Eledon Pharmaceuticals Reports Third Quarter 2026 Financial Results and Recent Business Highlights

November 12, 2026

Planned global Phase 3 LEGACY trial of tegoprubart in kidney transplantation remains on track to initiate in Q4 2026

FDA cleared the Company's IND application for a planned registrational path study of tegoprubart in islet cell transplantation for patients with type 1 diabetes

FDA Fast Track designation granted to tegoprubart for the prevention of rejection in kidney transplantation

Cash, cash equivalents and short-term investments of $69.7 million with cash runway into Q2 2027

IRVINE, Calif., Nov. 12, 2026 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (Nasdaq: ELDN) today reported its third quarter 2026 operating and financial results and provided recent business highlights.

"We continue to execute across our key strategic priorities and make meaningful progress in the tegoprubart clinical program across multiple transplant types, including plans to initiate our global Phase 3 LEGACY trial in kidney transplantation by year end," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "New patient-reported outcomes data from the Phase 2 BESTOW program further strengthened the evidence supporting tegoprubart's differentiated profile compared to today's standard of care immunosuppression therapy, while investigator-initiated studies and compassionate-use protocols help expand our understanding of tegoprubart and its therapeutic potential in different transplant settings where significant unmet needs remain."

Third Quarter 2026 Business Highlights

Kidney Transplantation

- New patient-reported outcomes data from the Phase 2 BESTOW clinical program were presented at the American Society of Nephrology (ASN) Kidney Week 2026 Annual Meeting in October 2026. Results demonstrated sustained improvements in quality of life and symptom burden in kidney transplant recipients treated with tegoprubart compared with tacrolimus, today's standard of care immunosuppression therapy. Tegoprubart-treated patients demonstrated a mean improvement on the total Modified Transplant Symptom Occurrence and Symptom Distress Scale (MTSOSD-59R) at 12 months while tacrolimus-treated patients experienced a mean worsening of symptom occurrence. Patients treated with tegoprubart also experienced a statistically significant improvement on the Kidney Disease Quality of Life Short Form (KDQOL-SF) Symptoms and Problems Scale through 12 months following transplantation compared with tacrolimus.
- Updated long-term data from the Phase 2 BESTOW extension study were presented at the International Congress of the Transplantation Society (TTS) in September 2026. Tegoprubart-treated patients maintained statistically significantly higher mean estimated glomerular filtration rate (eGFR) at 18, 21, and 24 months, with an approximately 13 mL/min/1.73m^2 advantage over tacrolimus at month 24 (71 vs. 58 mL/min/1.73m^2 (95% CI: 2.6, 23.3)). There were no reported cases of biopsy-proven acute rejection (BPAR) in the tegoprubart arm beyond six months post-transplant compared with seven BPAR events in the tacrolimus arm.
- The first highly sensitized kidney transplant patient was dosed with tegoprubart under a compassionate-use protocol at Duke University Medical Center. Highly sensitized patients requiring a kidney transplant face a substantial unmet need because pre-existing antibodies can significantly limit access to compatible donor organs and increase the risk of antibody-mediated rejection and graft loss post-transplant.
- The third patient was treated as part of the investigator-initiated study evaluating tegoprubart for kidney transplant tolerance induction at Massachusetts General Hospital (MGH).
- Tegoprubart received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the prevention of rejection in kidney transplantation.

Islet Cell Transplantation

- The FDA cleared the Investigational New Drug (IND) application for a planned Company-sponsored, registrational path clinical trial evaluating tegoprubart for the prevention of allograft rejection in type 1 diabetes (T1D) patients undergoing pancreatic islet cell transplantation.
- The first patients were enrolled in an investigator-initiated clinical trial underway at the University of Chicago Medicine Transplant Institute, evaluating tegoprubart for the prevention of allograft rejection in patients with T1D and renal dysfunction from chronic kidney disease who are receiving an islet cell transplant.
- The first islet cell transplant recipient was dosed with tegoprubart under a compassionate-use protocol allowing patients to

switch from tacrolimus-based immunosuppression therapy due to calcineurin inhibitor-related renal dysfunction.

- The University of Chicago Medicine Transplant Institute expanded its ongoing investigator-initiated study evaluating tegoprubart as the core immunosuppressant for T1D patients undergoing islet cell transplantation by enrolling three additional subjects. This will help build on previously reported study results in the 12 patients treated to date, who have achieved 100% insulin independence and demonstrated stable islet graft function through 22 months of follow-up with a favorable tolerability profile. No evidence of nephrotoxicity, hypertension, or neurotoxicity, which are side effects often associated with calcineurin inhibitors such as tacrolimus, has been observed to date.

Anticipated Upcoming Milestones

The Company anticipates the following milestones over the next 12 months:

- Initiate global Phase 3 LEGACY trial of tegoprubart in kidney transplantation in the fourth quarter of 2026. The LEGACY trial is expected to enroll approximately 600 patients, with a primary endpoint of non-inferiority of tegoprubart versus tacrolimus at 52 weeks based on a composite of BPAR, graft loss, and death.
- Initiate a Company-sponsored, registrational path study evaluating tegoprubart in T1D patients undergoing islet cell transplantation.
- Initiate an investigator-led study evaluating tegoprubart for the prevention of organ rejection in patients receiving a de novo liver transplant.
- Receive FDA regulatory guidance on the path to market for tegoprubart in kidney xenotransplantation.

Third Quarter 2026 Financial Results

Cash, cash equivalents and short-term investments totaled $69.7 million as of September 30, 2026, compared to $133.3 million as of December 31, 2025. The Company expects cash, cash equivalents and short-term investments currently on hand to fund operations into Q2 2027.

Research and development (R&D) expenses for the third quarter of 2026 were $17.8 million, including $0.9 million of non-cash stock-based compensation expense, compared to $15.0 million, including $1.1 million of non-cash stock-based compensation expense, for the comparable period in 2025.

General and administrative (G&A) expenses for the third quarter of 2026 were $3.9 million, including $1.0 million of non-cash stock-based compensation expense, compared to $4.1 million, including $1.4 million of non-cash stock-based compensation expense, for the comparable period in 2025.

Net loss for the third quarter of 2026 was $3.9 million, or $0.03 per basic common share, compared to a net loss of $17.5 million, or $0.21 per basic common share, for the comparable period in 2025. Net loss in the third quarter of 2026 included a non-cash gain of $17.0 million from changes in the fair value of warrant liabilities, while the 2025 net loss included a non-cash gain of $0.6 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 $21.0 million for the three months ended September 30, 2026, and $18.0 million for the three months ended September 30, 2025.

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-CD40L 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. Specifically, our ability to achieve our anticipated future development and corporate milestones depends on our ability to obtain additional financing on acceptable terms. 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 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 Report on Form 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

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)
(Unaudited)

	September 30, 2026	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,882	$ 22,808
Short-term investments	62,790	110,528
Prepaid expenses and other current assets	4,038	2,352
Total current assets	73,710	135,688
Operating lease asset, net	358	613
In-process research and development	32,386	32,386
Other assets	185	322
Total assets	$ 106,639	$ 169,009
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,842	$ 3,627
Current operating lease liabilities	341	358
Accrued expenses and other liabilities	8,519	14,359
Total current liabilities	11,702	18,344
Deferred tax liabilities	2,187	2,187
Non-current operating lease liabilities	35	283
Warrant liabilities	22,901	11,416
Total liabilities	36,825	32,230
Commitments and contingencies		
Convertible preferred stock, 5,000,000 shares authorized at September 30, 2026 and December 31, 2025:		
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 shares issued and outstanding at September 30, 2026 and December 31, 2025	2,151	2,151
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 75,800 and 110,086 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	36,867	53,543
Stockholders' equity:		
Common stock, $0.001 par value, 450,000,000 shares authorized at September 30, 2026 and 300,000,000 shares authorized at December 31, 2025; 81,442,402 and 75,430,033 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	82	75
Additional paid-in capital	506,631	482,189
Accumulated other comprehensive income (loss)	(126)	24
Accumulated deficit	(475,791)	(401,203)
Total stockholders' equity	30,796	81,085
Total liabilities, convertible preferred stock and stockholders' equity	$ 106,639	$ 169,009

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 17,761	$ 14,969	$ 53,188	$ 48,776
General and administrative	3,911	4,101	12,534	12,991
Total operating expenses	21,672	19,070	65,722	61,767
Loss from operations	(21,672)	(19,070)	(65,722)	(61,767)
Other income, net	714	1,047	2,694	3,680
Change in fair value of warrant liabilities	17,025	564	(11,560)	22,917
Net loss	$ (3,933)	$ (17,459)	$ (74,588)	$ (35,170)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale securities, net	(12)	57	(150)	(17)
Comprehensive loss	$ (3,945)	$ (17,402)	$ (74,738)	$ (35,187)
Basic and diluted net loss per share of common stock	$ (0.03)	$ (0.21)	$ (0.63)	$ (0.42)
Weighted-average common shares outstanding, basic and diluted	114,722,339	77,156,068	113,601,123	77,146,407
Basic and diluted net loss per share of Series X and Series X[1] non-voting convertible preferred stock	$ (1.83)	$ (11.61)	$ (34.84)	$ (23.40)
Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, basic and diluted	80,222	114,508	96,076	114,508

Eledon Pharmaceuticals

Source: Eledon Pharmaceuticals, Inc.