

Celldex Provides Corporate Update and Reports Full Year 2018 Results

March 7, 2019

HAMPTON, N.J., March 07, 2019 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the fourth quarter and year ended December 31, 2018. The Company will host a conference call at 4:30 p.m. ET today to provide an update on its pipeline and business.

"Celldex made important progress across our pipeline in the fourth quarter, continuing to execute on our ongoing CDX-1140 and CDX-3379 clinical programs and advancing earlier stage assets that we believe have the potential to play an important role in the future of the organization," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics.

"Data from both the CDX-1140 and MerTK programs were presented at SITC in November and we look forward to providing an update on CDX-1140 at AACR in early April. In the ongoing Phase 1 study of CDX-1140 in solid tumors and B cell lymphomas, we have completed six of the potential eight monotherapy dose levels and the first of six potential combination dose levels with CDX-301 and are pleased with the safety and biological profile we have observed to date. We also continue to follow patients in the Phase 2 study of CDX-3379 in advanced head and neck squamous cell cancer and plan to present data from this study at a medical meeting in the coming months. We believe 2019 will be an important year for Celldex with data anticipated across multiple programs," concluded Marucci.

Recent Highlights:

- Enrollment continues in the Phase 1 dose-escalation study of CDX-1140 with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas. CD40 has long been an important target for immunotherapy, as it plays a critical role in the activation of innate and adaptive immune responses; however, effectively balancing systemic dosing and safety has proven challenging to date for CD40-activating therapeutics. CDX-1140 is a unique, potent CD40 agonist that Celldex believes has the potential to successfully balance systemic doses for good tissue and tumor penetration with an acceptable safety profile. Interim data from the ongoing study have been accepted for presentation on Tuesday, April 2, 2019 at the American Association for Cancer Research (AACR) Annual Meeting.
 - Data to date from the six completed dosing cohorts (0.01, 0.03, 0.09, 0.18, 0.36 and 0.72 mg/kg) suggest that CDX-1140 is exhibiting a desirable safety profile and demonstrating clear signs of biological activity based on biomarker analysis. The seventh monotherapy cohort at 1.5 mg/kg is currently being enrolled, along with the combination therapy cohort of CDX-1140 (0.18 mg/kg) with CDX-301. CDX-301 is a dendritic cell growth factor being utilized as a priming agent to increase the number of cells available to respond to CDX-1140. In addition, Celldex is evaluating the potential for combination with varlilumab, especially in lymphomas which co-express CD40 and CD27 receptors.
 - [Early data from the Phase 1 study](#) were presented in November 2018 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. Dose dependent biological effects consistent with CD40-mediated immune activation were reported; CDX-1140 was well tolerated and no MTD had been reached.
- Enrollment is complete in the first stage of the Phase 2 study (n=13) of CDX-3379 in advanced head and neck squamous cell cancer in combination with Erbitux® in Erbitux-resistant patients who have been previously treated with or are ineligible for checkpoint therapy. According to the study's Simon two-stage design, if at least one patient achieves an objective response in the first stage, enrollment may progress to the second stage. While a confirmed complete response has been documented, Celldex will conduct a comprehensive review, including the full data set, before making decisions on future development, as patients are still undergoing treatment and are eligible for evaluation. Celldex plans to present updated data from the study at a future medical meeting in 2019.
- Celldex continues to advance a robust preclinical portfolio. [Data](#) from the Company's MerTK antibody program were presented in November 2018 at the SITC Annual Meeting and have been accepted for presentation at the AACR meeting on Monday, April 1, 2019. MerTK is emerging as a promising target for cancer immunotherapy; its expression in innate immune cells is believed to negatively regulate immune responses and genetic removal of MerTK renders mice resistant to some tumors. Data from the Company's bispecific program, CDX-527, have also been accepted for presentation at AACR on Monday, April 1, 2019. CDX-527 uses Celldex's proprietary highly active anti-PD-L1 and CD27 human antibodies to couple CD27 co-stimulation with blockade of the PD-L1/PD-1 pathway.

Fourth Quarter and Twelve Months 2018 Financial Highlights and 2019 Guidance

NASDAQ Compliance: Celldex completed a one for fifteen reverse stock split, which became effective February 8, 2019. On February 11, 2019, Celldex common stock began trading on a split-adjusted basis on the NASDAQ Capital Market. On February 26, 2019, Celldex received formal notice from NASDAQ that the Company had regained compliance with the minimum \$1.00 bid price requirement. The share and per share amounts below reflect the reverse stock split.

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2018 were \$94.0 million compared to \$105.6 million as of September 30, 2018. The decrease was primarily driven by fourth quarter cash used in operating activities of \$15.4 million, of which \$1.4 million were glembatumumab vedotin-related payments, partially offset by \$3.6 million in net proceeds from sales of common stock under the Cantor agreement. At December 31, 2018, Celldex had 12.0 million shares outstanding.

Revenues: Total revenue was \$1.8 million in the fourth quarter of 2018 and \$9.5 million for the year ended December 31, 2018, compared to \$3.5 million and \$12.7 million for the comparable periods in 2017. The decrease in revenue was primarily due to lower contract revenue from the International AIDS Vaccine Initiative and Frontier Biotechnologies.

R&D Expenses: Research and development (R&D) expenses were \$11.2 million in the fourth quarter of 2018 and \$66.4 million for the year ended December 31, 2018, compared to \$23.5 million and \$96.2 million for the comparable periods in 2017. The decrease in R&D expenses was primarily due to lower clinical trial, personnel and contract manufacturing costs.

G&A Expenses: General and administrative (G&A) expenses were \$4.3 million in the fourth quarter of 2018 and \$19.3 million for the year ended December 31, 2018, compared to \$5.9 million and \$25.0 million for the comparable periods in 2017. The decrease in G&A expenses was primarily due to lower personnel and commercial planning costs.

Intangible Asset and Goodwill Impairments: During the year ended December 31, 2018, the Company recorded \$18.7 million in non-cash impairment charges related to fully impaired glemba-related intangible assets and \$91.0 million in goodwill impairment charges as the carrying value of the Company's net assets exceeded the Company's fair value by an amount in excess of the goodwill asset.

Changes in Fair Value Remeasurement of Contingent Consideration: During the year ended December 31, 2018, the Company recorded a \$29.6 million gain on the fair value remeasurement of contingent consideration related to the Koltan acquisition primarily due to discontinuation of the glembatumumab vedotin and CDX-014 programs and updated assumptions for the varilumab and anti-KIT programs.

Net Loss: Net loss was \$9.4 million, or (\$0.81) per share, for the fourth quarter of 2018 and \$151.2 million, or (\$14.48) per share, for the year ended December 31, 2018, compared to a net loss of \$3.8 million, or (\$0.42) per share, and \$93.0 million, or (\$10.86) per share, for the comparable periods in 2017.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 2018, combined with the anticipated proceeds from future sales of common stock under the Cantor agreement, are sufficient to meet estimated working capital requirements and fund planned operations through 2020. This could be impacted if Celldex elects to pay Koltan contingent milestones, if any, in cash.

Webcast and Conference Call

Celldex executives will host a conference call at 4:30 p.m. ET today to discuss financial and business results and to provide an update on key 2019 objectives. The conference call will be webcast live over the internet and can be accessed by going to the "Events & Presentations" page under the "Investors & Media" section of the Celldex Therapeutics website at www.celldex.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 9948977.

A replay of the call will be available approximately two hours after the live call concludes through March 14, 2019. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 9948977. 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 includes immunotherapies and other targeted biologics derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. 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. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These 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 or that those goals will be achieved, 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 Company 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 maintain compliance with Nasdaq listing requirements; our ability to realize the anticipated benefits from the acquisition of Koltan; 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 and quarterly reports on Form 10-Q.

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.

Company Contact

Sarah Cavanaugh
Senior Vice President, Corporate Affairs & Administration
Celldex Therapeutics, Inc.
(781) 433-3161
scavanaugh@celldex.com

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

**CONSOLIDATED STATEMENTS
OF OPERATIONS DATA**

	Three Months Ended December 31,		Year Ended December 31,	
	2018	2017	2018	2017
	(Unaudited)			
REVENUES:				
Product Development and Licensing Agreements	\$ 549	\$ 665	\$ 3,341	\$ 3,153
Contracts and Grants	1,215	2,791	6,197	9,590
Total Revenue	1,764	3,456	9,538	12,743
OPERATING EXPENSES:				
Research and Development	11,207	23,464	66,449	96,171
General and Administrative	4,332	5,894	19,269	25,003
Goodwill Impairment	-	-	90,976	-
Intangible Asset Impairment	-	-	18,677	13,000
Gain on Fair Value Remeasurement of Contingent Consideration	(1,653)	(600)	(29,621)	(800)
Amortization of Acquired Intangible Assets	-	224	224	896
Total Operating Expense	13,886	28,982	165,974	134,270
Operating Loss	(12,122)	(25,526)	(156,436)	(121,527)
Investment and Other Income, Net	2,720	2,603	4,487	4,214
Net Loss Before Income Tax Benefit	(9,402)	(22,923)	(151,949)	(117,313)
Income Tax Benefit	-	19,082	765	24,282
Net Loss	\$ (9,402)	\$ (3,841)	\$ (151,184)	\$ (93,031)
Basic and Diluted Net Loss per Common Share	\$ (0.81)	\$ (0.42)	\$ (14.48)	\$ (10.86)
Shares Used in Calculating Basic and Diluted Net Loss per Share	11,626	9,101	10,442	8,570

(Reflects one for fifteen reverse stock split effective February 8, 2019)

**CONDENSED CONSOLIDATED
BALANCE SHEETS DATA**

	December 31, 2018	December 31, 2017
ASSETS		
Cash, Cash Equivalents and Marketable Securities	\$ 94,022	\$ 139,427
Other Current Assets	5,057	5,329
Property and Equipment, net	6,111	10,372
Intangible and Other Assets, net	50,619	160,496
Total Assets	\$ 155,809	\$ 315,624
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	\$ 12,602	\$ 27,736

Long-Term Liabilities	19,147	51,519
Stockholders' Equity	124,060	236,369
Total Liabilities and Stockholders' Equity	\$ 155,809	\$ 315,624



Source: Celldex Therapeutics, Inc.