Celldex Reports Third Quarter Financial Results and Provides Corporate Update

Nov 5, 2026

- *Best-in-disease results from Phase 3 EMBARQ-CSU1 and EMBARQ-CSU2 studies showed rapid, profound, sustained efficacy supporting barzolvolimab's potential to be a transformational therapy in CSU*
- *BLA submission for barzolvolimab in CSU anticipated in 2027*
- *Phase 3 barzolvolimab cold urticaria and symptomatic dermographism study (EMBARQ-ColdU and -SD) actively enrolling*
- *Excellent progress across all earlier stage pipeline programs*

HAMPTON, N.J., Nov. 05, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today reported financial results for the third quarter ended September 30, 2026 and provided a corporate update.

"Barzolvolimab has significant potential to address enormous populations of high unmet need and shift the treatment paradigm goal from symptom improvement to complete symptom resolution, which for patients means no itch, no hives, no swelling," said Anthony Marucci, Co-founder, President and Chief Executive Officer at Celldex. "This quarter we reported best-in-disease results from our two Phase 3 studies in CSU, demonstrating barzolvolimab's unparalleled ability to deliver complete response to patients —including even in patient populations suffering with severe disease or severe angioedema or with omalizumab refractory disease. We are moving quickly to bring this much needed medicine to patients and physicians. We are also making excellent progress advancing our ongoing Phase 3 study in symptomatic dermographism and cold urticaria and look forward to updating on these programs in 2027.

"Building on our leading science clinically validating the therapeutic potential of KIT inhibition in immune and inflammatory diseases, we will continue to chart the future of mast cell medicine, expanding barzolvolimab and CDX-622 development across a diverse spectrum of immune and inflammatory diseases and adding to our growing mast cell targeted pipeline to bring our science to additional patient populations that could benefit."

Recent Program Highlights

Barzolvolimab - KIT Inhibitor Program

Barzolvolimab is a first-in-class 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

- In September 2026, the Company reported best-in-disease topline results from the Phase 3 EMBARQ-CSU1 and -CSU2 studies of barzolvolimab in patients with CSU whose symptoms are inadequately controlled by H1-antihistamines. The primary and all key secondary endpoints across both studies and both dose groups were met. Results showed rapid, profound, and sustained efficacy, including unprecedented complete response rates, supporting barzolvolimab's potential to be a transformational therapy in CSU. Efficacy was sustained or deepened from Weeks 12 to 24, and barzolvolimab was well-tolerated with a favorable safety profile through 24 weeks, consistent with prior studies. Statistically significant and clinically meaningful benefit was also seen in antihistamine refractory patients with severe disease or severe angioedema, as well as in patients with CSU refractory to omalizumab. Treatment in both EMBARQ-CSU trials will continue to 52 weeks, and the Company anticipates a BLA submission in 2027.

  Data from the Phase 3 studies reported to date are consistent with results from the completed Phase 2 CSU study. In Phase 2, the primary endpoint was met at Week 12 and patients on study continued to receive barzolvolimab for a total of 52 weeks of treatment. Sustained and deepening disease efficacy and a well-tolerated long term safety profile were demonstrated over the 52-week treatment period. In addition, at 76 weeks, 7 months after the completion of dosing with barzolvolimab, over 40% of patients (150mg Q4W) continued to experience profound, sustained complete response and up to 64% of patients treated with barzolvolimab who had angioedema at baseline remained angioedema-free, supporting barzolvolimab's disease modifying potential.

- Enrollment is ongoing in Celldex's 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 Phase 2 study, all primary and secondary endpoints were met with high statistical significance at 12 weeks and sustained through the end of the 20-week treatment period. Patients with disease recurrence during the main study follow-up period qualified for an Open Label Extension (OLE). Barzolvolimab retreatment achieved similar profound efficacy to first exposure in patients with ColdU and SD.

Additional Indications

Celldex has clinically validated the therapeutic potential of the novel KIT inhibition mechanism of action with barzolvolimab and continues to grow the Company's pipeline across a diverse spectrum of immune and inflammatory diseases where mast cells are a critical driver.

- Additional indications for barzolvolimab will be announced by year end.
- 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.
- Topline data from the Phase 2 study in prurigo nodularis (PN) were presented in July 2026 and suggested that mast cells may not be the key pathogenic driver in PN. Based on these results, Celldex is discontinuing the Phase 2 PN study. Barzolvolimab was well-tolerated and demonstrated a favorable safety profile consistent with prior studies.

Novel Bispecific Antibody (BsAb) Platform

Celldex continues to drive groundbreaking science and is the first company to directly demonstrate that neutralizing soluble stem cell factor (SCF) can selectively inhibit KIT signaling in mast cells—a historically challenging target. Celldex's approach provides a clinically-validated anchor mechanism that enables the development of diverse BsAb candidates where a dual mechanism approach may overcome the heterogeneity inherent in the pathophysiology of many inflammatory disorders, expanding into new indications and broader patient populations that can benefit from our medicines. CDX-622 is the first candidate from this leading science, with additional BsAbs soon to follow.

- CDX-622 (SCF & TSLP) 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 soluble SCF and TSLP with CDX-622 is expected to simultaneously reduce tissue mast cells and inhibit Type 2 inflammatory responses, allowing for a complementary dual mechanism approach that may overcome the heterogeneity inherent in the pathophysiology of many inflammatory disorders. Results from the Phase 1 trial in healthy volunteers demonstrated rapid, profound, dose-dependent, and durable reductions in serum tryptase, without impacting other KIT-dependent functions. CDX-622 also exhibited monoclonal antibody-like pharmacokinetics, with extended half-life and good exposure with subcutaneous administration, consistent with good bioavailability. CDX-622 was well-tolerated in all study parts and at all dose levels.
- An open-label, single-dose Phase 1 proof of mechanism (POM) study is ongoing to assess the safety, pharmacodynamics, and pharmacokinetics of CDX-622 in adults with mild to moderate asthma. The Company plans to advance expansion into additional indications with CDX-622, including allergic rhinitis and food allergy.

Third Quarter 2026 Financial Highlights and 2026 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of September 30, 2026 were $650.3 million compared to $717.6 million as of June 30, 2026. The decrease was primarily driven by third quarter cash used in operating activities of $65.0 million. At September 30, 2026, Celldex had 78.5 million shares outstanding.

Revenues: No material revenue was recognized in the third quarter of 2026 or the nine months ended September 30, 2026, compared to $0.0 million and $1.4 million for the comparable periods in 2025, respectively. 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 $67.4 million in the third quarter of 2026 and $208.0 million for the nine months ended September 30, 2026, compared to $62.9 million and $169.7 million for the comparable periods in 2025. The increase in R&D expenses was primarily due to an increase in barzolvolimab clinical trial and contract manufacturing expense as well as an increase in employee headcount to support the development of barzolvolimab.

G&A Expenses: General and administrative (G&A) expenses were $14.8 million in the third quarter of 2026 and $39.4 million for the nine months ended September 30, 2026, compared to $10.7 million and $31.9 million for the comparable periods in 2025. The increase in G&A expenses was primarily due to an increase in barzolvolimab commercial planning expenses and an increase in employee headcount to support the commercialization of barzolvolimab.

Net Loss: Net loss was $75.6 million, or ($0.96) per share, for the third quarter of 2026, and $227.7 million, or ($3.06) per share, for the nine months ended September 30, 2026, compared to a net loss of $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.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at September 30, 2026 are sufficient to meet estimated working capital requirements and fund current planned operations through 2028.

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 current expectations regarding the submission of a Biologics License Application (“BLA”) to the FDA in 2027; 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,	
	2026	2025	2026	2025
	(Unaudited)		(Unaudited)	
Revenues:				
Product development and licensing agreements	$ -	$ -	$ 7	$ 57
Contracts and grants	-	-	30	1,367
Total revenues	-	-	37	1,424
Operating expenses:				
Research and development	67,407	62,931	207,950	169,741
General and administrative	14,844	10,686	39,396	31,897

Total operating expenses	82,251	73,617	247,346	201,638
Operating loss	(82,251)	(73,617)	(247,309)	(200,214)
Investment and other income, net	6,694	6,573	19,564	22,774
Net loss	$ (75,557)	$ (67,044)	$ (227,745)	$ (177,440)
Basic and diluted net loss per common share	$ (0.96)	$ (1.01)	$ (3.06)	$ (2.67)
Shares used in calculating basic and diluted net loss per share	78,531	66,420	74,356	66,399

Condensed Consolidated Balance Sheet Data	**September 30 2026 (Unaudited)**	**December 31 2025**
Assets		
Cash, cash equivalents and marketable securities	$ 650,319	$ 518,573
Other current assets	13,417	16,091
Property and equipment, net	10,997	5,334
Intangible and other assets, net	46,798	42,985
Total assets	$ 721,531	$ 582,983
Liabilities and stockholders' equity		
Current liabilities	$ 60,517	$ 50,991
Long-term liabilities	11,545	4,827
Stockholders' equity	649,469	527,165
Total liabilities and stockholders' equity	$ 721,531	$ 582,983

Source: Celldex Therapeutics, Inc.