Celldex Provides Corporate Update and Reports Second Quarter 2020 Results

Aug 6, 2020

--Conference Call and Webcast today at 4:30pm ET--

HAMPTON, N.J., Aug. 06, 2020 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the second quarter ended June 30, 2020. The Company will host a conference call at 4:30 p.m. ET today to provide an update on its pipeline and upcoming milestones.

“In the second quarter of 2020, we presented data from our KIT inhibitor, CDX-0159, in a late breaking session at the EAACI Annual Congress that suggested significant potential to dramatically impact mast cell driven disorders,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “These data provided important proof of concept for the CDX-0159 program and helped support a $150 million public offering driven by high quality health care investors to fully fund the Company’s planned operations through 2023. We are on track to initiate two studies in chronic urticaria later this year and are vetting additional mast cell driven indications to support expanded development in 2021.”

“We continue to focus our resources on the programs we believe hold the most promise for patients and shareholders and have prioritized the development of CDX-0159, CDX-1140, and the first candidate from our bi-specific program, CDX-527. We are discontinuing development of CDX-3379, which is in an exploratory study with cetuximab to assess the utility of biomarkers in head and neck cancer. The side effect profile of the combination remains challenging even with prophylactic treatment and, when considered with the emerging clinical activity, we believe our resources are best utilized to expand the development of CDX-0159 and our other pipeline programs. To this end, we intend to start the two planned studies of CDX-0159 this fall and to initiate a combination cohort of CDX-1140 with chemotherapy in treatment naïve metastatic pancreatic cancer and a Phase 1 study of CDX-527 in refractory, advanced cancers later this year. These programs will support data read outs later this year and in 2021,” concluded Marucci.

Recent Pipeline Highlights

CDX-0159—a humanized monoclonal antibody developed by Celldex that binds the KIT receptor with high specificity and potently inhibits its activity. The KIT receptor tyrosine kinase is expressed in a variety of cells, including mast cells, which mediate inflammatory responses such as hypersensitivity and allergic reactions. KIT signaling controls the differentiation, tissue recruitment, survival and activity of mast cells.

- Results from the Phase 1a dose escalation study of CDX-0159 were featured in a late breaking presentation in June at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2020. CDX-0159 demonstrated a favorable safety profile as well as profound and durable reductions of plasma tryptase, indicative of systemic mast cell ablation. Tryptase suppression below the level of detection was observed after a single 1.0 mg/kg dose and was maintained for more than 2 months at single doses of both 3.0 and 9.0 mg/kg of CDX-0159.

  -- As indicated in the EAACI presentation, a subset of subjects from the 3mg/kg and 9 mg/kg cohorts agreed to continued follow up for tryptase suppression. This follow up and analysis was completed in July and tryptase levels remained below the level of detection for over 3 months (14 weeks) in 50% of subjects in the 3 mg/kg cohort and over 4 months (18 weeks) in all subjects in the 9 mg/kg cohort.

- Celldex plans to initiate Phase 1b studies of CDX-0159 in chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CIndU), both mast cell driven diseases, this fall. Celldex is exploring cold-induced and symptomatic dermographism (scratch-induced) urticarias. Celldex is also exploring additional mast cell driven diseases for potential future development, including mast cell activation syndromes, asthma, allergic conditions and mast cell driven gastrointestinal disorders.

- Data from the Phase 1b studies in CIndU and CSU are anticipated in the first quarter and second half of 2021, respectively.

CDX-1140—a potent CD40 human agonist antibody developed by Celldex that the Company believes has the potential to successfully balance systemic doses for good tissue and tumor penetration with an acceptable safety profile.

- In the Phase 1 dose-escalation study of CDX-1140 in patients with recurrent, locally advanced or metastatic solid tumors and B cell lymphomas, both the monotherapy and combination with CDX-301 dose escalation portions of the trial are complete with an identified maximum tolerated dose (MTD) and recommended Phase 2 dose of CDX-1140 at 1.5 mg/kg—one of the highest systemic dose levels in the CD40 agonist class. Expansion cohorts are actively recruiting including:

-- CDX-1140 with KEYTRUDA® (pembrolizumab) in patients who have progressed on checkpoint therapy; and,
-- CDX-1140 with CDX-301 in patients with head and neck squamous cell carcinoma (HNSCC); and,
-- A combination of CDX-1140 with standard of care chemotherapy in first line metastatic pancreatic cancer is expected to initiate later this year.

- A data update from the ongoing Phase 1 study is planned for presentation in the fall of 2020.

CDX-527—the first candidate developed by Celldex from its bispecific platform which utilizes the Company'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.

- Celldex anticipates initiating a Phase 1 dose-escalation study in up to ~90 patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy later this year to be followed by tumor-specific expansion cohorts. The study is designed to determine the MTD during a dose-escalation phase and to recommend a dose level for further study in the subsequent expansion phase. The expansion is designed to further evaluate the tolerability, biologic and anti-tumor effects of selected dose level(s) of CDX-527 in specific tumor types.

- Initial data from the Phase 1 study are anticipated in the first half of 2021.

Recent Business Highlights

- On June 18, 2020, Celldex announced the closing of an underwritten public offering raising total gross proceeds of approximately $150.0 million.

Second Quarter 2020 Financial Highlights and 2020 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2020 were $206.9 million compared to $53.7 million as of March 31, 2020. The increase was primarily driven by net proceeds of $141.4 million from our June 2020 underwritten public offering and net proceeds of $23.7 million from sales of common stock under our Controlled Equity Offering℠ agreement with Cantor completed in the second quarter prior to the offering in June. These increases were offset by second quarter cash used in operating activities of $11.2 million.

Revenues: Total revenue was $0.2 million in the second quarter of 2020 and $3.0 million for the six months ended June 30, 2020, compared to $0.7 million and $2.1 million for the comparable periods in 2019. The increase in revenue for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily due to the $1.8 million milestone payment from Rockefeller University related to our manufacturing and development services agreement, partially offset by a decrease in services performed under our manufacturing and research and development agreement with Duke University.

R&D Expenses: Research and development (R&D) expenses were $9.7 million in the second quarter of 2020 and $21.4 million for the six months ended June 30, 2020, compared to $10.1 million and $21.2 million for the comparable periods in 2019. The increase in R&D expense for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily due to an increase in clinical trial and contract manufacturing expenses, partially offset by lower stock-based compensation expense.

G&A Expenses: General and administrative (G&A) expenses were $3.5 million in the second quarter of 2020 and $7.2 million for the six months ended June 30, 2020, compared to $3.9 million and $8.8 million for the comparable periods in 2019. The decrease in G&A expenses was primarily due to lower stock-based compensation expense.

Changes in Fair Value Remeasurement of Contingent Consideration: The gain on fair value remeasurement of contingent consideration was $5.1 million during the second quarter of 2020 and $4.9 million during the six months ended June 30, 2020, primarily due to updated assumptions for CDX-3379 related milestones due to the discontinuation of the CDX-3379 program and the passage of time.

Intangible Asset Impairment: The Company recorded a non-cash impairment charge of $3.5 million during the second quarter of 2020 due to the discontinuation of the CDX-3379 program.

Net Loss: Net loss was $11.0 million, or ($0.50) per share, for the second quarter of 2020, and $23.7 million, or ($1.20) per share, for the six months ended June 30, 2020, compared to a net loss of $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.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 30, 2020 are sufficient to meet estimated working capital requirements and fund planned operations through 2023.

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 2020 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 (800) 446-2782 (within the United States) or (847) 413-3235 (outside

the United States). The passcode is 49870841.

A replay of the call will 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; the effects of the outbreak of COVID-19 on our business and results of operations; our ability to realize the cost benefits of consolidating our office and laboratory space and to retain key personnel after that consolidation; 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; our ability to continue to obtain 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; 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	**Three Months Ended June 30,**		**Six Months Ended June 30,**	
	2020	**2019**	**2020**	**2019**
	(Unaudited)		**(Unaudited)**	
REVENUES:				
Product Development and Licensing Agreements	$ -	$ 195	$ 2,285	$ 325
Contracts and Grants	236	520	680	1,815
Total Revenue	236	715	2,965	2,140
OPERATING EXPENSES:				
Research and Development	9,705	10,081	21,400	21,232
General and Administrative	3,528	3,908	7,194	8,804
Intangible Asset Impairment	3,500	-	3,500	-
Other Asset Impairment	-	-	-	1,800
(Gain) Loss on Fair Value Remeasurement of Contingent Consideration	(5,132)	(1,017)	(4,898)	502

Total Operating Expense	11,601	12,972	27,196	32,338
Operating Loss	(11,365)	(12,257)	(24,231)	(30,198)
Investment and Other Income, Net	106	478	347	1,180
Net Loss Before Income Tax Benefit	(11,259)	(11,779)	(23,884)	(29,018)
Income Tax Benefit	228	-	228	-
Net Loss	$ (11,031)	$ (11,779)	$ (23,656)	$ (29,018)
Basic and Diluted Net Loss per Common Share	$ (0.50)	$ (0.84)	$ (1.20)	$ (2.21)
Shares Used in Calculating Basic and Diluted Net Loss per Share	22,082	13,952	19,744	13,129

CONDENSED CONSOLIDATED BALANCE SHEETS DATA

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 206,915	$ 64,383
Other Current Assets	2,077	2,315
Property and Equipment, net	4,044	4,031
Intangible and Other Assets, net	48,365	52,204
Total Assets	$ 261,401	$ 122,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 10,841	$ 11,643
Long-Term Liabilities	12,116	17,264
Stockholders' Equity	238,444	94,026
Total Liabilities and Stockholders' Equity	$ 261,401	$ 122,933

Company Contact
Sarah Cavanaugh
Senior Vice President, Corporate Affairs & Administration
Celldex Therapeutics, Inc.
(781) 433-3161
scavanaugh@celldex.com

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