Eledon Pharmaceuticals Reports Fourth Quarter and Full Year 2025 Operating and Financial Results

March 19, 2026

Reported updated results from 12 patients with type 1 diabetes treated with tegoprubart following islet transplantation in UChicago Medicine-led study

Presented 24-month follow-up data from Phase 1b long-term extension study which continues to support the favorable safety and tolerability profile of tegoprubart

Tegoprubart granted Orphan Drug designation by the FDA for the prevention of allograft rejection in liver transplantation

IRVINE, Calif., March 19, 2026 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (Nasdaq: ELDN) today reported its fourth quarter and full year 2025 operating and financial results and reviewed recent business highlights.

"Over the past year, Eledon has made significant progress advancing tegoprubart, our anti-CD40L antibody, as a potential next-generation immunosuppressive therapy across multiple transplantation settings," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "The over 100 patients treated across our transplantation programs to date provide a growing body of evidence that reinforces our conviction that tegoprubart can address key safety and efficacy issues with current standard-of-care transplant immunosuppression. Looking ahead, we anticipate multiple important milestones this year, including regulatory engagement to support advancement into Phase 3 development in kidney transplantation, initiation of an additional islet transplantation trial in type 1 diabetes, and the start of a clinical trial in liver transplantation."

Fourth Quarter 2025 and Recent Corporate Developments

- Announced that tegoprubart has been granted Orphan Drug designation by the U.S. Food and Drug Administration (FDA) for the prevention of allograft rejection in liver transplantation. Tegoprubart previously received Orphan Drug designation from the FDA for the prevention of allograft rejection in pancreatic islet cell transplantation and for the treatment of amyotrophic lateral sclerosis (ALS).
- Presented 24-month follow-up data from eight patients enrolled in the Phase 1b long-term extension trial evaluating tegoprubart in kidney transplantation at the American Society of Transplant Surgeons Winter Symposium. The data continue to support the favorable safety and tolerability profile of tegoprubart with no episodes of biopsy-proven acute rejection, graft loss, death, new-onset diabetes mellitus, or de novo donor-specific antibody formation reported during the study period. Mean estimated glomerular filtration rate (eGFR) increased over the measurement period, from 67.0 mL/min/1.73 m² at 12 months to 74.2 mL/min/1.73 m² at 24 months.
- Reported updated results from 12 patients with type 1 diabetes treated with tegoprubart as the core immunosuppressant following islet transplantation in an investigator-initiated trial conducted at the University of Chicago Medicine Transplant Institute. All 10 patients who were more than four weeks post-transplant achieved 100% insulin independence and a most recent hemoglobin A1C (HbA1c) below 6.0%, with a mean most recent HbA1c across the 10 patients of approximately 5.35%. Tegoprubart-based immunosuppression was generally well tolerated with reported post-transplant immunosuppression-related adverse events successfully treated by lowering the mycophenolic acid dose, if necessary. There were no rejection episodes, and no patients developed de novo donor-specific HLA antibodies. Additionally, no evidence of nephrotoxicity, hypertension or neurotoxicity, which are commonly associated with tacrolimus-based immunosuppression regimens, was observed. The study continues to generate significant patient demand with inquiries received from several hundred T1D patients.

Anticipated Upcoming Milestones

- Receive FDA guidance on the Phase 3 trial design assessing tegoprubart in kidney transplantation, followed by initiation of the Phase 3 trial pending regulatory alignment.
- Report long-term data from Phase 1 and Phase 2 BESTOW studies evaluating tegoprubart in kidney transplantation.
- Receive FDA regulatory guidance on path to market for tegoprubart in islet cell transplantation and xenotransplantation.
- Initiate an investigator-led study evaluating tegoprubart for the prevention of organ rejection in patients with renal dysfunction receiving an islet cell transplant.
- Initiate an investigator-led study evaluating tegoprubart for the prevention of organ rejection in patients receiving a de novo liver transplant.
- Initiate an investigator-led study evaluating tegoprubart for kidney transplant tolerance induction.

Full Year 2025 Financial Results

Research and development (R&D) expenses for the year ended December 31, 2025 were $66.3 million, including $4.2 million of non-cash stock-based compensation expense, compared to $52.0 million, including $4.3 million of non-cash stock-based compensation expense, for the comparable period in 2024. The increase was primarily driven by continued advancement of the tegoprubart clinical development programs, including expanded clinical trial activity and manufacturing scale-up, as well as increased personnel to support these efforts.

General and administrative expenses for the year ended December 31, 2025 were $17.0 million, including $6.2 million of non-cash stock-based compensation expense, compared to $18.6 million, including $8.8 million of non-cash stock-based compensation expense, for the comparable period in 2024. The decrease was primarily driven by lower stock-based compensation expense, partially offset by higher professional services and personnel-related costs.

Net loss for the year ended December 31, 2025 was $45.6 million, or $0.52 per basic share of common stock, compared to a net loss of $36.2 million, or $0.66 per basic share of common stock, for the comparable period in 2024. The 2025 net loss included a non-cash gain of $33.4 million from changes in the fair value of warrant liabilities, while the 2024 net loss included a non-cash gain of $30.9 million from such changes. Excluding the non-cash items related to changes in the fair value of warrant liabilities, Eledon would have recorded a net loss of $79.1 million for the year ended December 31, 2025 and $67.1 million for the year ended December 31, 2024.

About Eledon Pharmaceuticals and tegoprubart

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company that is developing immune-modulating therapies for the management and treatment of life-threatening conditions. The Company's lead investigational product is tegoprubart, an anti-CD40L antibody with high affinity for the CD40 Ligand, a well-validated biological target that has broad therapeutic potential. The central role of CD40L signaling in both adaptive and innate immune cell activation and function positions it as an attractive target for non-lymphocyte depleting, immunomodulatory therapeutic intervention. The Company is building upon a deep historical knowledge of anti-CD40 Ligand biology to conduct preclinical and clinical studies in kidney allograft transplantation, xenotransplantation, islet cell transplantation, liver transplantation and amyotrophic lateral sclerosis (ALS). Eledon is headquartered in Irvine, California. For more information, please visit the Company's website at www.eledon.com.

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Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Any statements about the company's future expectations, plans and prospects, including statements about planned clinical trials, the development of product candidates, expected timing for initiation of future clinical trials, expected timing for receipt of data from clinical trials, the company's capital resources and ability to finance planned clinical trials, as well as other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "looks forward," "could," "may," and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are inherently uncertain and are subject to numerous risks and uncertainties, including: our short operating history and shifts in our business strategy; our operating losses since inception; our need for additional funding to develop our lead drug candidate and our ability to secure additional funding on acceptable terms or at all; the impact of issuances of our common stock, including in the possibility of dilution or a decline in our stock price; our ability to successfully develop our product candidates; unfavorable global economic and financial market conditions; the regulatory environment of our business and our ability to obtain required regulatory approvals; results of non-clinical studies and clinical trials, and risks that non-clinical studies or early clinical trials may not be predictive of results of later-stage clinical trials; delays or difficulties in enrollment of patients in clinical trials; our ability to attract and retain our executives and key employees; legislation of the pharmaceutical and healthcare industries; cybersecurity and data privacy risks; the ability of our products to achieve marketing approval; competition in our industry; our ability to obtain insurance coverage; our dependence on contract research organizations; our ability to protect our intellectual property; public health crises; our ability to maintain proper and effective internal control over financial reporting and other risks disclosed in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission on March 19, 2026. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ materially from the forward-looking statements contained herein, are discussed in our Annual 10-K, and other filings with the U.S. Securities and Exchange Commission, which can be found at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor Contact:

Stephen Jasper
Gilmartin Group
(858) 525 2047
stephen@gilmartinir.com

Media Contact:

Jenna Urban
CG Life
(212) 253 8881
jurban@cglife.com

Source: Eledon Pharmaceuticals

ELEDON PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,808	$ 20,549

Short-term investments	110,528	119,629
Prepaid expenses and other current assets	2,352	3,552
Total current assets	135,688	143,730
Operating lease right-of-use asset, net	613	926
In-process research and development	32,386	32,386
Other assets	322	363
Total assets	$ 169,009	$ 177,405
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,627	$ 5,833
Current operating lease liability	358	314
Accrued expenses and other liabilities	14,359	5,430
Total current liabilities	18,344	11,577
Deferred tax liability	2,187	2,183
Non-current operating lease liability	283	640
Warrant liabilities	11,416	44,865
Total liabilities	32,230	59,265
Commitments and contingencies		
Convertible preferred stock, 5,000,000 shares authorized at December 31, 2025 and 2024:		
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 shares issued and outstanding at December 31, 2025 and 2024	2,151	2,151
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 110,086 shares issued and outstanding at December 31, 2025 and 2024	53,543	53,543
Stockholders' equity:		
Common stock, $0.001 par value, 300,000,000 and 200,000,000 shares authorized at December 31, 2025 and 2024, respectively; 75,430,033 and 59,789,275 shares issued and outstanding at December 31, 2025 and 2024, respectively	75	60
Additional paid-in capital	482,189	417,946
Accumulated other comprehensive income	24	26
Accumulated deficit	(401,203)	(355,586)
Total stockholders' equity	81,085	62,446
Total liabilities, convertible preferred stock and stockholders' equity	$ 169,009	$ 177,405

ELEDON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 66,267	$ 51,964
General and administrative	16,984	18,613
Total operating expenses	83,251	70,577
Other income, net	4,220	3,924
Change in fair value of warrant liabilities	33,449	30,900
Loss before income taxes	(45,582)	(35,753)
Provision for income taxes	(35)	(431)
Net loss	$ (45,617)	$ (36,184)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities, net	(2)	—
Comprehensive loss	$ (45,619)	$ (36,184)
Basic and diluted earnings per share of common stock	$ (0.52)	$ (0.66)
Weighted-average common shares outstanding, basic and diluted	81,836,246	48,543,787
Basic and diluted earnings per share of Series X and Series X[1] non-voting convertible preferred stock	$ (28.73)	$ (36.61)
Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, basic and diluted	114,508	114,508

Source: Eledon Pharmaceuticals, Inc.