Celldex Reports Second Quarter 2022 Financial Results and Provides Corporate Update

Aug 8, 2022

- Positive interim data from barzolvolimab Phase 1b Study in Chronic Spontaneous Urticaria presented at EAACI 2022 -

- First patients dosed in Phase 2 chronic urticaria studies -

HAMPTON, N.J., Aug. 08, 2022 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the second quarter ended June 30, 2022 and provided a corporate update.

“In late June, Celldex reported positive interim data from our ongoing Phase 1b study of barzolvolimab in chronic spontaneous urticaria, where multiple doses demonstrated rapid, marked and durable responses, including in patients with prior omalizumab treatment,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “We are very encouraged by these results which we believe demonstrate barzolvolimab’s potential to provide meaningful symptom relief to patients suffering from diseases driven by mast cells. These data, together with our previously reported positive results in chronic inducible urticaria, support the continued clinical development of barzolvolimab, including our recently initiated Phase 2 chronic urticaria studies.”

Mr. Marucci continued, “We are pleased with our recent advances and expansion of the barzolvolimab program into later stage studies and additional indications, along with the continued development of our bispecific platform. We also recently made the decision to transition development of CDX-1140 to investigator-led studies, allowing us to focus our resources on the programs we believe hold the most value for patients and shareholders. We look forward to providing updates on progress across our programs, with additional significant key milestones expected in the upcoming quarters.”

Recent Program Highlights

Barzolvolimab (also referred to as CDX-0159) - KIT Inhibitor Program

Barzolvolimab is 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.

- On June 30, Celldex reported interim data from the barzolvolimab multiple dose Phase 1b study in Chronic Spontaneous Urticaria (CSU) which were presented as a late-breaking electronic poster presentation as part of the European Academy of Allergy and Clinical Immunology (EAACI) Annual Congress 2022.
    - Barzolvolimab was well tolerated with a favorable safety profile; effects of multiple dose administration were consistent with observations in single dose studies. Barzolvolimab results in rapid, marked and durable responses in patients with moderate to severe CSU refractory to antihistamines, including patients with prior omalizumab treatment.
    - Mean reduction from baseline in urticaria activity (UAS7) of 66.6% in all patients in the 1.5 mg/kg dose group (n=8) at week 12 and 75.1% in all patients in the 3 mg/kg dose group (n=9) at week 8 (reflects only one dose), demonstrating clinically meaningful symptom improvements for patients.
    - Complete response (UAS7=0) of 57.1% in the 1.5 mg/kg dose group at week 12 and 44.4% at week 8 (reflects only one dose) in the 3 mg/kg dose group which is a key therapeutic goal.
    - 75% well-controlled disease by Urticaria Control Test (UCT) in the 1.5 mg/kg dose group at week 12 and 83.3% in the 3 mg/kg dose group at week 8 (reflects only one dose).
    - Tryptase suppression paralleled symptom improvement, demonstrating the impact of mast cell depletion on CSU disease activity.

- In June and July 2022, Celldex announced that the first patients have been dosed in the Phase 2 clinical studies of barzolvolimab for the treatment of CSU and the two most common forms of chronic inducible urticaria (CIndU) - cold urticaria (ColdU) and symptomatic dermographism (SD). These randomized, double-blind, placebo-controlled, parallel group Phase 2 studies are evaluating the efficacy and safety profile of multiple dose regimens of barzolvolimab in patients who remain symptomatic despite antihistamine therapy, to determine the optimal dosing strategies.

- Celldex continues to enroll patients in the barzolvolimab Phase 1b open label study in chronic inducible urticaria in a third cohort (single dose, 3 mg/kg) in cholinergic urticaria and a fourth cohort at a lower dose (single dose, 1.5 mg/kg) in cold

urticaria.

- Celldex continues to enroll patients in the barzolvolimab Phase 1b multi-center, randomized, double-blind, placebo-controlled study in patients with prurigo nodularis (PN), a chronic skin disease characterized by the development of hard, intensely itchy (pruritic) nodules on the skin.

- Celldex remains on track with the development of barzolvolimab in eosinophilic esophagitis (EoE), the most common type of eosinophilic gastrointestinal disease, and plans to initiate a Phase 2 trial in the fourth quarter of 2022.

CDX-527 - Bispecific Antibody Program

CDX-527 is 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 the Phase 1 dose-escalation study of CDX-527 in patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy, enrollment to the dose escalation portion of the study has been completed and an expansion cohort in ovarian cancer is currently enrolling patients.

CDX-1140 - CD40 Agonist Program

CDX-1140 is 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.

- Recently, Celldex reviewed updated data from the CDX-1140 Phase 1 expansion cohorts in combination with KEYTRUDA® (pembrolizumab) in patients with squamous cell head and neck cancer (SCCHN) and non-small cell lung cancer who had progressed on checkpoint therapy. Evidence of clinical benefit was most evident in patients with SCCHN, all of whom had progressive disease on prior anti-PD-1/L1 based therapies. Despite evidence of clinical benefit, questions remain to be answered about CDX-1140, and the broader CD40 agonist class, regarding the best clinical settings, regimens, and possible combinations before advancing into additional Celldex sponsored studies. Given our pipeline priorities and resource requirements, Celldex will not progress further Company-sponsored studies at this time and is exploring alternative means of answering these questions, including through investigator sponsored studies.

Recent Operational Highlights

- In June 2022, Cheryl L. Cohen and Dr. Garry Neil were appointed to the Celldex Board of Directors. Ms. Cohen currently serves as President of CLC Consulting, a pharmaceutical and biotechnology consulting firm that specializes in new product start-ups and commercialization. Dr. Neil currently serves as Chief Executive Officer at Avalo Therapeutics (formerly Cerecor, Inc.), a publicly held biotechnology company.

- In July 2022, Celldex executed a settlement agreement with Shareholder Representative Services (SRS), the representative of the former stockholders of Kolltan Pharmaceuticals, Inc. Celldex believes this is a favorable financial outcome for the Company and its shareholders and it achieves certainty and avoids the distraction and further cost of litigation. Total potential contingent milestones (payable in cash or stock at Celldex's discretion) from the merger agreement were reduced from $172.5 million to $80.0 million of which $15.0 million was paid in July.

Second Quarter 2022 Financial Highlights and 2022 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2022 were $356.8 million compared to $380.5 million as of March 31, 2022. The decrease was primarily driven by second quarter cash used in operating activities of $22.2 million. At June 30, 2022, Celldex had 46.8 million shares outstanding.

Revenues: Total revenue was $0.2 million in the second quarter of 2022 and $0.3 million for the six months ended June 30, 2022, compared to $3.5 million and $4.2 million for the comparable periods in 2021. The decrease in revenue was primarily due to a decrease in services performed under our manufacturing and research and development agreements with Rockefeller University and Gilead Sciences.

R&D Expenses: Research and development (R&D) expenses were $20.7 million in the second quarter of 2022 and $37.8 million for the six months ended June 30, 2022, compared to $12.4 million and $25.1 million for the comparable periods in 2021. The increase in R&D expenses was primarily due to an increase in clinical trial and personnel expenses.

G&A Expenses: General and administrative (G&A) expenses were $7.2 million in the second quarter of 2022 and $14.1 million for the six months ended June 30, 2022, compared to $4.3 million and $8.4 million for the comparable periods in 2021. The increase in G&A expenses was primarily due to higher legal costs related to reaching a binding settlement term sheet ("the Term Sheet") with SRS, commercial planning and stock-based compensation expenses.

Changes in Fair Value Remeasurement of Contingent Consideration: The gain on fair value remeasurement of contingent consideration was $6.3 million for the second quarter of 2022 and $6.9 million for the six months ended June 30, 2022, primarily due to the Company's decision to deprioritize the CDX-1140 program.

Litigation Settlement Related Loss: The Company recorded a one-time loss of $15.0 million in the second quarter of 2022 related to the initial payment due under the Term Sheet entered with SRS.

Net Loss: Net loss was $36.0 million, or ($0.77) per share, for the second quarter of 2022, and $59.1 million, or ($1.26) per share, for the six months ended June 30, 2022, compared to a net loss of $13.4 million, or ($0.34) per share, for the second quarter of 2021 and $29.9 million, or ($0.76) per share, for the six months ended June 30, 2021. The litigation settlement related loss had a ($0.32) impact on net loss per share in the three and six months ended June 30, 2022. The gain on fair value remeasurement of contingent consideration had a $0.14 and $0.15 impact on net loss per share in the three and six months ended June 30, 2022, respectively.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 30, 2022 are sufficient to meet estimated working capital requirements and fund planned operations through 2025.

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, including barzolvolimab (also referred to as CDX-0159), in current or future indications; 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 effects of the outbreak of COVID-19 on our business and results of operations; the availability, cost, delivery and quality of clinical 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
	(Unaudited)		(Unaudited)	

Revenues:				
Product development and licensing agreements	$ -	$ 26	$ 30	$ 29
Contracts and grants	163	3,454	307	4,136
Total revenues	163	3,480	337	4,165
Operating expenses:				
Research and development	20,731	12,356	37,786	25,076
General and administrative	7,154	4,306	14,066	8,426
(Gain) loss on fair value remeasurement of contingent consideration	(6,326)	258	(6,862)	741
Litigation settlement loss	15,000	-	15,000	-
Total operating expenses	36,559	16,920	59,990	34,243
Operating loss	(36,396)	(13,440)	(59,653)	(30,078)
Investment and other income, net	392	67	599	167
Net loss	$ (36,004)	$ (13,373)	$ (59,054)	$ (29,911)
Basic and diluted net loss per common share	$ (0.77)	$ (0.34)	$ (1.26)	$ (0.76)
Shares used in calculating basic and diluted net loss per share	46,759	39,616	46,749	39,615

Condensed Consolidated

Balance Sheet Data	**June 30, 2022 (Unaudited)**	**December 31, 2021**
Assets		
Cash, cash equivalents and marketable securities	$ 356,817	$ 408,250
Other current assets	11,162	2,589
Property and equipment, net	3,744	3,551
Intangible and other assets, net	31,238	30,264
Total assets	$ 402,961	$ 444,654
Liabilities and stockholders' equity		
Current liabilities	$ 29,949	$ 16,528
Long-term liabilities	7,919	8,650
Stockholders' equity	365,093	419,476
Total liabilities and stockholders' equity	$ 402,961	$ 444,654

Source: Celldex Therapeutics, Inc.