



Celldex Provides Corporate Update and Reports Fourth Quarter and Year End 2019 Results

Mar 26, 2020

HAMPTON, N.J., March 26, 2020 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the fourth quarter and year ended December 31, 2019.

"We are pleased that Celldex entered 2020 with significant momentum, following exciting data in late 2019 from the CDX-1140 program that suggest this candidate is a best in class CD40 agonist," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "We are actively recruiting patients across multiple expansion cohorts to further explore potential indications and new combination approaches. We also continue to advance the Phase 2 program of our ErbB3 inhibitor, CDX-3379, exploring a potential biomarker strategy in head and neck squamous cell carcinoma."

"Last month, we completed dosing in the Phase 1 healthy volunteer study of our KIT inhibitor, CDX-0159, which we intend to study in mast cell driven disorders. In addition to demonstrating a favorable safety profile, if CDX-0159 is able to decrease tryptase levels in healthy volunteers, a surrogate for systemic mast cell load, we believe this drug candidate could have significant potential in mast cell driven diseases. Based on the promising results observed to date, we have expanded development of CDX-0159 and are planning to initiate studies in chronic urticaria. We are also preparing to advance CDX-527, the first candidate from our bispecific platform, into the clinic."

"In closing, our mission at Celldex is focused on combatting devastating diseases. With the COVID-19 pandemic unfolding around the world, we have embraced the importance of public health guidelines while implementing operational plans aimed at minimizing disruptions to our core programs and protecting the health of our staff and the communities around us. We have observed that many medical and scientific conferences have canceled, delayed or made modifications to their format. We are following this closely and we may elect to report data outside of these settings if necessary. As always, we look forward to reporting on our progress, including updates across our clinical programs over the course of the year."

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.

- o 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).

In addition, a combination of CDX-1140 with chemotherapy in first line metastatic pancreatic cancer is planned.

- o [Interim data](#) from the dose escalation portion of the Phase 1 study were presented at the Society for Immunotherapy of Cancer's (SITC) 34th Annual Meeting in November 2019. CDX-1140 achieved one of the highest systemic dose levels (1.5 mg/kg) in the CD40 agonist class. Clinical activity in both the monotherapy arm and the combination arm with CDX-301 was observed, including tumor necrosis in two patients with head and neck cancer, a RECIST partial response in gastroesophageal cancer and stable disease. CDX-1140 was associated with manageable immune-related adverse events.

CDX-3379—a differentiated human monoclonal antibody designed to block the activity of ErbB3 (HER3). ErbB3 is expressed in many cancers, including HNSCC and is believed to be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies.

- o Enrollment continues in the Phase 2 study of CDX-3379 in advanced HNSCC in combination with Erbitux[®] (cetuximab) in Erbitux-resistant patients who have been previously treated with or are ineligible for checkpoint therapy.
- o [Data](#) presented at the 2019 American Society for Clinical Oncology (ASCO) Annual Meeting in June 2019 suggested that

observed antitumor activity with CDX-3379 might be associated with somatic mutations in the FAT1 and NOTCH1, NOTCH2 or NOTCH3 (NOTCH1-3) genes—genes associated with tumor suppression. Based on these biomarker observations and the clinical activity observed in the ongoing Phase 2 study, the study was 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.

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 urticarias, mast cell degranulation plays a central role in the onset and progression of the disease.

- o Dosing was recently completed in the ongoing Phase 1 single ascending dose escalation study of CDX-0159 in healthy subjects. This study is designed to evaluate the safety profile, pharmacokinetics and pharmacodynamics of CDX-0159 and to select a dose for further study in mast cell driven diseases. The Phase 1 study also evaluates plasma tryptase levels in healthy subjects. Tryptase is an enzyme synthesized and secreted by mast cells and decreases in plasma tryptase levels reflect a systemic reduction in mast cell burden, even in healthy volunteers. If CDX-0159 is able to decrease systemic mast cell load in healthy volunteers, Celldex believes the drug candidate could have significant potential in mast cell driven diseases. Based on promising results observed to date, Celldex has expanded development of CDX-0159.

-- The Company intends to further study CDX-0159 in chronic spontaneous urticaria (CSU) and chronic inducible urticaria (CINDU), both mast cell-related diseases, and plans to initiate studies by year end. CSU 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. About 50% of patients with CSU 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. CINDUs are forms of urticaria that have an attributable cause or trigger associated with them, typically resulting in hives or wheals. Celldex is exploring cold-induced and dermographism-induced (scratching the skin) urticarias.

-- [A review](#) of the CDX-0159 early development program was presented at the American College of Allergy, Asthma & Immunology Annual Scientific Meeting in November 2019 in the Distinguished Industry Oral Abstract Session.

Celldex continues to advance a robust preclinical portfolio and data from the Company's CDX-527 bispecific candidate were presented in November at SITC 2019. 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. [The data](#) presented at SITC demonstrate that CDX-527 is more potent at T cell activation and anti-tumor immunity than the combination of parental monoclonal antibodies. Celldex plans to initiate a Phase 1 study in the second half of 2020.

Fourth Quarter and Twelve Months 2019 Financial Highlights and 2020 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2019 were \$64.4 million compared to \$72.9 million as of September 30, 2019. The decrease was primarily driven by fourth quarter cash used in operating activities of \$11.0 million, partially offset by \$2.4 million in net proceeds from sales of common stock under the Cantor agreement. At December 31, 2019, Celldex had 17.0 million shares outstanding.

Revenues: Total revenue was \$0.9 million in the fourth quarter of 2019 and \$3.6 million for the year ended December 31, 2019, compared to \$1.8 million and \$9.5 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 \$10.3 million in the fourth quarter of 2019 and \$42.7 million for the year ended December 31, 2019, compared to \$11.2 million and \$66.4 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 \$3.2 million in the fourth quarter of 2019 and \$15.4 million for the year ended December 31, 2019, compared to \$4.3 million and \$19.3 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.

Intangible Asset and Goodwill Impairments: During the first quarter of 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 year ended December 31, 2019, the Company recorded a \$1.3 million gain on the fair value remeasurement of contingent consideration primarily due to changes in discount rates, the passage of time and updated assumptions for the varilumab program.

Net Loss: Net loss was \$10.4 million, or (\$0.64) per share, for the fourth quarter of 2019 and \$50.9 million, or (\$3.51) per share, for the year ended December 31, 2019, compared to a net loss of \$9.4 million, or (\$0.81) per share, and \$151.2 million, or (\$14.48) per share, for the comparable periods in 2018.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 2019 are sufficient to meet estimated working capital requirements and fund planned operations into the first quarter of 2021. This guidance excludes anticipated proceeds from future sales of common stock under the Cantor agreement or other potential fundraising.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA. 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; the effects of the outbreak of COVID-19 on our business and results of operations; 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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CELLEX THERAPEUTICS, INC.
(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Three Months		Year	
	Ended December 31,		Ended December 31,	
	2019	2018	2019	2018
	(Unaudited)			
REVENUES:				
Product Development and Licensing Agreements	\$ 94	\$ 549	\$ 473	\$ 3,341
Contracts and Grants	793	1,215	3,100	6,197
Total Revenue	887	1,764	3,573	9,538

OPERATING EXPENSES:

Research and Development	10,339	11,207	42,672	66,449
General and Administrative	3,219	4,332	15,426	19,269
Goodwill Impairment	-	-	-	90,976
Intangible Asset Impairment	-	-	-	18,677
Other Asset Impairment	-	-	1,800	-
(Gain)/Loss on Fair Value Remeasurement of Contingent Consideration	318	(1,653)	(1,294)	(29,621)
Amortization of Acquired Intangible Assets	-	-	-	224
Total Operating Expense	13,876	13,886	58,604	165,974
Operating Loss	(12,989)	(12,122)	(55,031)	(156,436)
Investment and Other Income, Net	2,542	2,720	4,153	4,487
Net Loss Before Income Tax Benefit	(10,447)	(9,402)	(50,878)	(151,949)
Income Tax Benefit	-	-	-	765
Net Loss	\$ (10,447)	\$ (9,402)	\$ (50,878)	\$ (151,184)
Basic and Diluted Net Loss per Common Share	\$ (0.64)	\$ (0.81)	\$ (3.51)	\$ (14.48)
Shares Used in Calculating Basic and Diluted Net Loss per Share	16,442	11,626	14,507	10,442

(Reflects one for fifteen reverse stock split effective February 8, 2019)

**CONDENSED CONSOLIDATED
BALANCE SHEETS DATA**

	December 31, 2019	December 31, 2018
ASSETS		
Cash, Cash Equivalents and Marketable Securities	\$ 64,383	\$ 94,022
Other Current Assets	2,315	5,057
Property and Equipment, net	4,031	6,111
Intangible and Other Assets, net	52,204	50,619
Total Assets	<u>\$ 122,933</u>	<u>\$ 155,809</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	\$ 11,643	\$ 12,602
Long-Term Liabilities	17,264	19,147
Stockholders' Equity	94,026	124,060
Total Liabilities and Stockholders' Equity	<u>\$ 122,933</u>	<u>\$ 155,809</u>



Source: Celldex Therapeutics, Inc.