



Celldex Reports Second Quarter 2025 Financial Results and Provides Corporate Update

Aug 7, 2025

- *Strong execution and continued progress across pipeline*
- *Unprecedented data delivered from Phase 2 CSU study demonstrating profound, sustained complete response and improved quality of life 7 months after completion of barzolvolimab dosing*
- *Data anticipated from Phase 2 studies of barzolvolimab in EoE and CIndU and Phase 1 study of CDX-622 in healthy volunteers in 2H 2025*

HAMPTON, N.J., Aug. 07, 2025 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today reported financial results for the second quarter ended June 30, 2025 and provided a corporate update.

"In the second quarter of 2025, data from our now completed Phase 2 study in chronic spontaneous urticaria were presented that we believe clearly show that barzolvolimab is best in disease and achieves the goal of treatment for patients and physicians —rapid, profound, durable complete response which is correlated with meaningful improvements in quality of life," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. "The Celldex team is working diligently to bring this important medicine to patients and we remain focused on executing across our Phase 3 program in CSU, which is on track and expected to be fully enrolled next summer."

"The second half of the year will bring additional important data readouts from our barzolvolimab Phase 2 studies in CIndU and EoE and our CDX-622 Phase 1 study in healthy volunteers and we look forward to sharing our continued progress."

Recent Program Highlights

Barzolvolimab - 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.

Chronic Urticarias

Phase 3 Development

- A [global Phase 3 program in chronic spontaneous urticaria \(CSU\)](#) consisting of two Phase 3 trials (EMBARQ-CSU1 and EMBARQ-CSU2) was initiated in July and enrollment is ongoing. The studies are designed to establish the efficacy and safety of barzolvolimab in adult patients with CSU who remain symptomatic despite H1 antihistamine treatment and also include patients who remain symptomatic after treatment with biologics. EMBARQ-CSU1 and EMBARQ-CSU2 will enroll approximately 915 patients each across approximately 40 countries and 500 sites. In addition, Celldex plans to initiate a global Phase 3b long term extension (LTE) study for patients who complete the EMBARQ-CSU Phase 3 trials. The study will consist of 2 Groups: Group 1 (Observation Group), containing patients whose disease remains well controlled (UAS7<16) and Group 2 (Barzolvolimab Retreatment Group) containing patients whose disease is currently moderate to severe (UAS7≥16). Patients in Group 2 will receive up to an additional year of treatment with barzolvolimab. Patients in the observation group (Group 1) whose CSU flares to a UAS7≥16 in the first 6 months of the LTE will also be able to receive treatment.
- The Company is currently planning a global Phase 3 program in chronic inducible urticaria (CIndU), which is expected to initiate in 2H 2025.

Phase 2 Development

- Barzolvolimab met all primary and secondary endpoints at 12 weeks across the Company's Phase 2 studies in [CSU](#) and [CIndU](#). Results were highly statistically significant and clinically meaningful.
 - [76 week data](#), which includes 24-weeks of off-treatment follow-up, from the Phase 2 study in CSU were presented in a late breaking oral presentation in June at the European Academy of Allergy and Clinical Immunology (EAACI)

Congress 2025. Seven months after completion of dosing, patients continued to experience profound clinical benefit, with up to 41% of patients reporting a complete response at 76 weeks and 48% of patients reporting that their disease no longer impacted their quality of life. Barzolvolimab demonstrated a well tolerated safety profile throughout the study.

- [52 week data](#) on the impact of barzolvolimab on angioedema symptoms in the Phase 2 CSU study were also presented at EAACI. Up to 77% of patients treated with barzolvolimab who had angioedema at baseline were angioedema free (AAS7=0) at Week 52 and patients treated with barzolvolimab were angioedema free up to 72% of the time over the 52 week treatment period.
- 20 week treatment data from the Phase 2 CIndU study will be presented later this year. After completing treatment, patients on study are followed for 24 weeks and patients with returning symptoms can enter an open label extension during the follow up period.

Additional Indications

- Enrollment is complete in the Phase 2 study in eosinophilic esophagitis (EoE) and data from this study (12 week analysis) are expected in 2H 2025. This randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of barzolvolimab in patients with active EoE.
- Enrollment continues in the Phase 2 study in prurigo nodularis (PN). This randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of barzolvolimab in patients with moderate to severe PN.
- Enrollment is ongoing in the Phase 2 study in atopic dermatitis (AD). This randomized, double-blind, placebo-controlled, parallel group study is evaluating the efficacy and safety profile of barzolvolimab in patients with moderate to severe AD.

Bispecific Antibody Platform

CDX-622 – Bispecific SCF & TSLP

CDX-622 targets two complementary pathways that drive chronic inflammation, potentially neutralizing the alarmin thymic stromal lymphopoietin (TSLP) and depleting mast cells via stem cell factor (SCF) starvation. Combined neutralization of SCF and TSLP with CDX-622 is expected to simultaneously reduce tissue mast cells and inhibit Type 2 inflammatory responses to potentially offer enhanced therapeutic benefit in inflammatory and fibrotic disorders.

- Enrollment is ongoing in the Phase 1 study in healthy volunteers. This two-part randomized, double-blind, placebo-controlled, dose escalation study is designed to assess the safety, pharmacokinetics, and pharmacodynamics of single ascending doses (Part 1) and multiple ascending doses (Part 2) of CDX-622 in up to 56 healthy participants. The pharmacodynamic biomarkers from blood and skin will be highly informative on the ability of CDX-622 to engage and neutralize SCF and TSLP. Data from Part 1 of the study are expected in 2H 2025.

Second Quarter 2025 Financial Highlights and 2025 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2025 were \$630.3 million compared to \$673.3 million as of March 31, 2025. The decrease was primarily driven by second quarter cash used in operating activities of \$44.0 million. At June 30, 2025, Celldex had 66.4 million shares outstanding.

Revenues: Total revenue was \$0.7 million in the second quarter of 2025 and \$1.4 million for the six months ended June 30, 2025, compared to \$2.5 million and \$2.7 million for the comparable periods in 2024. The decrease in revenue was primarily due to a decrease in services performed under our manufacturing and research and development agreements with Rockefeller University.

R&D Expenses: Research and development (R&D) expenses were \$54.2 million in the second quarter of 2025 and \$106.8 million for the six months ended June 30, 2025, compared to \$39.7 million and \$71.3 million for the comparable periods in 2024. The increase in R&D expenses was primarily due to an increase in barzolvolimab clinical trial, barzolvolimab contract manufacturing and personnel expenses.

G&A Expenses: General and administrative (G&A) expenses were \$10.4 million in the second quarter of 2025 and \$21.2 million for the six months ended June 30, 2025, compared to \$9.1 million and \$18.2 million for the comparable periods in 2024. The increase in G&A expenses was primarily due to an increase in stock-based compensation expense and an increase in employee headcount.

Net Loss: Net loss was \$56.6 million, or (\$0.85) per share, for the second quarter of 2025, and \$110.4 million, or (\$1.66) per share, for the six months ended June 30, 2025, compared to a net loss of \$35.8 million, or (\$0.54) per share, for the second quarter of 2024, and \$68.7 million, or (\$1.10) per share, for the six months ended June 30, 2024.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 30, 2025 are sufficient to meet estimated working capital requirements and fund current planned operations through 2027.

About Celldex

Celldex is pioneering new horizons in immunology to deliver life-changing therapies. We are relentless in our pursuit of novel antibody-based treatments that engage the human immune system and directly affect critical pathways to improve the lives of patients with allergic, inflammatory and autoimmune disorders. 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 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.

Company Contact

Sarah Cavanaugh
Senior Vice President, Corporate Affairs & Administration
(508) 864-8337
scavanaugh@celldex.com

Patrick Till
Meru Advisors
(484) 788-8560
ptill@meruadvisors.com

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

Consolidated Statements of Operations Data	Three Months Ended June 30,		Six Months Ended June 30,	
	2025 (Unaudited)	2024	2025 (Unaudited)	2024
Revenues:				
Product development and licensing agreements	\$ 7	\$ -	\$ 57	\$ 2
Contracts and grants	723	2,498	1,367	2,652
Total revenues	730	2,498	1,424	2,654
Operating expenses:				
Research and development	54,196	39,687	106,810	71,348
General and administrative	10,391	9,128	21,211	18,231
Total operating expenses	64,587	48,815	128,021	89,579

Operating loss	(63,857)	(46,317)	(126,597)	(86,925)
Investment and other income, net	7,257	10,475	16,201	18,275
Net loss	\$ (56,600)	\$ (35,842)	\$ (110,396)	\$ (68,650)
Basic and diluted net loss per common share	\$ (0.85)	\$ (0.54)	\$ (1.66)	\$ (1.10)
Shares used in calculating basic and diluted net loss per share	66,392	66,019	66,388	62,445

Condensed Consolidated Balance Sheet Data	June 30	December 31
	2025 (Unaudited)	2024
Assets		
Cash, cash equivalents and marketable securities	\$ 630,337	\$ 725,281
Other current assets	18,067	21,878
Property and equipment, net	4,392	4,346
Intangible and other assets, net	39,611	40,835
Total assets	<u>\$ 692,407</u>	<u>\$ 792,340</u>
Liabilities and stockholders' equity		
Current liabilities	\$ 32,963	\$ 39,501
Long-term liabilities	4,038	5,834
Stockholders' equity	655,406	747,005
Total liabilities and stockholders' equity	<u>\$ 692,407</u>	<u>\$ 792,340</u>



Source: Celldex Therapeutics, Inc.