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): August 11, 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 August 14, 2025, Eledon Pharmaceuticals, Inc. (the "Company") issued a press release regarding its quarter ended June 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 4.02 Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

Change of Accounting for Non-Voting Convertible Preferred Stock

In the course of preparing the Company's unaudited condensed consolidated financial statements as of and for the three and six months ended June 30, 2025, the Company, reassessed the rights and preferences of its Series X and Series X[1] non-voting convertible preferred stock, $0.001 par value ("Preferred Stock"), and concluded that, because the Preferred Stock's rights and preferences are substantially identical to those of the Company's common stock, $0.001 par value, the Preferred Stock should be treated as a separate class of common stock for purposes of calculating earnings per share in accordance with Accounting Standards Codification ("ASC") 260-10, "Earnings Per Share."

Additionally, in connection with this reassessment, the Company concluded that it had incorrectly classified the Preferred Stock as permanent equity in the consolidated balance sheets. The Preferred Stock includes a provision that, upon the occurrence of a fundamental transaction (that is defined to include a third-party tender or exchange offer) in which more than 50 percent of the common stockholders receive cash or other assets, the holders of Preferred Stock, upon any subsequent conversion, are entitled to receive the same form of consideration, even if they did not participate in the original transaction. Because this feature may result in settlement in cash or other non-equity consideration upon an event outside the Company's control, the Preferred Stock does not meet the criteria for permanent equity classification, and management has determined it should instead be classified as temporary equity under ASC 480-10-S99-3A. The Preferred Stock is not subsequently remeasured to its redemption value because redemption is not considered probable.

The Company's management has discussed these corrections with the Audit Committee of the Board of Directors (the "Audit Committee"). On August 11, 2025, the Company's management and the Audit Committee concluded that the previously issued (i) audited consolidated financial statements for the fiscal years ended December 31, 2024 and December 31, 2023 included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission on March 20, 2025 (the "2024 Form 10-K"); (ii) unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2025 included in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 14, 2025 (the "2025 Form 10-Q"), and (iii) unaudited condensed consolidated financial statements as of and for (a) the three and nine months ended September 30, 2024 included in the Company's Quarterly Report on Form 10-Q filed with the SEC on November 11, 2024, (b) the three and six months ended June 30, 2024 included in the Company's Quarterly Report on Form 10-Q filed with the SEC on August 19, 2024 and (c) the three months ended March 31, 2024 included in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024 and amended by a Form 10-Q/A on August 19, 2024 (together, the "Impacted 2024 Quarterly Reports") and, together with together the 2024 Form 10-K and the 2025 Form 10-Q, (the "Impacted Reports") were each materially misstated and should no longer be relied upon.

The identified errors did not result in any impact on the Company's cash and short-term investment position, liquidity, or results of operations.

These identified errors will result in a restatement of the Company's consolidated balance sheets, consolidated statements of operations and comprehensive loss, and consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the years ended December 31, 2024 and December 31, 2023 and as of and for the three months ended March 31, 2024, the three and six months ended June 30, 2024, the three and nine months ended September 30, 2024 and the three months ended March 31, 2025. As a result, management and the Audit Committee determined on August 11, 2025 that the Impacted Reports require restatement and should no longer be relied upon.

In addition, any previously issued or filed earnings releases, investor presentations or other communications describing the Company's consolidated financial statements as of and for the years ended December 31, 2024 and 2023, as of and for the three months ended March 31, 2024, the three and six months ended June 30, 2024, the three and nine months ended September 30, 2024 and the three months ended March 31, 2025 should no longer be relied on.

In connection with the restatement described above, the Company identified a material weakness in its internal control over financial reporting related to its accounting for equity instruments. Due to the material weakness, the Company has concluded, and will disclose within the applicable Impacted Reports, that its internal control over financial reporting was not effective as of December 31, 2024 and that its disclosure controls and procedures were not effective as of March 31, 2024, June 30, 2024, September 31, 2024, December 31, 2024 and March 31, 2025.

The Company has discussed the matters disclosed in this Current Report on Form 8-K with its independent registered public accounting firm, Deloitte & Touche LLP, and its predecessor registered public accounting firms, Crowe LLP and KMJ Corbin & Company LLP, and intends to file an amendment to each of the 2024 Form 10-K and the 2025 Form 10-Q to restate the Company's consolidated financial statements included in such Impacted Reports to correct the errors related to the reclassification of the Preferred Stock as described above. The Company does not intend to file amendments to the Impacted 2024 Quarterly Reports, but instead intends to summarize the effects of the restatement with respect to the quarters ended March 31, 2024, June 30, 2024, and September 30, 2024 in the restated 2024 Form 10-K and to restate prospectively in the corresponding 2025 quarterly filings restated financial information for each of such 2024 quarterly periods, reflecting the reclassification of the Preferred Stock and the restatement of the Company's consolidated financial statements included in the previously issued Impacted 2024 Quarterly Reports as described above.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release Issued on August 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 hereunto duly authorized.

Eledon Pharmaceuticals, Inc.

Date: August 14, 2025

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

Eledon Pharmaceuticals Reports Second Quarter 2025 Operating and Financial Results

Updated data from ongoing open-label Phase 1b trial demonstrated a mean 12-month eGFR of approximately 68 mL/min/1.73 m^2 post-transplant for patients on tegoprubart

Company on track to report topline results from Phase 2 BESTOW trial in kidney transplantation in November 2025

Cash, cash equivalents and short-term investments of $107.6 million as of June 30, 2025

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

“We are proud to enter the second half of the year with strong momentum as we have achieved all of our key milestones to date including advancing tegoprubart in kidney, islet cell (type 1 diabetes), and liver allotransplantation, as well as in xenotransplantation. The positive data we recently presented at the World Transplant Congress reinforce the potential of tegoprubart to improve long-term transplant outcomes while reducing the toxic side effects often associated with the current standard of care,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “With these encouraging results in hand, we look forward to sharing topline data later this year from our Phase 2 BESTOW trial in kidney transplantation and to continuing to explore tegoprubart’s broad potential in other transplant indications.”

Year-to-Date 2025 Business Highlights

- Presented updated data at the World Transplant Congress (WTC) in August 2025 from the ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of organ rejection in kidney transplant patients. Updated data from 32 participants demonstrated that tegoprubart continues to be well tolerated with no cases of death, graft loss, drug related tremor, sepsis, or new-onset diabetes. Kidney function, as assessed by estimated glomerular filtration rate (eGFR), generally stabilized after the first month post-transplant and remained in the range of approximately 68 mL/min/1.73 m^2 through 12 months for participants (n=12) who remained on tegoprubart. For comparison, data from historical studies using the standard of care, calcineurin inhibitor-based immunosuppression therapy, typically report aggregate mean eGFRs of approximately 53 mL/min/1.73 m^2 at 12 months after kidney transplant.
- In June 2025, a third patient was treated with tegoprubart as a cornerstone component of the immunosuppression treatment regimen following kidney xenotransplantation conducted at Massachusetts General Hospital (MGH) in collaboration with eGenesis.
- Announced the first three islet cell transplant recipients treated at the University of Chicago Medicine’s Transplant Institute in an investigator-initiated trial evaluating tegoprubart as

part of an immunosuppression regimen for the prevention of islet transplant rejection achieved insulin independence. An additional three islet transplant recipients have now been enrolled as well, bringing the total enrollment in the trial to six patients.

- Preclinical data in liver allotransplantation utilizing tegoprubart was presented at WTC 2025 demonstrating markedly prolonged graft survival in non-human primates (NHPs) by targeting the CD40 Ligand pathway and the potential for transplant tolerance induction.
- Announced a second investigator-initiated trial at the University of Chicago Medicine's Transplant Institute evaluating tegoprubart as part of an immunosuppression regimen for the prevention of islet transplant rejection in patients with impaired kidney function.
- Hosted an R&D Day in New York City that highlighted recent progress for the Company's lead investigational candidate, tegoprubart, with a focus on its clinical development progress in organ and cell transplantation, including the ongoing Phase 2 BESTOW trial. The event featured members of Eledon's executive team and leading experts in the field of transplantation. A replay of the R&D Day event can be found on Eledon's website at https://ir.eledon.com/news-and-events/events
- In June 2025, the Company was added to the Russell 3000® and Russell 2000® Indexes following the annual reconstitution, broadening visibility among investors as Eledon approaches key regulatory milestones.

Anticipated Upcoming Milestones for 2H 2025

- November 2025: Report topline results from the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.
- Launch an investigator-initiated trial at MGH evaluating tegoprubart as part of an immunosuppression regimen to induce donor-specific immune tolerance through mixed chimerism.
- Enroll three additional patients in the investigator-led clinical trial at UChicago Medicine in subjects with type 1 diabetes treated with tegoprubart as part of an immunosuppression regimen for the prevention of pancreatic islet transplant rejection.

Second Quarter 2025 Financial Results

Cash, cash equivalents and short-term investments totaled $107.6 million as of June 30, 2025 compared to $140.2 million as of December 31, 2024. The company expects current cash, cash equivalents and short-term investments to fund operations to the end of 2026.

Research and development (R&D) expenses for the second quarter of 2025 were $20.3 million, including $1.1 million of non-cash stock-based compensation expense, compared to $10.1 million, including $0.8 million of non-cash stock-based compensation expense, for the comparable period in 2024.

General and administrative expenses for the second quarter of 2025 were $4.5 million, including $1.6 million of non-cash stock-based compensation expense, compared to $4.4 million, including $2.2 million of non-cash stock-based compensation expense, for the comparable period in 2024.

Net loss for the second quarter of 2025 was $11.2 million, or $0.13 per basic common share, compared to a net loss of $44.9 million, or $0.92 per basic common share, for the comparable period in 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: risks relating to the safety and efficacy of our drug candidates; risks relating to clinical development timelines, including interactions with regulators and clinical sides, as well as patient enrollment; risks relating to costs of clinical trials and the sufficiency of the company's capital resources to fund planned clinical trials; and risks associated with the impact of the ongoing coronavirus pandemic. 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 significantly 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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Source: Eledon Pharmaceuticals

Exhibit 99.1

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

	June 30, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,741	$ 20,549
Short-term investments	101,829	119,629
Prepaid expenses and other current assets	3,834	3,552
Total current assets	111,404	143,730
Operating lease asset, net	773	926
In-process research and development	32,386	32,386
Other assets	346	363
Total assets	$ 144,909	$ 177,405
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,831	$ 5,833
Current operating lease liabilities	336	314
Accrued expenses and other liabilities	7,552	5,430
Total current liabilities	13,719	11,577
Deferred tax liabilities	2,183	2,183
Non-current operating lease liabilities	467	640
Warrant liabilities	22,512	44,865
Total liabilities	38,881	59,265
Commitments and contingencies	—	—
Convertible preferred stock, 5,000,000 shares authorized at June 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 June 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 June 30, 2025 and December 31, 2024	2,151	2,151
Stockholders' equity:		
Common stock, $0.001 par value, 300,000,000 shares authorized at June 30, 2025 and 200,000,000 at December 31, 2024; 59,881,775 and 59,789,275 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively	60	60
Additional paid-in capital	423,619	417,946
Accumulated other comprehensive income (loss)	(48)	26
Accumulated deficit	(373,297)	(355,586)
Total stockholders' equity	50,334	62,446
Total liabilities, convertible preferred stock and stockholders' equity	$ 144,909	$ 177,405

Exhibit 99.1

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 June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	$ 20,276	$ 10,106	$ 33,807	$ 17,516
General and administrative	4,457	4,396	8,890	7,855
Total operating expenses	24,733	14,502	42,697	25,371
Loss from operations	(24,733)	(14,502)	(42,697)	(25,371)
Other income, net	1,224	869	2,633	1,443
Change in fair value of warrant liabilities	12,293	(31,274)	22,353	(44,610)
Net loss	$ (11,216)	$ (44,907)	$ (17,711)	$ (68,538)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities, net	(30)	—	(74)	—
Comprehensive loss	$ (11,246)	$ (44,907)	$ (17,785)	$ (68,538)
Basic and diluted earnings per share of common stock (2024 As Restated)	$ (0.13)	$ (0.92)	$ (0.21)	$ (1.61)
Weighted-average common shares outstanding, basic and diluted	77,156,068	42,278,411	77,141,196	36,133,906
Basic and diluted earnings per share of Series X and Series X[1] non-voting convertible preferred stock (2024 As Restated)	$ (7.46)	$ (51.29)	$ (11.78)	$ (89.60)
Weighted-average shares outstanding of Series X and Series X[1] non-voting convertible preferred stock, basic and diluted (2024 As Restated)	114,508	114,508	114,508	114,508