Celldex Reports First Quarter Financial Results and Provides Corporate Update

May 7, 2026

- *Enrollment completed six months ahead of guidance in both barzolvolimab Phase 3 chronic spontaneous urticaria studies (EMBARQ-CSU 1 and 2); Topline data expected in Q4 26; BLA submission planned for 2027*
- *Phase 3 barzolvolimab cold urticaria and symptomatic dermographism study (EMBARQ-ColdU and -SD) actively enrolling*
- *Phase 1 CDX-622 proof of mechanism study in asthma ongoing*
- *2026 expected to deliver multiple key data readouts across the pipeline*
- *Raised $345 million in gross proceeds from a follow-on public offering, closed in April 2026*

HAMPTON, N.J., May 07, 2026 (GLOBE NEWSWIRE) -- Celldex (NASDAQ:CLDX) today reported financial results for the first quarter ended March 31, 2026 and provided a corporate update.

"We began the year with a significant milestone - the early completion of enrollment in our Phase 3 CSU studies - and we have continued to build on that momentum over the quarter," said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex. "This spring, barzolvolimab was featured in five presentations at leading medical meetings, further reinforcing its potential as a first-in-class, best-in-disease therapy with the ability to transform the treatment landscape for patients in need of better options. This progress enabled the successful completion of a $345 million financing in early April, strengthening our balance sheet and supporting continued investments in our commercialization preparations and growing pipeline."

"As we look ahead, our focus remains on execution—driving strong enrollment across our Phase 3 study in ColdU and SD and advancing towards multiple important data readouts this year," Mr. Marucci continued. "These include topline data from our Phase 3 barzolvolimab CSU studies, results from Phase 2 studies in prurigo nodularis and atopic dermatitis, and additional data from our novel bispecific program, CDX-622."

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 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 were presented at the 2026 AAAAI Annual Meeting (February 27 – March 2) and the 2026 AAD Annual Meeting (March 27 – 31) further demonstrating a first-in-class and best-in-disease profile. Key highlights include:

    - Barzolvolimab retreatment achieves similar profound efficacy to first exposure in patients with ColdU and SD; ability to retreat facilitates a real-world paradigm in which treatment may be intermittent for patients with ColdU and SD
    - Sustained off-treatment efficacy despite barzolvolimab clearance and normalization of tryptase, suggesting disease modification in patients with CSU treated for full 52 weeks

- Greatly improved quality of life and reduced disease impact for patients with ColdU/SD at Week 20
- Greatly improved quality of life and reduced disease impact for patients with CSU, ColdU and SD across all measured domains: symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment

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 multi-part Phase 1 study in healthy volunteers. 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.

First Quarter 2026 Financial Highlights and 2026 Guidance

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2026 were $451.5 million compared to $518.6 million as of December 31, 2025. The decrease was primarily driven by first quarter cash used in operating activities of $65.6 million. At March 31, 2026, Celldex had 66.6 million shares outstanding. In April 2026, the Company issued 11,896,750 shares of its common stock in an underwritten public offering, resulting in gross proceeds to the Company of $345.0 million.

Revenues: Total revenue was $0.0 million in the first quarter of 2026, compared to $0.7 million for the comparable period in 2025. 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 $73.0 million in the first quarter of 2026, compared to $52.6 million for the comparable period 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 $11.4 million in the first quarter of 2026, compared to $10.8 million for the comparable period in 2025. The increase in G&A expenses was primarily due to an increase in barzolvolimab commercial planning expenses.

Net Loss: Net loss was $78.7 million, or ($1.18) per share, for the first quarter of 2026, compared to a net loss of $53.8 million, or ($0.81) per share, for the comparable period in 2025.

Financial Guidance: Celldex believes that the cash, cash equivalents and marketable securities at March 31, 2026, along with the approximately $323.9 million in net proceeds from our April 2026 underwritten public offering, 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.

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

Consolidated Statements of Operations Data	**Three Months Ended March 31,**	
	2026	**2025**
	(Unaudited)	
Revenues:		
Product development and licensing agreements	$ -	$ 50
Contracts and grants	15	645
Total revenues	15	695
Operating expenses:		
Research and development	73,001	52,614
General and administrative	11,449	10,820
Total operating expenses	84,450	63,434
Operating loss	(84,435)	(62,739)
Investment and other income, net	5,750	8,943
Net loss	$ (78,685)	$ (53,796)
Basic and diluted net loss per common share	$ (1.18)	$ (0.81)

Shares used in calculating basic and diluted net loss per share	66,566	66,383

Condensed Consolidated Balance Sheet Data	March 31, 2026 (Unaudited)	December 31, 2025
Assets		
Cash, cash equivalents and marketable securities	$ 451,458	$ 518,573
Other current assets	7,764	16,091
Property and equipment, net	7,396	5,334
Intangible and other assets, net	44,636	42,985
Total assets	$ 511,254	$ 582,983
Liabilities and stockholders' equity		
Current liabilities	$ 51,472	$ 50,991
Long-term liabilities	3,556	4,827
Stockholders' equity	456,226	527,165
Total liabilities and stockholders' equity	$ 511,254	$ 582,983

Source: Celldex Therapeutics, Inc.