UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 14, 2025

Eledon Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-36620**	**20-1000967**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
19800 MacArthur Blvd. Suite 250 Irvine, California		**92612**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 949 238-8090

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	ELDN	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On November 14, 2025, Eledon Pharmaceuticals, Inc. (the "Company") issued a press release regarding its quarter ended September 30, 2025. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished to comply with Item 2.02 of Form 8-K, and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release Issued on November 14, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Eledon Pharmaceuticals, Inc.

Date: November 14, 2025

By: /s/ David-Alexandre C. Gros, M.D.
Name: David-Alexandre C. Gros, M.D.
Title: Chief Executive Officer

Exhibit 99.1

Eledon Pharmaceuticals Announces Recent Business Highlights and Third Quarter 2025 Financial Results

Data from Phase 2 BESTOW trial demonstrated a favorable safety and tolerability profile, substantially reducing the metabolic, neurologic, and cardiovascular toxicities commonly associated with tacrolimus

Data supports advancement into Phase 3 development as a potential new standard for the prevention of kidney transplant rejection

Strengthened balance sheet with $57.5 million financing to advance transplantation programs

IRVINE, Calif., November 14, 2025 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (Nasdaq: ELDN) today reported its third quarter 2025 operating and financial results and reviewed recent business highlights.

“The results from our Phase 2 BESTOW trial demonstrated tegoprubart’s excellent efficacy and safety, importantly avoiding many of the long-term toxicities commonly seen with current standard-of-care immunosuppressive therapies,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “Further, the proceeds from our recent financing enhance our ability to advance tegoprubart’s programs in kidney transplantation, islet cell transplantation, and xenotransplantation, addressing critical unmet needs in transplant medicine.”

Third Quarter 2025 and Business Highlights

- Presented results from the Phase 2 BESTOW trial evaluating tegoprubart for the prevention of organ rejection in patients receiving a kidney transplant at the American Society of Nephrology’s Kidney Week 2025 Annual Meeting in Houston, TX. Tegoprubart demonstrated a favorable safety and tolerability profile, substantially reducing the metabolic, neurologic, and cardiovascular toxicities commonly associated with tacrolimus. Kidney function, as measured by estimated glomerular filtration rate (eGFR), was approximately 69 mL/min/1.73^2 at 12-months for participants in the tegoprubart treatment arm (n=51).

- Based on the Phase 2 BESTOW results, Eledon plans to advance tegoprubart into Phase 3 development following discussions with regulators on study design and data requirements. Insights from the Phase 2 BESTOW data set and the ongoing long-term extension study will be incorporated to optimize the Phase 3 protocol and strengthen the regulatory package.

- On November 13, 2025, Eledon completed an underwritten public offering of common stock and pre-funded warrants, resulting in total gross proceeds of $57.5 million and net proceeds of approximately $53.6 million after deducting underwriting discounts, commissions, and estimated offering expenses.

Anticipated Upcoming YE2025 and 2026 Milestones

- **4Q 2025**: Enroll final three patients with Type 1 diabetes in the investigator-led clinical study at UChicago Medicine evaluating tegoprubart in islet cell transplantation.
- **2026:** Receive U.S. Food & Drug Administration ("FDA") guidance on the Phase 3 trial design for kidney transplantation, and subsequently initiate a Phase 3 trial in kidney transplantation.
- **2026:** Report long-term data from the Phase 1 and Phase 2 BESTOW studies in kidney transplantation.
- **2026:** Report data from nine patients in the investigator-led islet cell transplantation study.
- **2026:** Receive FDA regulatory guidance on path to market for islet cell transplantation & xenotransplantation.

Third Quarter 2025 Financial Results

Cash, cash equivalents and short-term investments totaled $93.4 million as of September 30, 2025 compared to $140.2 million as of December 31, 2024.

Research and development (R&D) expenses for the third quarter of 2025 were $15.0 million, including $1.1 million of non-cash stock-based compensation expense, compared to $16.5 million, including $0.4 million of non-cash stock-based compensation expense, for the comparable period in 2024.

General and administrative expenses for the third quarter of 2025 were $4.1 million, including $1.4 million of non-cash stock-based compensation expense, compared to $4.0 million, including $1.4 million of non-cash stock-based compensation expense, for the comparable period in 2024.

Net loss for the third quarter of 2025 was $17.5 million, or $0.21 per basic common share, compared to a net income of $77.0 million, or $1.05 per basic common share, for the comparable period in 2024. Net income in the third quarter of 2024 included a non-cash gain of $96.4 million related to changes in the fair value of warrant liabilities. Excluding this non-cash gain, Eledon would have recorded a net loss of $19.5 million for the third quarter of 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, liver allograft 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.

Follow Eledon Pharmaceuticals on social media: LinkedIn; Twitter

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 establish and maintain proper and effective internal control over financial reporting and other risks disclosed in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, filed with the Securities and Exchange Commission on November 14, 2025. 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 quarterly 10-Q, 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.

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Exhibit 99.1

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Source: Eledon Pharmaceuticals

Exhibit 99.1

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

	September 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,669	$ 20,549
Short-term investments	89,732	119,629
Prepaid expenses and other current assets	2,900	3,552
Total current assets	96,301	143,730
Operating lease asset, net	694	926
In-process research and development	32,386	32,386
Other assets	476	363
Total assets	$ 129,857	$ 177,405
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,627	$ 5,833
Current operating lease liabilities	346	314
Accrued expenses and other liabilities	9,323	5,430
Total current liabilities	14,296	11,577
Deferred tax liabilities	2,183	2,183
Non-current operating lease liabilities	376	640
Warrant liabilities	21,948	44,865
Total liabilities	38,803	59,265
Commitments and contingencies		
Convertible preferred stock, 5,000,000 shares authorized at September 30, 2025 and December 31, 2024:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 110,086 shares issued and outstanding at September 30, 2025 and December 31, 2024	53,543	53,543
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 shares issued and outstanding at September 30, 2025 and December 31, 2024	2,151	2,151
Stockholders' equity:		
Common stock, $0.001 par value, 300,000,000 shares authorized at September 30, 2025 and 200,000,000 at December 31, 2024; 59,881,775 and 59,789,275 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	60	60
Additional paid-in capital	426,047	417,946
Accumulated other comprehensive income	9	26
Accumulated deficit	(390,756)	(355,586)
Total stockholders' equity	35,360	62,446
Total liabilities, convertible preferred stock and stockholders' equity	$ 129,857	$ 177,405

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,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 14,969	$ 16,520	$ 48,776	$ 34,036
General and administrative	4,101	3,990	12,991	11,845
Total operating expenses	19,070	20,510	61,767	45,881
Loss from operations	(19,070)	(20,510)	(61,767)	(45,881)
Other income, net	1,047	1,042	3,680	2,485
Change in fair value of warrant liabilities	564	96,439	22,917	51,829
Net income (loss)	$ (17,459)	$ 76,971	$ (35,170)	$ 8,433
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities, net	57	102	(17)	102
Comprehensive income (loss)	$ (17,402)	$ 77,073	$ (35,187)	$ 8,535
Net income (loss) attributable to common shares - basic	$ (16,130)	$ 54,429	$ (32,492)	$ 5,551
Basic net income (loss) per common share	$ (0.21)	$ 1.05	$ (0.42)	$ 0.13
Weighted-average number of shares outstanding, basic	77,156,068	51,945,920	77,146,407	41,443,049
Net income (loss) attributable to common shares - diluted	$ (16,130)	$ (15,703)	$ (32,492)	$ (53,230)
Diluted net loss per common share (2024 As Restated)	$ (0.21)	$ (0.28)	$ (0.42)	$ (1.23)
Weighted-average number of shares outstanding - diluted	77,156,068	55,478,342	77,146,407	43,106,746
Net income (loss) attributable to Series X and Series X[1] non-voting convertible preferred stock - basic	$ (1,330)	$ 6,666	$ (2,679)	$ 852
Basic net income (loss) per Series X and Series X[1] non-voting convertible preferred stock (2024 As Restated)	$ (11.61)	$ 58.21	$ (23.40)	$ 7.44
Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, basic	114,508	114,508	114,508	114,508
Net loss attributable to Series X and Series X[1] non-voting convertible preferred stock - diluted	$ (1,330)	$ (1,801)	$ (2,679)	$ (7,856)
Diluted net loss per Series X and Series X[1] non-voting convertible preferred stock (2024 As Restated)	$ (11.61)	$ (15.73)	$ (23.40)	$ (68.60)
Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, diluted	114,508	114,508	114,508	114,508