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 13, 2024

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, 2024, Eledon Pharmaceuticals, Inc. (the "Company") issued a press release regarding its quarter ended June 30, 2024. 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 Warrant Derivative Liabilities

On May 20, 2024, the partners and professional staff of KMJ Corbin & Company LLP ("KMJ"), which was engaged as the Company's independent registered public accounting firm joined Crowe LLP ("Crowe"). In connection with this transition, the Audit Committee of the Board of Directors of the Company (the "Audit Committee") dismissed KMJ as the Company's independent registered public accounting firm on July 10, 2024. On July 10, 2024, following the dismissal of KMJ, the Company, through and with the approval of its Audit Committee, appointed Crowe as its independent registered public accounting firm. In the course of preparing the Company's financial statements as of and for the three and six months ended June 30, 2024, the Company, in consultation with Crowe, determined that a correction was necessary with respect to the Company's reporting and recording of the fair value of (i) certain common stock warrants (the "Common Warrants") issued by the Company in May 2023 pursuant to a Securities Purchase Agreement dated as of April 28, 2023 by and among the Company and certain institutional and accredited investors (the "Securities Purchase Agreement"), and (ii) the potential issuance of pre-funded warrants in lieu of additional shares of common stock, $0.001 par value per share (the "Subsequent Closing Warrants"), issuable by the Company in a second closing and a third closing of the Securities Purchase Agreement contingent upon the satisfaction or waiver of certain specified conditions set forth therein.

The Company has historically reported the Common Warrants and Subsequent Closing Warrants as equity instruments, because (i) of the respective holders' ability to settle the Common Warrants and Subsequent Closing Warrants by issuance of a fixed number of shares of common stock or Pre-funded Warrants and (ii) the Common Warrants and Subsequent Closing Warrants contain a fixed exercise price and contain no cash settlement obligation. However, in July 2024, management of the Company, in consultation with Crowe, concluded that the Common Warrants and the Subsequent Closing Warrants do not meet the conditions to be classified as equity instruments under Accounting Standards Codification ("ASC") 815-40, "Derivatives and Hedging — Contracts in Entity's Own Equity," and must instead be recorded as liabilities on the Company's balance sheet at their fair value and remeasured at fair value for each subsequent reporting period.

The Company's management has discussed these non-cash corrections with the Audit Committee. On August 13, 2024, management and the Audit Committee together concluded that the Company's previously issued (i) audited financial statements as of and for (i) the fiscal year ended December 31, 2023 included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 28, 2024, as amended on April 26, 2024 and (ii) the Company's previously issued unaudited condensed financial statements as of and for (a) 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, (b) the three and nine months ended September 30, 2023 included in the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2023 and (c) the three and six months ended June 30, 2023 included in the Company's Quarterly Report on Form 10-Q filed with the SEC on August 10, 2023 (together, the "Impacted Reports") were each materially misstated.

The Company is currently not in a position to provide a reasonable estimate of the anticipated changes in its results of operations for the periods impacted, for any Impacted Reports. However, the errors are not expected to result in any impact on its cash and short-term investment position, cash runway, or operations.

These identified non-cash errors will result in a restatement of the Additional paid-in capital and Total liabilities and Other income (expense) line items in the Company's financial statement captions. The majority of the financial

restatement impact is expected to be reversed in the second half of 2024, as the second and third closings pursuant to the Securities Purchase Agreement are expected to be settled.

As a result, management and the Audit Committee determined on August 13, 2024 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 financial statements as and for the year ended December 31, 2023 or as of and for the three months ended March 31, 2024 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 Impacted Reports, that its internal control over financial reporting was not effective as of December 31, 2023 and that its disclosure controls and procedures were not effective as of June 30, 2023, September 31, 2023, December 31, 2023 and March 31, 2024.

The Company has discussed the matters disclosed in this Current Report on Form 8-K with its independent registered public accounting firm, Crowe, and its predecessor registered public accounting firm, KMJ, and intends to file amendments to each of the Impacted Reports reflecting the reclassification of the Common Warrants and Subsequent Closing Warrants and the restatement of the Company's financial statements included in the previously issued Impacted Reports as described above. The restatement of the financial statements discussed above does not impact the Company's financial results for the three months ended June 30, 2024 as reported in the Company's earnings release furnished with the SEC in Item 2.02 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release Issued on August 14, 2024
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, 2024

By: /s/ David-Alexandre C. Gros, M.D.

Name: David Alexandre C. Gros, M.D.
Title: Chief Executive Officer

Exhibit 99.1

Eledon Pharmaceuticals Reports Preliminary Second Quarter 2024 Operating Results

Presented updated data on 13 participants from ongoing Phase 1b trial evaluating tegoprubart for prevention of rejection in kidney transplantation

80 participants (two-thirds of projected recruitment) enrolled in Phase 2 BESTOW trial

Completed an oversubscribed $50 million private placement; Company expects sufficient liquidity through December 2025

IRVINE, Calif., August 14, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (Nasdaq: ELDN) today reported recent business highlights for its second quarter 2024.

“We have entered the second half of the year with a strong balance sheet following our oversubscribed $50 million private placement and we are highly encouraged by the progress and reception from the transplant community for our Phase 2 BESTOW trial, which remains on track to complete enrollment by the end of this year,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “Looking at this progress and the data we presented in June, we continue to believe that tegoprubart has the potential to displace calcineurin inhibitors, the current standard of care, as a first-line immunosuppression agent for patients undergoing kidney transplant.”

Second Quarter 2024 and Recent Corporate Developments

- Enrolled the 80th participant in July 2024 in the ongoing Phase 2 BESTOW trial assessing tegoprubart head-to-head with tacrolimus for the prevention of organ rejection in kidney transplantation.

- Presented updated data at the American Transplant Congress (ATC) in June 2024 from the ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of organ rejection in kidney transplant patients. Updated data from 13 participants demonstrated that tegoprubart was generally safe and well tolerated, with an overall mean estimated glomerular filtration rate (eGFR) of all reported time points after day 30 post-transplant of 70.5 mL/min/1.73m2. Two participants completed over 12 months on therapy post-transplant, and both demonstrated mean eGFRs above 90 mL/min/1.73m2 at one-year post-transplant.

- Completed an oversubscribed private placement financing for total gross proceeds of $50.0 million, before deducting any offering related expenses.

Anticipated Upcoming Milestones

- End of 2024: Complete enrollment in the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.

- Mid-2025: Report updated interim clinical data from the ongoing Phase 1b and long-term safety and efficacy extension studies of tegoprubart in kidney transplantation.

Financial Results

In the course of preparing the Company's financial statements as of and for the three and six months ended June 30, 2024, the Company, in consultation with Crowe LLP, the Company's independent registered public accounting firm, determined that a reclassification was necessary with respect to the Company's reporting and recording of the fair value of certain common stock warrants and pre-funded warrants associated with the Company's Securities Purchase Agreement dated as of April 28, 2023 (and the potential second and third closings thereof), resulting in a reclassification of these warrants as liabilities on the Company's balance sheet, on a mark-to-market basis.

The Company expects to restate its audited consolidated financial statements that appeared in its Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 28, 2024, as amended on April 26, 2024, and its unaudited condensed consolidated financial statements that appeared in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 15, 2024 (together, the "Impacted Reports"). As previously disclosed on the Company's Form 12b-25 Notification of Late Filing filed with the SEC today, the Company also expects to delay the filing of its Form 10-Q for the three and six months ended June 30, 2024 in light of the time and resources needed to prepare a complete and accurate Form 10-Q in light of the restatement process . See also the Company's Current Report on Form 8-K filed today for additional information.

This accounting reclassification is non-cash and is not expected to have an economic impact on the Company's operations or on the Company's cash, cash equivalents and short-term investments, or cash runway.

Eledon ended the second quarter with approximately $83.6 million in cash and cash equivalents, which includes the $50.0 million received in the private placement financing transaction during the second quarter.

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 CD40 Ligand (CD40L), a well-validated biological target within the costimulatory CD40/CD40L cellular pathway. 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 allogeneic kidney transplantation, xenotransplantation, 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 enrollment in our clinical trials, the development and future success of product candidates, the company's capital resources and ability to finance operations through December 2025, our filing of amendments to the Impacted Reports and our Form 10-Q for the three and six months ended June 30, 2024, 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 completion of our financial closing procedures; final adjustments; completion of the review by our independent registered public accounting firm; the safety and efficacy of our drug candidates; risks relating to clinical development timelines, including interactions with regulators and clinical sites, 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-Qs, 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.

Exhibit 99.1

Investor Contact:

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

Media Contact:

Jenna Urban
Berry & Company Public Relations
(212) 253 8881
jurban@berrypr.com

Source: Eledon Pharmaceuticals