Celldex Reports Fourth Quarter and Year End 2025 Financial Results and Provides Corporate Update

Feb 25, 2026

- *Enrollment completed in both Phase 3 chronic spontaneous urticaria global registration studies (EMBARQ-CSU 1 and 2) six months ahead of guidance; Topline data expected in Q4 26; BLA submission planned for 2027*
- *Phase 3 cold urticaria and symptomatic dermographism study (EMBARQ-ColdU and -SD) actively accruing*
- *Enrollment completed in Phase 2 prurigo nodularis and atopic dermatitis studies with topline data expected in 2026*
- *Phase 1 CDX-622 Proof of Mechanism study in asthma initiated*
- *Company prepares for landmark year of clinical readouts in 2026*

HAMPTON, N.J., Feb. 25, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today reported financial results for the fourth quarter and year ended December 31, 2025 and provided a corporate update.

"The enthusiasm for barzolvolimab continues to build, driven by unparalleled efficacy data across multiple indications," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex. "This is underscored by the completion of enrollment in our Phase 3 CSU studies six months ahead of guidance and strong interest from clinical trial sites in our recently initiated Phase 3 study in cold urticaria and symptomatic dermographism."

"During 2026, we are excited for multiple important data readouts across our pipeline, including topline data from our barzolvolimab Phase 3 studies in CSU, Phase 2 studies in prurigo nodularis and atopic dermatitis, and additional data from our novel bispecific program, CDX-622," continued Mr. Marucci. "We continue to prepare for the planned BLA filing and commercialization of barzolvolimab in CSU, which has the potential to transform the treatment landscape and position Celldex as a pioneering immunology company—leading in mast cell biology and delivering groundbreaking therapies for patients who are waiting for better treatment options."

Recent Program Highlights

Barzolvolimab - KIT Inhibitor Program

Barzolvolimab is a humanized monoclonal antibody with a novel mechanism of action that targets mast cells by binding with high specificity to a unique part of the KIT receptor and potently inhibiting its activity. The KIT receptor is abundantly expressed by mast cells and critical for their function and survival. Mast cells are drivers of inflammatory responses such as hypersensitivity and allergic reactions and, in certain inflammatory diseases, such as chronic urticarias, mast cell activation plays a central role in the onset and progression of the disease.

Chronic Urticarias

- This morning, Celldex announced that enrollment was completed six months ahead of guidance in the global Phase 3 program in chronic spontaneous urticaria (CSU)—demonstrating strong interest in barzolvolimab. The Phase 3 program consists of two trials—EMBARQ-CSU1 and EMBARQ-CSU2. 1,939 patients were enrolled—the largest program conducted in antihistamine refractory CSU, including patients with advanced therapy experienced/refractory CSU. The studies included 43 countries and over 500 sites. EMBARQ-CSU1 and EMBARQ-CSU2 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 advanced therapies. Topline data are anticipated in Q4 2026, supporting a planned BLA filing in 2027.

- In December 2025, Celldex initiated a global Phase 3 study in cold urticaria (ColdU) and symptomatic dermographism (SD)—*EMBARQ-ColdU and -SD*. Barzolvolimab is the first drug in development to demonstrate clinical benefit in patients with ColdU and SD in a large, randomized, placebo-controlled study. In the recently completed Phase 2 study, all primary and secondary endpoints were met with high statistical significance at 12 weeks and sustained through the end of the treatment period (20 weeks).

- Data from the Phase 2 studies of barzolvolimab in both CSU and ColdU/SD have been accepted for multiple presentations at the 2026 AAAAI Annual Meeting (February 27 – March 2). This includes a late breaking poster presentation on new data from the Phase 2 ColdU and SD study entitled *"Retreatment with Barzolvolimab Leads to Rapid Improvement in Urticaria Control After Symptom Recurrence in Chronic Inducible Urticaria"* on Sunday, March 1, 2026.

Prurigo Nodularis and Atopic Dermatitis

- Enrollment is complete 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. Topline data from this study are expected to be presented in the summer of 2026.

- Enrollment is complete 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. Topline data from this study are expected to be presented in late 2026.

Novel 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 enhance half-life (YTE).

- Enrollment is complete in the Phase 1 study in healthy volunteers. The Phase 1a clinical trial is a three-part, randomized, double-blind, placebo-controlled, dose escalation study designed to assess the safety, pharmacokinetics, and pharmacodynamics of CDX-622 in up to 80 healthy participants (Part 1: single intravenous (IV) dose, Part 2: 4 IV doses, Part 3: single subcutaneous (SubQ) dose). Positive data from the single ascending dose portion of the study was presented in October 2025. Data from the multiple ascending dose portion of the study and SubQ administration are anticipated in the third quarter of 2026. The pharmacodynamic biomarkers from blood and skin will be highly informative on the ability of CDX-622 to engage and neutralize SCF and TSLP.

- In January 2026, we initiated an open-label, single-dose Phase 1 proof of mechanism (POM) study to assess the safety, pharmacodynamics, and pharmacokinetics of CDX-622 in adults with mild to moderate asthma. Participants will receive a single IV infusion of CDX-622 and be followed for 12 weeks. PD effects of CDX-622 on fractional exhaled nitric oxide (FeNO), absolute eosinophil count (AEC) and serum biomarkers, including TSLP- and SCF-related biomarkers, will be evaluated.

Fourth Quarter and Twelve Months 2025 Financial Highlights and 2026 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of December 31, 2025 were $518.6 million compared to $583.2 million as of September 30, 2025. The decrease was primarily driven by fourth quarter cash used in operating activities of $63.9 million. The increase in cash used in operating activities in the fourth quarter was primarily driven by higher clinical expenses, including the accelerated enrollment completion of the Phase 3 CSU program, and manufacturing barzolvolimab expenses. At December 31, 2025, Celldex had 66.5 million shares outstanding.

Revenues: Total revenue was $0.1 million in the fourth quarter of 2025 and $1.5 million for the year ended December 31, 2025, compared to $1.2 million and $7.0 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 $75.3 million in the fourth quarter of 2025 and $245.1 million for the year ended December 31, 2025, compared to $46.9 million and $163.6 million for the comparable periods in 2024. The increase in R&D expenses was primarily due to an increase in barzolvolimab clinical trial and contract manufacturing expenses and an increase in employee headcount.

G&A Expenses: General and administrative (G&A) expenses were $11.9 million in the fourth quarter of 2025 and $43.8 million for the year ended December 31, 2025, compared to $10.3 million and $38.5 million for the comparable periods in 2024. The increase in G&A expenses was primarily due to an increase in employee headcount and an increase in barzolvolimab commercial planning expenses.

Net Loss: Net loss was $81.3 million, or ($1.22) per share, for the fourth quarter of 2025, and $258.8 million, or ($3.90) per share, for the year ended December 31, 2025, compared to a net loss of $47.1 million, or ($0.71) per share, for the fourth quarter of 2024, and $157.9 million, or ($2.45) per share, for the year ended December 31, 2024.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at December 31, 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.

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 December 31,		Year Ended December 31,	
	2025	2024	2025	2024
	(Unaudited)			
Revenues:				
Product development and licensing agreements	$ 40	$ 8	$ 97	$ 13
Contracts and grants	81	1,167	1,448	7,007
Total revenues	121	1,175	1,545	7,020
Operating expenses:				
Research and development	75,333	46,939	245,074	163,550
General and administrative	11,941	10,263	43,838	38,548
Total operating expenses	87,274	57,202	288,912	202,098
Operating loss	(87,153)	(56,027)	(287,367)	(195,078)
Investment and other income, net	5,836	8,935	28,610	37,215

Net loss	$ (81,317)	$ (47,092)	$ (258,757)	$ (157,863)
Basic and diluted net loss per common share	$ (1.22)	$ (0.71)	$ (3.90)	$ (2.45)
Shares used in calculating basic and diluted net loss per share	66,489	66,353	66,422	64,395

Condensed Consolidated Balance Sheet Data	**December 31, 2025**	**December 31, 2024**
Assets		
Cash, cash equivalents and marketable securities	$ 518,573	$ 725,281
Other current assets	16,091	21,878
Property and equipment, net	5,334	4,346
Intangible and other assets, net	42,985	40,835
Total assets	$ 582,983	$ 792,340
Liabilities and stockholders' equity		
Current liabilities	$ 50,991	$ 39,501
Long-term liabilities	4,827	5,834
Stockholders' equity	527,165	747,005
Total liabilities and stockholders' equity	$ 582,983	$ 792,340

Source: Celldex Therapeutics, Inc.