Celldex Therapeutics, Inc. Logo

Celldex Provides Corporate Update and Reports First Quarter 2019 Results

May 7, 2019

HAMPTON, N.J., May 07, 2019 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the first quarter ended March 31, 2019.

“Celldex presented positive data across multiple programs at AACR in April, including from our promising CDX-1140 program,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We have successfully cleared a critical hurdle for CD40 agonists, reaching dose levels with good systemic exposure that are biologically active and well tolerated. Importantly, these dose levels exceed the maximum tolerated dose levels reported with other CD40 agonists, which we believe may support enhanced tissue and tumor penetration. We are also pleased with the results to date in our unique combination of CDX-1140 with CDX-301, where CDX-301 amplifies the numbers of dendritic cells in patients prior to their activation with CDX-1140. To this end, we continue to believe that CDX-1140 can play a very important role in cancer immunotherapy, especially in combination with drugs that target other key immune pathways and are actively planning additional combination cohorts to begin later this year.”

“We also recently completed the first stage of the Phase 2 study of CDX-3379 and are pleased that this portion of the study met the clinical criteria that are required to progress the study to the next stage. We look forward to presenting more detailed data from this study at ASCO in early June. We are currently conducting a thorough analysis of the overall CDX-3379 program in collaboration with our clinical advisors to determine the optimal path for this candidate. In conclusion, we continue to make considerable progress across our entire pipeline and look forward to updating shareholders over the course of the year,” said Marucci.

Recent Highlights:

- CDX-1140—a 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.
    - Enrollment is nearing completion in the monotherapy arm and progressing on track in the CDX-301 combination arm of the Phase 1 dose-escalation study of CDX-1140 with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas. Seven monotherapy dosing cohorts ranging from 0.01 to 1.5 mg/kg have been completed and the dose limiting toxicity (DLT) window successfully cleared; patients are currently being enrolled in the final monotherapy cohort at 3.0 mg/kg. Two combination cohorts in solid tumors (0.09 and 0.18 mg/kg) with CDX-301 have been completed and the DLT window successfully cleared. Patients enrolled in the third cohort at 0.36 mg/kg have been dosed and are currently completing the DLT observation period. Assuming successful clearance, the 0.72 mg/kg combination cohort with CDX-301 should open shortly.
    - Additional patient enrollment (backfill) has been initiated to characterize the effects of CDX-1140 in the tumor microenvironment and expansion cohorts are being actively planned. Future combination opportunities include PD-1 or PD-L1 inhibitors, chemotherapy, radiation therapy and Celldex’s potent CD27 agonist monoclonal antibody varlilumab.
    - Data from the ongoing study were presented at the American Association for Cancer Research (AACR) Annual Meeting 2019 in April and support that CDX-1140 is a potent activator of CD40 and can be safely administered at doses that Celldex believes will support good tissue and tumor penetration.
- CDX-3379—a differentiated human monoclonal antibody designed to block the activity of ErbB3 (HER3). ErbB3 is expressed in many cancers, including head and neck squamous cell cancer (HNSCC) and is believed to be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies.
    - As previously reported, enrollment is complete in the first stage of the Phase 2 study (n=13) of CDX-3379 in advanced HNSCC 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 is currently conducting a comprehensive review to inform decisions on potential future development. Celldex plans to present updated data from the study in a poster session at the 2019 American Society for Clinical Oncology (ASCO) Annual Meeting on Saturday, June 1, 2019.
- Celldex continues to advance a robust preclinical portfolio with data from multiple programs presented at AACR.
    - Data from the Company’s CDX-527 bispecific candidate and its TAM program were presented at the AACR Annual Meeting 2019 in April. 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. TAM receptors (Tyro3, Axl, MerTK) are

receptor tyrosine kinases (RTKs) expressed in innate immune cells. These receptors have been gaining importance in the immunotherapy field due to their role as checkpoint molecules on macrophages, dendritic cells, and other immune cells, where they can negatively regulate anti-tumor immunity.

First Quarter 2019 Financial Highlights and 2019 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2019 were $85.1 million compared to $94.0 million as of December 31, 2018. The decrease was primarily driven by first quarter cash used in operating activities of $13.2 million, partially offset by $4.2 million in net proceeds from sales of common stock under the Cantor agreement. At March 31, 2019, Celldex had 12.8 million shares outstanding.

Revenues: Total revenue was $1.4 million in the first quarter of 2019 compared to $4.1 million for the comparable period in 2018. The decrease in revenue was primarily due to lower revenue from the contract manufacturing and research and development agreement with the International AIDS Vaccine Initiative and the collaboration agreement with Bristol-Myers Squibb Company.

R&D Expenses: Research and development (R&D) expenses were $11.2 million in the first quarter of 2019 compared to $21.9 million for the comparable period in 2018. 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 $4.9 million in the first quarter of 2019 compared to $5.6 million for the comparable period in 2018. The decrease in G&A expenses was primarily due to lower personnel and commercial planning costs.

Intangible Asset and Goodwill Impairments: During the quarter ended March 31, 2018, the Company recorded $18.7 million in non-cash impairment charges related to fully impaired glembatumumab vedotin-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 quarter ended March 31, 2019, the Company recorded a $1.5 million loss on fair value remeasurement of contingent consideration primarily due to changes in discount rates and the passage of time. During the quarter ended March 31, 2018, the Company recorded a $13.6 million gain on the fair value remeasurement of contingent consideration primarily due to updated assumptions for glembatumumab vedotin-related milestones as a result of the METRIC study failure and discontinuation of the glembatumumab vedotin program.

Net Loss: Net loss was $17.2 million, or ($1.40) per share, for the first quarter of 2019 compared to a net loss of $118.1 million, or ($12.61) per share, for the comparable period in 2018.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2019, 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.

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 maintain compliance with Nasdaq listing requirements; our ability to realize the anticipated benefits from the acquisition of Kolltan; 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	**Three Months Ended March 31, 2019 (Unaudited)**	**2018**
REVENUES:		
Product Development and Licensing Agreements	$ 129	$ 992
Contracts and Grants	1,296	3,076
Total Revenue	1,425	4,068
OPERATING EXPENSES:		
Research and Development	11,151	21,875
General and Administrative	4,896	5,593
Goodwill Impairment	-	90,976
Intangible Asset Impairment	-	18,677
Other Asset Impairment	1,800	-
Loss/(Gain) on Fair Value Remeasurement of Contingent Consideration	1,519	(13,600)
Amortization of Acquired Intangible Assets	-	224
Total Operating Expense	19,366	123,745
Operating Loss	(17,941)	(119,677)
Investment and Other Income, Net	702	780
Net Loss Before Income Tax Benefit	(17,239)	(118,897)
Income Tax Benefit	-	765
Net Loss	$ (17,239)	$ (118,132)
Basic and Diluted Net Loss per Common Share	$ (1.40)	$ (12.61)
Shares Used in Calculating Basic and Diluted Net Loss per Share	12,297	9,370

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	**March 31, 2019 (Unaudited)**	**December 31, 2018**
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 85,068	$ 94,022
Other Current Assets	3,783	5,057
Property and Equipment, net	5,462	6,111
Intangible and Other Assets, net	53,264	50,619
Total Assets	$ 147,577	$ 155,809
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 11,989	$ 12,602
Long-Term Liabilities	22,895	19,147
Stockholders' Equity	112,693	124,060
Total Liabilities and Stockholders' Equity	$ 147,577	$ 155,809

Source: Celldex Therapeutics, Inc.