Celldex Therapeutics, Inc. Logo

Celldex Provides Corporate Update and Reports Third Quarter 2018 Results

November 7, 2018

HAMPTON, N.J., Nov. 07, 2018 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the third quarter ended September 30, 2018.

“We made considerable progress in the third quarter, particularly in the development program for CDX-1140, our promising antibody targeted to CD40,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We have completed four of the potential eight monotherapy dose levels in the ongoing Phase 1 study and remain encouraged by the safety and biological profile we have observed to date. We look forward to sharing interim data at the SITC Annual Meeting later this week. During the third quarter, we also began enrolling patients in a combination cohort of CDX-1140 with our dendritic cell mobilizer, CDX-301. We are very interested to explore the potential of CDX-1140 in the presence of greater dendritic cell activity.”

“Additionally, we are nearing completion of enrollment to the first stage of the Phase 2 study of CDX-3379 in advanced head and neck squamous cell cancer and anticipate data from this portion of the study in the first quarter of 2019,” continued Marucci. “We are also advancing several preclinical programs that we believe can play an important role in enhancing the immune system’s response to cancer, including CDX-0159, our TAM program targeting Tyro3, AXL and MerTK, and our growing bispecific antibody program.”

Recent Highlights:

- Enrollment continues in the Phase 1 dose-escalation study of CDX-1140 in solid tumors. Interim data from the ongoing study have been accepted for presentation on Friday, November 9, 2018 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting. This study is designed to enroll up to 150 patients with recurrent, locally advanced or metastatic solid tumors and was recently amended to also include 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. Data to date from the four completed dosing cohorts (0.01, 0.03, 0.09 and 0.18 mg/kg) suggest that CDX-1140 is exhibiting a desirable safety profile and demonstrating early signs of biological activity based on biomarker analysis. The fifth monotherapy cohort at 0.36 mg/kg is currently being enrolled, along with the combination therapy cohort of CDX-1140 (0.09 mg/kg) with CDX-301 which was initiated in late August. CDX-301 is a dendritic cell growth factor that will be used as a priming agent to potentially 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.

- Enrollment is nearing completion 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 partial response has been documented, Celldex will wait to review the full data set before making decisions on future development, as a number of patients are still undergoing treatment and are not yet eligible for response evaluation.

- Data from the glioblastoma cohort in the Phase 1/2 study of varlilumab and Opdivo® have been accepted for presentation on Saturday, November 17, 2018 at the Society for Neuro-oncology (SNO) Annual Meeting.

- As previously disclosed, on May 29, 2018, Celldex received written notice from the Listing Qualifications department of the Nasdaq Stock Market indicating that the Company was not in compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Global Market. As is standard, the Company was afforded 180 days to regain compliance. Unless Celldex regains compliance with the minimum bid requirement by November 26, 2018 (the 180th day), the Company plans to apply to transfer to the Nasdaq Capital Market. Assuming Celldex’s application is accepted, the proposed transition should be seamless for Celldex shareholders and should allow the company an additional 180-day period in which to regain compliance. If Celldex is unable to regain compliance with the minimum bid price requirement, the Company may implement a reverse stock split to maintain its listing, a measure that was approved by shareholders at the Company’s 2018 Annual Meeting.

Third Quarter 2018 and First Nine Months 2018 Financial Highlights and 2018 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2018 were $105.6 million compared to $114.0 million as of June 30, 2018. The decrease was primarily driven by third quarter cash used in operating activities of approximately $14.4 million, of which $3.2 million were glembatumumab vedotin-related payments, partially offset by the receipt of $5.5 million from sales of common stock under the Cantor agreement. Celldex expects that it will make an additional $2.0 million in glembatumumab vedotin-related payments related to the discontinuation of that program. At September 30, 2018, Celldex had 168.6 million shares outstanding.

Revenues: Total revenue was $0.9 million in the third quarter of 2018 and $7.8 million for the nine months ended September 30, 2018, compared to $3.9 million and $9.3 million for the comparable periods in 2017. The decrease in revenue was primarily due to lower contract revenue from the International AIDS Vaccine Initiative.

R&D Expenses: Research and development (R&D) expenses were $11.9 million in the third quarter of 2018 and $55.2 million for the nine months ended September 30, 2018, compared to $21.9 million and $72.7 million for the comparable periods in 2017. The decrease in R&D expense was primarily due to lower clinical trial, contract manufacturing and personnel expenses.

G&A Expenses: General and administrative (G&A) expenses were $3.7 million in the third quarter of 2018 and $14.9 million for the nine months ended September 30, 2018, compared to $5.3 million and $19.1 million for the comparable periods in 2017. The decrease in G&A expenses was primarily due to lower personnel and marketing expenses.

Changes in Fair Value Remeasurement of Contingent Consideration: Gain on the fair value remeasurement of contingent consideration related to the Kolltan acquisition was $6.9 million in the third quarter of 2018 and $28.0 million for the nine months ended September 30, 2018, primarily due to discontinuation of the glembatumumab vedotin and CDX-014 programs and updated assumptions for the varlilumab and anti-KIT programs.

Net Loss: Net loss was $7.2 million, or ($0.04) per share, for the third quarter of 2018, and $141.8 million, or ($0.94) per share, for the nine months ended September 30, 2018, compared to a net loss of $26.4 million, or ($0.20) per share, for the third quarter of 2017 and $89.2 million, or ($0.71) per share, for the nine months ended September 30, 2017.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 30, 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 Kolltan contingent milestones, if any, in cash.

Opdivo® is a registered trademark of Bristol-Myers Squibb. Erbitux® is a registered trademark of Eli Lilly & Co.

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 meet, and with respect to the minimum bid price requirement, to regain compliance with, Nasdaq listing requirements; our ability to realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently; 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.

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

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	**Quarter Ended September 30,**		**Nine Months Ended September 30,**	
	2018	**2017**	**2018**	**2017**
	(Unaudited)		**(Unaudited)**	
REVENUE				
Product Development and				

Licensing Agreements	$ 131	$ 1,238	$ 2,792	$ 2,488
Contracts and Grants	810	2,686	4,982	6,799
Total Revenue	941	3,924	7,774	9,287
OPERATING EXPENSE				
Research and Development	11,918	21,915	55,242	72,707
General and Administrative	3,722	5,346	14,936	19,109
Goodwill Impairment	-	-	90,976	-
Intangible Asset Impairment	-	13,000	18,677	13,000
Gain on Fair Value Remeasurement of Contingent Consideration	(6,935)	(4,600)	(27,968)	(200)
Amortization of Acquired Intangible Assets	-	224	224	672
Total Operating Expense	8,705	35,885	152,087	105,288
Operating Loss	(7,764)	(31,961)	(144,313)	(96,001)
Investment and Other Income, Net	521	398	1,767	1,611
Net Loss Before Income Tax Benefit	(7,243)	(31,563)	(142,546)	(94,390)
Income Tax Benefit	-	5,200	765	5,200
Net Loss	$ (7,243)	$ (26,363)	$ (141,781)	$ (89,190)
Basic and Diluted Net Loss per Common Share	$ (0.04)	$ (0.20)	$ (0.94)	$ (0.71)
Weighted Average Common Shares Outstanding	163,679	129,640	150,636	125,856

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	**September 30, 2018 (Unaudited)**	**December 31, 2017**
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 105,618	$ 139,427
Other Current Assets	5,351	5,329
Property and Equipment, net	6,699	10,372
Intangible and Other Assets, net	50,619	160,496
Total Assets	$ 168,287	$ 315,624
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 16,851	$ 27,736
Long-Term Liabilities	23,302	51,519
Stockholders' Equity	128,134	236,369
Total Liabilities and Stockholders' Equity	$ 168,287	$ 315,624

Source: Celldex Therapeutics, Inc.