Celldex Reports Third Quarter 2025 Financial Results and Provides Corporate Update

Nov 10, 2025

- *Strong execution and continued progress across pipeline*
- *Positive Phase 2 barzolvolimab data in Chronic Spontaneous Urticaria (CSU) demonstrating rapid, profound improvement in UCT7 scores with sustained disease control post treatment and strong efficacy regardless of baseline IgE levels*
- *Positive Phase 2 barzolvolimab data in Cold Urticaria (ColdU) and Symptomatic Dermographism (SD) demonstrating sustained efficacy and favorable safety profile at 20 weeks; first large, randomized, placebo-controlled study to demonstrate clinical benefit in these indications; Phase 3 study in ColdU and SD to initiate December 2025*
- *Positive Phase 1 CDX-622 (SCF & TSLP) data; first stem cell factor neutralizing bispecific antibody to be studied in humans*

HAMPTON, N.J., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today reported financial results for the third quarter ended September 30, 2025 and provided a corporate update.

"This quarter, Celldex continued to demonstrate our leadership in the field of mast cell biology, presenting exciting data across our pipeline programs," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex. "Barzolvolimab is the first in the field to demonstrate clinical benefit in a large, randomized, placebo-controlled study of cold urticaria and symptomatic dermographism, and we were also pleased to report additional endpoints from our Phase 2 CSU study and promising data from CDX-622, the first stem cell factor neutralizing bispecific antibody to be studied in humans, which we designed to also target TSLP."

"As we look to the close of 2025, we will continue to drive progress across our entire pipeline, expecting multiple data readouts throughout next year. Importantly, we are actively preparing for the potential commercialization of barzolvolimab and we are thrilled to announce today that Teri Lawver has joined Celldex as Senior Vice President, Chief Commercial Officer. Teri's deep background in successfully launching multiple important immunology drugs will play a critical role in Celldex's mission to deliver life-changing therapies to patients in need."

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 2024 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. A Phase 3b long term extension (LTE) study has been established for patient entry after completion of the EMBARQ-CSU Phase 3 trials.

- The Company plans to initiate a global Phase 3 study in cold urticaria (ColdU) and symptomatic dermographism (SD) in December 2025.

Phase 2 Development

- Barzolvolimab met all primary and secondary endpoints at 12 weeks in the Company's Phase 2 study in CSU. Results were highly statistically significant and clinically meaningful. Sustained and deepening disease efficacy was demonstrated through the 52 week treatment period with 71% of patients (150 mg Q4W) experiencing complete response at 52 weeks. 7 months after the completion of dosing with barzolvolimab, over 40% of patients (150 mg Q4W) continued to experience complete response, suggestive of disease modification at 76 weeks. Additional data has been presented demonstrating profound improvements in quality of life and angioedema at multiple timepoints across the study. In September at EADV

2025, data were presented demonstrating rapid and strong efficacy regardless of baseline immunoglobulin E (IgE) levels and in November 2025 at the ACAAI Annual Scientific Meeting, data were presented demonstrating that barzolvolimab leads to rapid and profound improvements in UCT7 scores with sustained disease control post treatment. Barzolvolimab demonstrated a well tolerated safety profile throughout the study. The study is complete.

- Barzolvolimab met all primary and secondary endpoints at 12 weeks in the Company's Phase 2 study in ColdU and SD. Results were highly statistically significant and clinically meaningful and subsequent data presented demonstrated profound improvements in quality of life. Patients continued to receive barzolvolimab and, in November 2025, 20 week placebo controlled treatment data were presented at ACAAI. At 20 weeks, up to 66% of patients with ColdU and 49% of patients with SD obtained a complete response compared to 16% and 10% of patients on placebo, respectively. Up to 78% of patients with ColdU and 58% of patients with SD obtained a partial or complete response compared to 25% and 16% of patients on placebo, respectively. Marked improvement in critical temperature and friction thresholds were observed over the 20 week treatment period. Barzolvolimab was well tolerated with a favorable safety profile consistent with previous studies. Patients were followed for up to 24 weeks after treatment completion and patients with returning or continuing symptoms were given the option to enter an open label extension (OLE) during this follow up period. Consistent with the clinical endpoint results at Week 20, placebo-treated patients entered the OLE at a faster rate compared to barzolvolimab-treated patients. The study was recently completed and data from the OLE are expected to be presented in Q1 2026.

Additional Indications

- 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. Initial data from this study are expected to be presented in 2H 2026.

- 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. Initial data from this study are expected to be presented in 2H 2026.

- Data from the Phase 2 study in eosinophilic esophagitis (EoE) were presented in August 2025. The primary endpoint of the study was met, absolute change from baseline to Week 12 in peak esophageal intraepithelial mast cell count, demonstrating barzolvolimab's ability to potently deplete mast cells in the gastrointestinal tract. This profound mast cell depletion did not result in improved clinical outcomes providing direct evidence that mast cells are not a primary driver in EoE. A favorable safety profile, consistently with previously reported studies, was demonstrated for barzolvolimab 300 mg Q4 weekly dosing regimen. Based on these results, further development in EoE was discontinued. The results do support future development with KIT- or SCF-targeted therapies in other GI indications where mucosal mast cells are believed to play an important role.

Bispecific Antibody Platform

CDX-622 – Bispecific SCF & TSLP

CDX-622 targets two complementary pathways that drive chronic inflammation, potently 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. CDX-622 has been engineered to disable effector function (AQQ) and reduce clearance (YTE).

- Enrollment is ongoing in the Phase 1 study in healthy volunteers. This three-part randomized, double-blind, placebo-controlled, dose escalation study is designed to assess the safety, pharmacokinetics, and pharmacodynamics of single ascending doses (Part 1), multiple ascending doses (Part 2) and single ascending doses administered subcutaneously (Part 3) of CDX-622 in up to 80 healthy participants. Data from Part 1 of the study were presented in October at the CIA Biennial Symposium. CDX-622 was well tolerated with no dose limiting toxicities and no emergent events related to systemic KIT inhibition. CDX-622 exhibited a good pharmacokinetic profile and induced rapid and sustained dose dependent reductions in serum tryptase, indicative of mast cell inhibition and depletion. Patients are now being enrolled to Part 2 of the study with data anticipated in Q3 2026.

Third Quarter 2025 Financial Highlights and 2025 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2025 were $583.2 million compared to $630.3 million as of June 30, 2025. The decrease was primarily driven by third quarter cash used in operating activities of $48.6 million. At September 30, 2025, Celldex had 66.4 million shares outstanding.

Revenues: Total revenue was $0.0 million in the third quarter of 2025 and $1.4 million for the nine months ended September 30, 2025, compared to $3.2 million and $5.8 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 $62.9 million in the third quarter of 2025 and $169.7 million for the nine months ended September 30, 2025, compared to $45.3 million and $116.6 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 $10.7 million in the third quarter of 2025 and $31.9 million for the nine months ended September 30, 2025, compared to $10.1 million and $28.3 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 $67.0 million, or ($1.01) per share, for the third quarter of 2025, and $177.4 million, or ($2.67) per share, for the nine months ended September 30, 2025, compared to a net loss of $42.1 million, or ($0.64) per share, for the third quarter of 2024, and $110.8 million, or ($1.74) per share, for the nine months ended September 30, 2024.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 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) and CDX-622, 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.

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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,	
	2025	2024	2025	2024
	(Unaudited)		(Unaudited)	

Revenues:				
Product development and licensing agreements	$ -	$ 3	$ 57	$ 5
Contracts and grants	-	3,188	1,367	5,840
Total revenues	-	3,191	1,424	5,845
Operating expenses:				
Research and development	62,931	45,263	169,741	116,611
General and administrative	10,686	10,054	31,897	28,285
Total operating expenses	73,617	55,317	201,638	144,896
Operating loss	(73,617)	(52,126)	(200,214)	(139,051)
Investment and other income, net	6,573	10,005	22,774	28,280
Net loss	$ (67,044)	$ (42,121)	$ (177,440)	$ (110,771)
Basic and diluted net loss per common share	$ (1.01)	$ (0.64)	$ (2.67)	$ (1.74)
Shares used in calculating basic and diluted net loss per share	66,420	66,294	66,399	63,737

Condensed Consolidated Balance Sheet Data	**September 30 2025 (Unaudited)**	**December 31 2024**
Assets		
Cash, cash equivalents and marketable securities	$ 583,223	$ 725,281
Other current assets	21,116	21,878
Property and equipment, net	4,829	4,346
Intangible and other assets, net	39,271	40,835
Total assets	$ 648,439	$ 792,340
Liabilities and stockholders' equity		
Current liabilities	$ 46,465	$ 39,501
Long-term liabilities	3,611	5,834
Stockholders' equity	598,363	747,005
Total liabilities and stockholders' equity	$ 648,439	$ 792,340

Source: Celldex Therapeutics, Inc.