



Celldex Reports Second Quarter Financial Results and Provides Corporate Update

Aug 6, 2026

- *Barzolvolimab Phase 3 chronic spontaneous urticaria studies (EMBARQ-CSU 1 and 2) ongoing, topline data expected in Sept/Oct 2026; BLA submission planned for 2027*
- *Phase 3 barzolvolimab cold urticaria and symptomatic dermographism study (EMBARQ-ColdU and -SD) actively enrolling; Phase 2 topline data in AD expected in late 2026*
- *Positive results from Phase 1 trial of bispecific CDX-622 showed rapid, profound, dose-dependent reductions in serum tryptase and CDX-622 was well tolerated; Phase 1 CDX-622 proof of mechanism study in asthma ongoing*

HAMPTON, N.J., Aug. 06, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today reported financial results for the second quarter ended June 30, 2026 and provided a corporate update.

"We are leaders in mast cell science with a pipeline of programs that have the potential to dramatically shift treatment paradigms for patients," said Anthony Marucci, Co-founder, President and Chief Executive Officer at Celldex. "Barzolvolimab, followed by our first bispecific candidate CDX-622, are a powerful portfolio combination targeting inflammatory diseases where mast cells are implicated, with the goal of ultimately bringing our leading science to additional patient populations that could benefit from our medicines. We are looking forward to sharing the topline results from our two Phase 3 trials of barzolvolimab in the early fall and are actively driving towards potential commercialization."

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

- [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 September/October 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 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).
- In June 2026, Celldex presented [long-term barzolvolimab results](#) that demonstrated sustained off-treatment improvement in patients with CSU at the European Academy of Allergy and Clinical Immunology (EAACI) Annual Meeting. Treatment with barzolvolimab resulted in rapid, significant, and durable improvements in angioedema patients with moderate to severe CSU. Seven months after the completion of dosing (Week 76), up to 64% of patients treated with barzolvolimab who had angioedema at baseline remained angioedema-free. Results support the potential of barzolvolimab to shift treatment goals from symptom control to disease modification.

Atopic Dermatitis and Prurigo Nodularis

- 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 demonstrated that the trial did not meet primary or key secondary endpoints. Barzolvolimab was well-tolerated and demonstrated a favorable safety profile consistent with prior studies. Rapid and profound suppression of circulating tryptase indicative of systemic mast cell depletion was observed. These data suggest that mast cells may not be the key pathogenic driver in PN. Based on these results, Celldex is discontinuing the Phase 2 PN study.

Novel Bispecific Antibody Platform

CDX-622 – Bispecific SCF & TSLP

CDX-622 is a uniquely engineered novel bispecific antibody that targets soluble SCF and the alarmin thymic stromal lymphopoietin (TSLP), two critical pathways that may contribute to the pathology of several allergic and inflammatory disorders with significant unmet medical need. Combined neutralization of 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. CDX-622 has been engineered to disable effector function (AQQ) and enhance half-life (YTE).

- In June 2026, first-in-human data were presented that demonstrated that neutralizing the soluble form of SCF can selectively inhibit KIT signaling in mast cells. This approach provides a validated anchor mechanism that enables the development of diverse bispecific antibody candidates where a dual mechanism approach may overcome the heterogeneity inherent in the pathophysiology of many inflammatory disorders.
 - [Results from the Phase 1 trial](#) demonstrated rapid, profound, dose-dependent, and durable reductions in serum tryptase, indicative of tissue mast cell depletion. 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. There were no dose-limiting toxicities or related serious adverse events.
- Additionally in June, Celldex presented a study in non-human primates at the European Mast Cell and Basophil Research Network (EMBRN) that showed that targeting soluble SCF effectively depleted mast cells in a manner similar to targeting membrane SCF, but without measurable effect on spermatogenesis or melanogenesis in non-human primates.
- In January 2026, an open-label, single-dose Phase 1 proof of mechanism (POM) study was initiated to assess the safety, pharmacodynamics, and pharmacokinetics of CDX-622 in adults with mild to moderate asthma. Based on recently reported data, the Company is advancing expansion into additional indications with CDX-622, including allergic rhinitis and food allergy.

Second Quarter 2026 Financial Highlights and 2026 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2026 were \$717.6 million compared to \$451.5 million as of March 31, 2026. The increase was primarily driven by net proceeds of \$323.8 million from our April 2026 underwritten public offering, partially offset by second quarter cash used in operating activities of \$57.4 million. At June 30, 2026, Celldex had 78.5 million shares outstanding.

Revenues: No material revenue was recognized in the second quarter of 2026 or the six months ended June 30, 2026, compared to \$0.7 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 \$67.5 million in the second quarter of 2026 and \$140.5 million for the six months ended June 30, 2026, compared to \$54.2 million and \$106.8 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 expenses and an increase in employee headcount.

G&A Expenses: General and administrative (G&A) expenses were \$13.1 million in the second quarter of 2026 and \$24.6 million for the six months ended June 30, 2026, compared to \$10.4 million and \$21.2 million for the comparable periods in 2025. The increase in G&A expenses was primarily due to an increase in barzolvolimab commercial planning expenses.

Net Loss: Net loss was \$73.5 million, or (\$0.94) per share, for the second quarter of 2026, and \$152.2 million, or (\$2.11) per share, for the six months ended June 30, 2026, compared to a net loss of \$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.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at June 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 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 Contacts

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

Elizabeth Higgins
Executive Director, Investor Relations & Corporate Communications
(857) 404-2088
ehiggins@celldex.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,	
	2026	2025	2026	2025
	(Unaudited)		(Unaudited)	
Revenues:				
Product development and licensing agreements	\$ 7	\$ 7	\$ 7	\$ 57
Contracts and grants	15	723	30	1,367
Total revenues	22	730	37	1,424
Operating expenses:				
Research and development	67,542	54,196	140,543	106,810
General and administrative	13,103	10,391	24,552	21,211
Total operating expenses	80,645	64,587	165,095	128,021
Operating loss	(80,623)	(63,857)	(165,058)	(126,597)
Investment and other income, net	7,120	7,257	12,870	16,201

Net loss	\$	(73,503)	\$	(56,600)	\$	(152,188)	\$	(110,396)
Basic and diluted net loss per common share	\$	(0.94)	\$	(0.85)	\$	(2.11)	\$	(1.66)
Shares used in calculating basic and diluted net loss per share		77,840		66,392		72,234		66,388

Condensed Consolidated Balance Sheet Data

	June 30		December 31	
	2026		2025	
	(Unaudited)			
Assets				
Cash, cash equivalents and marketable securities	\$	717,587	\$	518,573
Other current assets		7,344		16,091
Property and equipment, net		9,756		5,334
Intangible and other assets, net		47,662		42,985
Total assets	\$	782,349	\$	582,983
Liabilities and stockholders' equity				
Current liabilities	\$	61,325	\$	50,991
Long-term liabilities		6,460		4,827
Stockholders' equity		714,564		527,165
Total liabilities and stockholders' equity	\$	782,349	\$	582,983



Source: Celldex Therapeutics, Inc.