Celldex Provides Corporate Update and Reports Third Quarter 2020 Results

Nov 5, 2020

HAMPTON, N.J., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported business and financial highlights for the third quarter ended September 30, 2020.

“In the third quarter, building on the compelling CDX-0159 data presented at EAACI, we initiated two Phase 1b studies in chronic spontaneous urticaria and chronic inducible urticaria which will provide the foundation for several important data readouts in 2021,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We also advanced the first candidate from our bispecific program, CDX-527, into the clinic in solid tumors and continued to expand the ongoing CDX-1140 program, adding a combination cohort with chemotherapy in pancreatic cancer.

In addition, we are completing our work prioritizing opportunities to expand development of CDX-0159 into additional therapeutic areas. Our analysis supports that there are multiple mast cell driven indications that have the potential to be dramatically impacted by an agent that targets the root cause of the disease—the mast cell itself—and we remain on track to start a third study in a mast cell disease setting next summer. We are closing out a busy, successful year and look forward to continuing this momentum in 2021,” concluded Marucci.

Recent Pipeline Highlights

While Celldex’s clinical development programs have not been significantly, negatively impacted by COVID-19 to date, the Company continues to carefully monitor the evolving situation closely across all development programs and work to minimize potential impact/disruptions.

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 a Phase 1a dose escalation study of CDX-0159 were featured in a late breaking presentation in June at the 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.

- Celldex initiated dosing in a Phase 1b multi-center study of CDX-0159 in chronic spontaneous urticaria (CSU) in October. This study is a randomized, double-blind, placebo-controlled clinical trial designed to assess the safety of multiple ascending doses of CDX-0159 in up to 40 patients with CSU who remain symptomatic despite treatment with antihistamines. Secondary and exploratory objectives include pharmacokinetic and pharmacodynamic assessments, including measurement of tryptase and stem cell factor levels and clinical activity outcomes (impact on urticaria symptoms, disease control, clinical response) as well as quality of life assessments. Results from the study are expected in the second half of 2021.

- Patient screening has begun in a second Phase 1b study in chronic inducible urticaria (CIndU). This study, which is being conducted by Dr. Marcus Maurer, Professor of Dermatology and Allergy and Director of Research at the Department of Dermatology and Allergy at the Allergie-Centrum-Charité of the Charité - Universitätsmedizin in Berlin, is exploring cold-induced urticaria and symptomatic dermographism (scratch-induced urticaria). The initiation of the study was slowed by the need to incorporate, align and obtain approval on COVID-19 screening and management protocols with the responsible Ethics Committee and German Health Authority. The Company plans to present data from the study at the end of the first quarter.

- 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.

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 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,

- A combination of CDX-1140 with standard of care chemotherapy in first line metastatic pancreatic cancer.

- Updated interim data from the ongoing Phase 1 study has been accepted for poster presentation at the Society for Immunotherapy of Cancer's (SITC) 35th Anniversary Annual Meeting & Pre-Conference Programs (SITC 2020) and will include updated data from the monotherapy and CDX-301 combination cohorts focusing on the MTD level (1.5 mg/kg), as well as preliminary safety data from the combination cohort with pembrolizumab.

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.

- In August, Celldex initiated 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 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, and 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.

- The CDX-527 Phase 1 study design will be presented as a clinical trial in progress poster at SITC 2020.

In addition to the CDX-1140 and CDX-527 presentations, the Company will also present preclinical data from its Axl discovery program at SITC 2020. Axl is a member of the TAM (Tyro3/Axl/MerTK) family of receptor tyrosine kinases and a negative regulator of innate immunity.

Third Quarter 2020 Financial Highlights and 2020 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2020 were $199.6 million compared to $206.9 million as of June 30, 2020. The decrease was primarily driven by third quarter cash used in operating activities of $11.9 million, partially offset by net proceeds of $4.3 million from sales of common stock under Celldex's Controlled Equity Offering ^{SM} agreement with Cantor. At September 30, 2020, Celldex had 39.6 million shares outstanding.

Revenues: Total revenue was $0.7 million in the third quarter of 2020 and $3.6 million for the nine months ended September 30, 2020, compared to $0.5 million and $2.7 million for the comparable periods in 2019. The increase in revenue was primarily due to the $1.8 million milestone payment from Rockefeller University related to Celldex's manufacturing and development services agreement, partially offset by a decrease in services performed under the Company's manufacturing and research and development agreement with Duke University.

R&D Expenses: Research and development (R&D) expenses were $10.7 million in the third quarter of 2020 and $32.1 million for the nine months ended September 30, 2020, compared to $11.1 million and $32.3 million for the comparable periods in 2019. The decrease in R&D expense was primarily due to a decrease in contract research and stock-based compensation expenses, partially offset by an increase in clinical trials and contract manufacturing expenses.

G&A Expenses: General and administrative (G&A) expenses were $3.6 million in the third quarter of 2020 and $10.8 million for the nine months ended September 30, 2020, compared to $3.4 million and $12.2 million for the comparable periods in 2019. The decrease in G&A expenses was primarily due to a decrease in stock-based compensation and facility expenses.

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

Changes in Fair Value Remeasurement of Contingent Consideration: The $0.7 million loss on fair value remeasurement of contingent consideration recorded during the third quarter of 2020 and the $4.2 million gain on fair value remeasurement of contingent consideration recorded during the nine months ended September 30, 2020 were primarily due to updated assumptions for CDX-3379 related milestones due to the discontinuation of the CDX-3379 program in the second quarter of 2020, changes in discount rates and the passage of time.

Net Loss: Net loss was $14.2 million, or ($0.36) per share, for the third quarter of 2020, and $37.9 million, or ($1.44) per share, for the nine months ended September 30, 2020, compared to a net loss of $11.4 million, or ($0.75) per share, for the third quarter of 2019 and $40.4 million, or ($2.92) per share, for the nine months ended September 30, 2019.

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

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ USA.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer. 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; 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 cost of paying development, regulatory approval and sales-based milestones under our merger agreement with Kolltan, including the cost, timing, and outcome of our declaratory judgment action against the Kolltan stockholder representative with respect to certain of those milestones; 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.

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CELLDEX THERAPEUTICS, INC.
(In thousands, except per share amounts)

CONSOLIDATED STATEMENTS OF OPERATIONS DATA	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(Unaudited)		(Unaudited)	
REVENUES:				
Product Development and Licensing Agreements	$ 12	$ 55	$ 2,297	$ 379
Contracts and Grants	656	491	1,336	2,307
Total Revenue	668	546	3,633	2,686
OPERATING EXPENSES:				
Research and Development	10,708	11,101	32,109	32,333
General and Administrative	3,640	3,403	10,833	12,207
Intangible Asset Impairment	-	-	3,500	-
Other Asset Impairment	-	-	-	1,800
Loss (Gain) on Fair Value Remeasurement of Contingent Consideration	662	(2,114)	(4,236)	(1,612)
Total Operating Expense	15,010	12,390	42,206	44,728
Operating Loss	(14,342)	(11,844)	(38,573)	(42,042)

Investment and Other Income, Net	118	431	465	1,611
Net Loss Before Income Tax Benefit	(14,224)	(11,413)	(38,108)	(40,431)
Income Tax Benefit	-	-	228	-
Net Loss	$ (14,224)	$ (11,413)	$ (37,880)	$ (40,431)
Basic and Diluted Net Loss per Common Share	$ (0.36)	$ (0.75)	$ (1.44)	$ (2.92)
Shares Used in Calculating Basic and Diluted Net Loss per Share	39,278	15,282	26,303	13,854

CONDENSED CONSOLIDATED BALANCE SHEETS DATA

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Cash, Cash Equivalents and Marketable Securities	$ 199,594	$ 64,383
Other Current Assets	3,331	2,315
Property and Equipment, net	3,813	4,031
Intangible and Other Assets, net	49,032	52,204
Total Assets	$ 255,770	$ 122,933
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities	$ 12,200	$ 11,643
Long-Term Liabilities	13,595	17,264
Stockholders' Equity	229,975	94,026
Total Liabilities and Stockholders' Equity	$ 255,770	$ 122,933

Source: Celldex Therapeutics, Inc.