Celldex Therapeutics, Inc. Logo

Celldex Provides Corporate Update and Reports Second Quarter 2018 Results

August 8, 2018

HAMPTON, N.J., Aug. 08, 2018 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the second quarter ended June 30, 2018. The Company will host a conference call at 4:30 p.m. ET today to provide an in-depth update on its pipeline and upcoming milestones for 2018.

“During the second quarter, we continued to focus on advancing CDX-1140, our promising antibody targeted to CD40, a key activator of immune response, and CDX-3379, which blocks the ErbB3 receptor, an important regulator of cancer cell growth and survival,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We have completed the third monotherapy dose level in the ongoing Phase 1 study of CDX-1140 and are encouraged with the tolerability, immune system activation and early signs of biological activity we have seen to date. We will also be exploring the potential of combining CDX-1140 with our dendritic cell mobilizer, CDX-301, and plan to begin enrolling those cohorts in September. In the next few months, we expect to complete enrollment in the first stage of our Phase 2 combination study of CDX-3379 and Erbitux® in advanced head and neck squamous cell carcinoma. Additionally, we have IND enabling studies underway with CDX-0159, our anti-KIT antibody, with the aim of adding it as a new clinical program in 2019.”

Recent Highlights:

- Enrollment continues in the Phase 1 dose-escalation study of CDX-1140 in multiple types of solid tumors. 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, balancing systemic dosing and safety has proven elusive to date for CD40 targeted 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. Three dosing cohorts have been completed, 0.01, 0.03 and 0.09 mg/kg, and data to date from these cohorts suggest that CDX-1140 has a desirable safety profile and, based on biomarker data, is demonstrating early signs of biological activity. The fourth cohort at 0.18 mg/kg is currently being enrolled. As planned, the study protocol was recently amended to explore CDX-1140 in combination with CDX-301, and enrollment to this cohort is expected to begin in September. 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, combination with varlilumab could have significant potential, especially in lymphomas which co-express CD40 and CD27 receptors.

- Enrollment continues in the Phase 2 study of CDX-3379 in advanced head and neck squamous cell carcinoma (HNSCC) in combination with Erbitux in Erbitux-resistant patients who have been previously treated with checkpoint therapy or are not candidates for checkpoint therapy. Celldex intends to complete enrollment to the first stage of the Phase 2 study and will use these data to inform next decisions. In line with this, the Company continues to explore potential other opportunities in additional indications where ErbB3 is believed to play a role.

- Data from the Phase 1/2 study of varlilumab in combination with Opdivo® across multiple solid tumors were presented in an oral presentation at the 2018 ASCO Annual Meeting in June. In the ovarian cancer cohort, for patients with paired tumor samples from before and during treatment, increases in tumor expression of PD-L1 and CD8+ tumor infiltrating lymphocyte (TIL) levels were observed. These increases were associated with improved clinical outcomes, including improved progression-free survival (PFS) and response rate. Celldex recently reviewed preliminary data from the HNSCC and renal cell carcinoma (RCC) cohorts. Twenty-seven patients with HNSCC were treated in the study (3 in Phase 1; 24 in Phase 2). Patients had a median of two prior lines of therapy. 96% had Stage IV disease. 63% had PD-L1 negative tumors. 52% had HPV positive tumors. The overall response rate was 15% (n=4 confirmed) across 27 response-evaluable patients. In this small sample size, no correlation between PD-L1 status and clinical outcome was observed. Given the changing treatment paradigm in renal cell carcinoma, only 14 patients with RCC were treated in the study, all in Phase 2. All patients had prior anti-angiogenic therapy, with a range of 1 to 4 prior treatments. 100% had Stage IV disease, and 50% had PD-L1 negative tumors. 39% of patients experienced stable disease. Celldex plans to present data from the glioblastoma cohort at a medical meeting later this year.

Second Quarter and First Six Months 2018 Financial Highlights and 2018 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2018 were $114.0 million compared to $123.2 million as of March 31, 2018. The decrease was primarily driven by second quarter cash used in operating activities of approximately $17.4 million, of which $5.5 million were glembatumumab vedotin-related payments, partially offset by the receipt of $8.3 million from sales of common stock under the Cantor agreement. Celldex expects that it will make an additional $5.0 to $6.0 million in glembatumumab vedotin-related payments related to the discontinuation of that program. At June 30, 2018, Celldex had 156.6 million shares outstanding.

Revenues: Total revenue was $2.8 million in the second quarter of 2018 and $6.8 million for the six months ended June 30, 2018, compared to $3.8 million and $5.4 million for the comparable periods in 2017. The decrease in revenue for the second quarter of 2018 compared to the second quarter of 2017 was primarily due to lower contract revenue from the International AIDS Vaccine Initiative. The increase in revenue for the six months ended

June 30, 2018 compared to the six months ended June 30, 2017 was primarily due to an increase in revenue related to the collaboration agreement with Bristol-Myers Squibb Company.

R&D Expenses: Research and development (R&D) expenses were $21.4 million in the second quarter of 2018 and $43.3 million for the six months ended June 30, 2018, compared to $25.0 million and $50.8 million for the comparable periods in 2017. The decrease in R&D expenses was primarily due to lower personnel, clinical trial, contract manufacturing and contract research expense, partially offset by severance expense of $1.0 million.

G&A Expenses: General and administrative (G&A) expenses were $5.6 million in the second quarter of 2018 and $11.2 million for the six months ended June 30, 2018, compared to $6.5 million and $13.8 million for the comparable periods in 2017. The decrease in G&A expenses was primarily due to lower personnel and marketing expense.

Changes in Fair Value Remeasurement of Contingent Consideration: Gain on the fair value remeasurement of contingent consideration related to the Kolltan acquisition was $7.4 million in the second quarter of 2018 and $21.0 million for the six months ended June 30, 2018, primarily due to discontinuation of the glembatumumab vedotin and CDX-014 programs and updated assumptions for the varlilumab program.

Net Loss: Net loss was $16.4 million, or ($0.11) per share, for the second quarter of 2018, and $134.5 million, or ($0.93) per share, for the six months ended June 30, 2018, compared to a net loss of $28.6 million, or ($0.23) per share, for the second quarter of 2017 and $62.8 million, or ($0.51) per share, for the six months ended June 30, 2017.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 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.

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 2018 objectives. The conference call and presentation 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 4768019.

A replay of the call will be available approximately two hours after the live call concludes through August 15, 2018. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 4768019. The webcast will also be archived on the Company's website.

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 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.

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	Quarter Ended June 30, 2018 (Unaudited)	2017	Six Months Ended June 30, 2018 (Unaudited)	2017
REVENUE				
Product Development and Licensing Agreements	$ 1,667	$ 694	$ 2,662	$ 1,250
Contracts and Grants	1,096	3,135	4,172	4,113
Total Revenue	2,763	3,829	6,834	5,363
OPERATING EXPENSE				
Research and Development	21,448	24,999	43,323	50,792
General and Administrative	5,621	6,534	11,215	13,763
Goodwill Impairment	-	-	90,976	-
Intangible Asset Impairment	-	-	18,677	-
(Gain)/Loss on Fair Value Remeasurement of Contingent Consideration	(7,433)	1,000	(21,033)	4,400
Amortization of Acquired Intangible Assets	-	224	224	448
Total Operating Expense	19,636	32,757	143,382	69,403
Operating Loss	(16,873)	(28,928)	(136,548)	(64,040)
Investment and Other Income, Net	466	362	1,245	1,213
Net Loss Before Income Tax Benefit	(16,407)	(28,566)	(135,303)	(62,827)
Income Tax Benefit	-	-	765	-
Net Loss	$ (16,407)	$ (28,566)	$ (134,538)	$ (62,827)
Basic and Diluted Net Loss per Common Share	$ (0.11)	$ (0.23)	$ (0.93)	$ (0.51)
Weighted Average Common Shares Outstanding	147,428	125,202	144,007	123,932

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	June 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 114,009	$ 139,427
Other Current Assets	6,271	5,329
Property and Equipment, Net	7,478	10,372
Intangible and Other Assets, Net	50,619	160,496
Total Assets	$ 178,377	$ 315,624
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 19,982	$ 27,736
Long-Term Liabilities	30,348	51,519
Stockholders' Equity	128,047	236,369
Total Liabilities and Stockholders' Equity	$ 178,377	$ 315,624

Primary Logo

Source: Celldex Therapeutics, Inc.