |
|  | (Unauc       | lited) |              |        |
| REVENUE                                    |              |        |              |        |
| Product Development and                    |              |        |              |        |
| Licensing Agreements                       | \$ 43        | \$ 45  | \$ 146       | \$ 110 |
| Contracts and Grants                       | 53           | 30     | 281          | 36     |
| Product Royalties                          | 3,551        | 2,358  | 10,775       | 9,119  |
|  |              |        |              |        |
| Total Revenue                              | 3,647        | 2,433  | 11,202       | 9,265  |
|  |              |        |              |        |
| OPERATING EXPENSE                          |              |        |              |        |
| Research and Development                   | 13,748       | 9,824  | 47,398       | 32,439 |
| Royalty                                    | 3,551        | 2,358  | 10,775       | 9,119  |
| General and Administrative                 | 2,644        | 2,343  | 10,016       | 9,193  |
| Amortization of Acquired Intangible Assets | 254          | 291    | 1,090        | 1,913  |

| Total Operating Expense                    | 20,197      | 14,816      | 69,279      | 52,664              |
|--|-------------|-------------|-------------|---------------------|
| Operating Loss                             | (16,550)    | (12,383)    | (58,077)    | (43,399)            |
| Investment and Other Income, Net           | 94          | 89          | 530         | 396                 |
| Interest Expense                           | (351)       | (438)       | (1,576)     | (1,796)             |
| Net Loss                                   | \$ (16,807) | \$ (12,732) | \$ (59,123) | \$ (44,799 <u>)</u> |
| Basic and Diluted Net Loss                 |             |             |             |                     |
| per Common Share                           | \$ (0.27)   | \$ (0.29)   | \$ (1.02)   | \$ (1.13)           |
|  |             |             |             |                     |
| Weighted Average Common Shares Outstanding | 62,544      | 44,175      | 57,713      | 39,501              |

#### CONDENSED CONSOLIDATED

| BALANCE SHEETS  | December 31,        | December 31,        |
|---|---------------------|---------------------|
|   | 2012                | 2011                |
| ASSETS  |                     |                     |
| Cash, Cash Equivalents and Marketable Securities            | \$ 83,962           | \$ 53,312           |
| Other Current Assets  | 1,152               | 1,372               |
| Property and Equipment, net                                 | 7,205               | 9,093               |
| Intangible and Other Assets, net                            | 33,222              | 34,217              |
| Total Assets  | \$ 125,541          | \$ 97,994           |
|   |                     |                     |
| LIABILITIES AND STOCKHOLDERS' EQUITY                        |                     |                     |
| LIABILITIES AND STOCKHOLDERS' EQUITY<br>Current Liabilities | \$ 17,685           | \$ 14,298           |
|   | \$ 17,685<br>12,082 | \$ 14,298<br>14,974 |
| Current Liabilities   |                     |                     |

Corp Communications

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