Celldex Therapeutics, Inc. Logo

Celldex Provides Corporate Update and Reports Second Quarter 2019 Results

August 7, 2019

HAMPTON, N.J., Aug. 07, 2019 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the second quarter ended June 30, 2019. The Company will host a conference call at 4:30 p.m. ET today to provide an update on its pipeline and upcoming milestones for the remainder of 2019.

“Celldex made considerable progress in the first half of the year across multiple programs,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We presented exciting data from our CDX-3379 program in head and neck squamous cell carcinoma at ASCO, where we observed intriguing clinical activity across a number of patients with similar gene mutation patterns. As a result, we have expanded the study to allow for a deeper evaluation of these biomarkers for patient selection. This could be important for the field as patients with refractory head and neck cancer face extremely limited treatment options and a particularly poor prognosis.

We also reported data from multiple programs at AACR, including from our ongoing dose escalation study of CDX-1140. We recently successfully completed the monotherapy dosing cohorts and are advancing nicely through the combination cohorts with our dendritic cell growth factor, CDX-301. We are currently finalizing plans to initiate a combination cohort with a checkpoint inhibitor and look forward to presenting data from the ongoing program this fall.

Finally, we made an important addition to the Celldex leadership team. In June, we announced that Dr. Diane Young has joined Celldex as Senior Vice President, Chief Medical Officer. Dr. Young brings a deep background in successful drug development to Celldex that will strengthen our clinical development efforts and support the continued progress of our product pipeline,” concluded Marucci.

Recent Pipeline 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 complete in the monotherapy arm and progressing on track in the CDX-301 combination arm of the Phase 1 dose-escalation study of CDX-1140 in patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas. Celldex plans to present data from the ongoing study at a medical meeting this fall.
  -- Eight monotherapy dosing cohorts ranging from 0.01 to 3.0 mg/kg have been completed and the dose limiting toxicity (DLT) window successfully cleared.
  -- Three combination cohorts in solid tumors (0.09, 0.18 and 0.36 mg/kg) with CDX-301 have been completed and the DLT window successfully cleared. Patients enrolled in the fourth cohort at 0.72 mg/kg have been dosed and are currently completing the DLT observation period. Assuming successful clearance, the 1.5 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.
- Interim data from the 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.

- Enrollment continues in the Phase 2 study 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.
  -- Interim data from the study (n=15) were presented at the 2019 American Society for Clinical Oncology (ASCO) Annual Meeting in June that suggested notable clinical activity in this refractory patient population and a promising biomarker strategy.
  -- Emerging data from the Phase 2 study and earlier studies of CDX-3379 suggest that antitumor activity may be associated with somatic mutations in the FAT1 and NOTCH1, NOTCH2 or NOTCH3 (NOTCH1-3) genes—genes associated with tumor suppression.
  -- In the exploratory analyses presented at ASCO, seven patients were identified as having FAT1 mutated tumors and four of these patients demonstrated clinical response (3 confirmed).
  - All four clinical responses occurred in patients with the primary tumor site of oral cavity.
  - Three of the four clinical responses occurred in patients with NOTCH1-3 mutations.
  - Also, of note, all patients (n=7 of 18) who experienced clinical benefit (objective response or stable disease greater than or equal to 12 weeks) had FAT1 and/or NOTCH1-3 mutations.
  -- Inactivating mutations in the FAT1 and NOTCH genes occur in sizeable subsets of HPV negative HNSCC tumors, having been identified in 32% (FAT1) and 26% (NOTCH) of these tumors, respectively.

-- Based on these biomarker observations and the clinical activity observed in the ongoing Phase 2 study, the study has been expanded (n= ~45 patients, including at least 15 patients with FAT1 mutations) to allow for an evaluation of the utility of biomarkers for patient selection. Enrollment is ongoing.

• CDX-0159—a monoclonal antibody that specifically binds the KIT receptor and potently inhibits its activity. The KIT receptor tyrosine kinase is expressed in a variety of cells, including mast cells. In certain inflammatory diseases, such as chronic idiopathic urticaria (CIU), mast cell degranulation plays a central role in the onset and progression of the disease.

- Celldex plans to submit an Investigation New Drug (IND) Application and initiate a Phase 1a study of CDX-0159 by year-end 2019. The study is designed to evaluate the safety profile, pharmacokinetics and pharmacodynamics of single ascending doses of CDX-0159 in healthy subjects. Following completion of this study, the Company plans to further study CDX-0159 in CIU, a mast cell-related disease. CIU presents as itchy hives, angioedema or both for at least six weeks without a specific trigger; multiple episodes can play out over years or even decades. The prevalence of CIU is estimated to be 0.5% to 1% of the total population or up to 3.2 million cases in the United States. About 50% of patients with CIU achieve symptomatic control with antihistamines or leukotriene receptor antagonists. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine/leukotriene refractory patients. Consequently, there is a need for more effective later line therapies.

• 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 in April 2019 at the AACR Annual meeting. 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.

Recent Business Highlights:

• Diane C. Young, M.D. joined Celldex as Senior Vice President, Chief Medical Officer in July 2019. Over the span of a 30 year career in biopharmaceuticals, Dr. Young, a medical oncologist, has led clinical and cross-functional research and development teams responsible for the global development of numerous novel therapies from Phase 1 through successful product registrations. Dr. Young received her M.D. from Harvard Medical School and is board certified in Internal Medicine and Medical Oncology.

• Celldex continues to preserve our financial resources and direct them towards reaching meaningful development milestones across our pipeline. In June, the Company decided to consolidate its Massachusetts lab and manufacturing facilities. The lease for the Needham, MA facility will not be renewed and most functions and employees will be integrated into the Company's Fall River, MA facility. The Company estimates that this consolidation along with a reduction in square footage at our Hampton, NJ facility earlier this year will decrease our facility footprint by over 35% and will save the Company over $3.5 million annually, starting in the second half of 2020.

Second Quarter 2019 Financial Highlights and 2019 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2019 were $81.3 million compared to $85.1 million as of March 31, 2019. The decrease was primarily driven by second quarter cash used in operating activities of $11.0 million, partially offset by $7.2 million in net proceeds from sales of common stock under the Cantor agreement. At June 30, 2019, Celldex had 14.8 million shares outstanding.

Revenues: Total revenue was $0.7 million in the second quarter of 2019 and $2.1 million for the six months ended June 30, 2019, compared to $2.8 million and $6.8 million for the comparable periods in 2018. The decrease in revenue was primarily due to lower revenue from the collaboration agreement with Bristol-Myers Squibb Company and the contract manufacturing and research and development agreements with the International AIDS Vaccine Initiative and Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were $10.1 million in the second quarter of 2019 and $21.2 million for the six months ended June 30, 2019, compared to $21.4 million and $43.3 million for the comparable periods 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 $3.9 million in the second quarter of 2019 and $8.8 million for the six months ended June 30, 2019, compared to $5.6 million and $11.2 million for the comparable periods in 2018. The decrease in G&A expenses was primarily due to lower personnel and commercial planning costs and lower lease restructuring expense.

Changes in Fair Value Remeasurement of Contingent Consideration: The Company recorded a $1.0 million gain on fair value remeasurement of contingent consideration during the second quarter of 2019 and a $0.5 million loss on fair value remeasurement of contingent consideration during the six months ended June 30, 2019, primarily due to changes in discount rates and the passage of time.

Net Loss: Net loss was $11.8 million, or ($0.84) per share, for the second quarter of 2019, and $29.0 million, or ($2.21) per share, for the six months ended June 30, 2019, compared to a net loss of $16.4 million, or ($1.67) per share, for the second quarter of 2018 and $134.5 million, or ($14.01) per share, for the six months ended June 30, 2018.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 30, 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.

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 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 9256839.

A replay of the call will be available approximately two hours after the live call concludes through August 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 9256839. 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 cost benefits of consolidating our office and laboratory space and to retain key personnel after that consolidation; 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	**Quarter Ended June 30,**		**Six Months Ended June 30,**	
	2019 (Unaudited)	**2018**	**2019 (Unaudited)**	**2018**
REVENUES:				
Product Development and Licensing Agreements	$ 195	$ 1,667	$ 325	$ 2,662
Contracts and Grants	520	1,096	1,815	4,172
Total Revenue	715	2,763	2,140	6,834
OPERATING EXPENSES:				
Research and Development	10,081	21,448	21,232	43,323
General and Administrative	3,908	5,621	8,804	11,215
Goodwill Impairment	-	-	-	90,976
Intangible Asset Impairment	-	-	-	18,677
Other Asset Impairment	-	-	1,800	-
(Gain)/Loss on Fair Value Remeasurement				

of Contingent Consideration	(1,017)	(7,433)	502	(21,033)
Amortization of Acquired Intangible Assets	-	-	-	224
Total Operating Expense	12,972	19,636	32,338	143,382
Operating Loss	(12,257)	(16,873)	(30,198)	(136,548)
Investment and Other Income, Net	478	466	1,180	1,245
Net Loss Before Income Tax Benefit	(11,779)	(16,407)	(29,018)	(135,303)
Income Tax Benefit	-	-	-	765
Net Loss	$ (11,779)	$ (16,407)	$ (29,018)	$ (134,538)
Basic and Diluted Net Loss per Common Share	$ (0.84)	$ (1.67)	$ (2.21)	$ (14.01)
Shares Used in Calculating Basic and Diluted Net Loss per Share	13,952	9,829	13,129	9,600

CONDENSED CONSOLIDATED BALANCE SHEETS DATA

	June 30, 2019 (Unaudited)	**December 31, 2018**
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 81,342	$ 94,022
Other Current Assets	3,023	5,057
Property and Equipment, net	5,086	6,111
Intangible and Other Assets, net	52,793	50,619
Total Assets	$ 142,244	$ 155,809
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 11,509	$ 12,602
Long-Term Liabilities	21,109	19,147
Stockholders' Equity	109,626	124,060
Total Liabilities and Stockholders' Equity	$ 142,244	$ 155,809

Source: Celldex Therapeutics, Inc.