August 8, 2017

Celldex Reports Second Quarter 2017 Results

Conference Call Scheduled for Tuesday, August 8 at 4:30 p.m. Eastern Time

HAMPTON, N.J., Aug. 08, 2017 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the second quarter ended June 30, 2017.

"In the second quarter, we continued to see strong physician enthusiasm for our Phase 2 METRIC study of glembatumumab vedotin in triple negative breast cancer and recently met our target enrollment of 300 patients," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "We expect enrollment will be formally closed by the end of September to allow all patients currently in the screening queue the opportunity to complete the screening process and enroll in the study."

"In June, we presented data from glemba's Phase 2 program in checkpoint refractory metastatic melanoma and the Phase 1 dose-escalation varlilumab/Opdivo combination study in solid tumors, both in oral presentations at ASCO. We anticipate a productive second half of the year as we complete enrollment across multiple early-stage studies and look forward to topline data from the METRIC study in the first half of 2018."

Recent Highlights

- **Continued progress in METRIC enrollment:** Target enrollment (n=300) in METRIC has been reached. Given the lack of treatment options for patients with triple negative breast cancers, previously screened patients whose tumors overexpress gpNMB will be allowed to enter the study before enrollment is formally completed, which is estimated to occur by the end of September 2017. The Company expects topline data from the study approximately six to eight months after formal closing of enrollment. METRIC is a Phase 2b randomized study of glembatumumab vedotin in patients with metastatic triple negative breast cancers that overexpress gpNMB.

- **Single-agent glembatumumab vedotin Phase 2 study in checkpoint-refractory metastatic melanoma presented in an oral presentation at American Society of Clinical Oncology (ASCO) in June:** Mature data (n=62) from the study were presented at ASCO. As previously reported in October 2016, the primary endpoint of the cohort (threshold of 6 or more objective responses in 52 evaluable patients) was exceeded. 7 of 62 (11%) patients experienced a confirmed response, and an additional three patients also experienced single timepoint partial responses. Since data were reported in October, one patient converted from a confirmed partial response to a confirmed complete response. Median overall survival (OS) for all patients was 9.0 months (95% CI: 6.1, 13.0). Patients who experienced rash in Cycle 1 experienced a more prolonged OS with a median of 15.8 months (p=0.026, HR=0.44) as compared to those who did not experience rash.

  Enrollment recently completed in the glembatumumab vedotin and varlilumab combination arm, and data from this portion of the study are expected in the fall of 2017. Enrollment continues in the glembatumumab vedotin plus checkpoint inhibitor (Opdivo® or Keytruda®) arm in patients who failed prior checkpoint therapy, a population with limited treatment options.

- **Phase 1 varlilumab/Opdivo® study presented in an oral presentation at ASCO:** Updated data (n=36) from the Phase 1 portion of this study were presented at ASCO. The majority of patients enrolled in this study had PD-L1 negative tumor at baseline and presented with stage IV, heavily-pretreated disease. 80% of patients enrolled presented with refractory or recurrent colorectal (n=21) or ovarian cancer (n=8), a population expected to have minimal response to checkpoint blockade. The primary objective of the Phase 1 portion of the study was to evaluate the safety and tolerability of the combination. The combination was well tolerated at all varlilumab dose levels tested without any evidence of increased autoimmunity or inappropriate immune activation. Notable disease control was observed across multiple dosing regimens (stable disease or better for at least 3 months). Three partial responses (PR) were observed including a patient with PD-L1 negative, MMR proficient colorectal cancer, a patient with low PD-L1 (5% expression) squamous cell head and neck cancer and a patient with PD-L1 negative ovarian cancer. A subgroup analysis was conducted in patients with ovarian cancer based on an observed increase of PD-L1 and tumor-infiltrating lymphocytes in this patient population. In patients with paired baseline and on-treatment biopsies (n=13), only 15% were PD-L1 positive (≥ 1% tumor cells) at baseline compared to 77% during treatment (p=0.015).

Patients with increased tumor PD-L1 expression and tumor CD8 T cells correlated with better clinical outcome with treatment (stable disease or better).

The Phase 2 portion of the combination study includes cohorts in colorectal cancer, ovarian cancer, head and neck squamous cell carcinoma, renal cell carcinoma and glioblastoma, and is currently enrolling patients. The Company plans to complete enrollment across all cohorts in the Phase 2 portion of the study in the first quarter of 2018 and will work with Bristol-Myers Squibb to present data from the study at a future medical meeting.

- **Phase 1 study of CDX-0158 continues to enroll patients:** This dose escalation study in patients with advanced refractory gastrointestinal stromal tumors (GIST) and other KIT-positive tumors is designed to determine the maximum tolerated dose, recommend a dose for further study and characterize the safety profile of CDX-0158. Data from the study continue to be expected by year-end 2017.

- **CDX-3379 advancing to Phase 2:** The Company has finalized plans for an open-label Phase 2 study in patients with recurrent/metastatic head and neck squamous cell cancer who are refractory to Erbitux® (cetuximab). The Company anticipates initiating this study in the fourth quarter of 2017.

- **Enrollment ongoing in Phase 1 study of CDX-014:** This study in advanced renal cell carcinoma (clear cell and papillary) is designed to determine the maximum tolerated dose and to recommend a dose level for further study. Celldex continues to expect the Phase 1 dose-escalation portion of the study will complete enrollment by year-end 2017.

Second Quarter and First Six Months 2017 Financial Highlights and Updated 2017 Guidance

Cash position: Cash, cash equivalents and marketable securities as of June 30, 2017 were $154.0 million compared to $167.0 million as of March 31, 2017. The decrease was primarily driven by second quarter cash used in operating activities of $20.8 million. This decrease was partially offset by the receipt of $8.7 million from sales of common stock under the Cantor agreement. At June 30, 2017, Celldex had 127.4 million shares outstanding.

Revenues: Total revenue was $3.8 million in the second quarter of 2017 and $5.4 million for the six months ended June 30, 2017, compared to $1.4 million and $2.7 million for the comparable periods in 2016. The increase in revenue was primarily due to the manufacturing service agreement with the International AIDS Vaccine Initiative.

R&D Expenses: Research and development (R&D) expenses were $25.0 million in the second quarter of 2017 and $50.8 million for the six months ended June 30, 2017, compared to $25.7 million and $53.2 million for the comparable periods in 2016.

The $0.7 million decrease in second quarter R&D expenses was primarily due to a decrease in varlilumab contract manufacturing expenses of $4.3 million, partially offset by an increase in glembatumumab vedotin contract manufacturing expenses of $1.9 million and increases in personnel and facility costs related to the Kolltan acquisition.

The $2.4 million decrease in year-to-date R&D expenses was primarily due to decreases in varlilumab and Rintega contract manufacturing expenses of $5.1 million and $2.6 million, respectively, partially offset by an increase in glembatumumab vedotin contract manufacturing expenses of $3.4 million and increases in personnel and facility costs related to the Kolltan acquisition.

G&A Expenses: General and administrative (G&A) expenses were $6.5 million in the second quarter of 2017 and $13.8 million for the six months ended June 30, 2017, compared to $7.8 million and $17.1 million for the comparable periods in 2016.

The $1.3 million decrease in second quarter G&A expenses was primarily due to lower commercial planning costs of $0.6 million and lower stock-based compensation of $0.4 million.

The $3.3 million decrease in year-to-date G&A expenses was primarily due to lower commercial planning costs of $2.4 million and lower stock-based compensation of $0.9 million.

Loss on Fair Value Remeasurement of Contingent Consideration: Loss on the fair value remeasurement of contingent consideration related to the Kolltan acquisition was $1.0 million in the second quarter of 2017 and $4.4 million for the six months ended June 30, 2017, primarily due to changes in discount rates and the passage of time.

Net loss: Net loss was $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, compared to a net loss of $32.0 million, or ($0.32) per share, and $66.6

million, or ($0.67) per share, for the comparable periods in 2016.

Financial guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 30, 2017, 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 2018; however, this guidance assumes Celldex elects to pay future Kolltan contingent milestones, if any, in stock rather than 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 2017 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 52336196.

A replay of the call will be available approximately two hours after the live call concludes through August 15, 2017. To access the replay, dial (855) 859-2056 (within the United States) or (404) 537-3406 (outside the United States). The passcode is 52336196. The webcast will also be archived on the Company's website.

Opdivo® is a registered trademark of Bristol-Myers Squibb. Keytruda® is a registered trademark of Merck Sharp & Dohme Corp. 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 antibodies, antibody-drug conjugates and other protein-based therapeutics 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 glembatumumab vedotin and other 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; our ability to maintain and derive benefit from the Fast Track designation for glembatumumab vedotin which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; 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.

CELLDEX THERAPEUTICS, INC.

(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Quarter Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(Unaudited)		(Unaudited)	
REVENUE				
Product Development and Licensing Agreements	$ 694	$ 604	$ 1,250	$ 1,057
Contracts and Grants	3,135	785	4,113	1,635
Total Revenue	3,829	1,389	5,363	2,692
OPERATING EXPENSE				
Research and Development	24,999	25,711	50,792	53,158
General and Administrative	6,534	7,790	13,763	17,097
Loss on Fair Value Remeasurement of Contingent Consideration	1,000	-	4,400	-
Amortization of Acquired Intangible Assets	224	254	448	507
Total Operating Expense	32,757	33,755	69,403	70,762
Operating Loss	(28,928)	(32,366)	(64,040)	(68,070)
Investment and Other Income, Net	362	414	1,213	1,445
Net Loss	$ (28,566)	$(31,952)	$ (62,827)	$ (66,625)
Basic and Diluted Net Loss per Common Share	$ (0.23)	$ (0.32)	$ (0.51)	$ (0.67)
Weighted Average Common Shares Outstanding	125,202	98,817	123,932	98,753

CONDENSED CONSOLIDATED BALANCE SHEETS DATA	June 30, 2017 (Unaudited)	December 31, 2016
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 153,984	$ 189,776
Other Current Assets	6,068	5,793
Property and Equipment, net	12,069	13,192
Intangible and Other Assets, net	173,950	174,597
Total Assets	$ 346,071	$ 383,358
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 28,788	$ 35,223
Long-Term Liabilities	85,826	82,704
Stockholders' Equity	231,457	265,431
Total Liabilities and Stockholders' Equity	$ 346,071	$ 383,358

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