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

May 12, 2022
Date of Report
(Date of earliest event reported)

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.)

19900 MacArthur Blvd., Suite 550
Irvine, California 92612
(Address of principal executive offices, including Zip Code)

(949) 238-8090
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K 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 Capital 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 May 12, 2022, Eledon Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the period ended March 31, 2022. 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 Number	Description
99.1	Press Release, dated May 12, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* **

SIGNATURE

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: May 12, 2022

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

Eledon Pharmaceuticals Reports First Quarter 2022 Operating and Financial Results

Topline data for Phase 2a tegoprubart study in amyotrophic lateral sclerosis (ALS) anticipated in June 2022

First patient dosed in Phase 2a trial evaluating tegoprubart in IgA Nephropathy with initial readout expected in late 2022

Successfully completed non-human primate study evaluating tegoprubart monotherapy in the prevention of kidney allograft rejection

Conference call today at 4:30 PM ET

IRVINE, Calif., May 12, 2022 — Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN), a patient-focused clinical stage biopharmaceutical company committed to the development of innovative and impactful treatments for organ and cell transplantation, autoimmune conditions, and neurodegenerative disease, today reported its first quarter 2022 operating and financial results.

"We are excited to approach the first of four distinct opportunities to highlight tegoprubart's broad therapeutic potential this year, beginning with our upcoming ALS readout in June. Based on the growing body of evidence validating the CD40/CD40L pathway, we remain more encouraged than ever in the potential of tegoprubart as a best-in-class anti CD40L antibody," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "We continue to make progress across our clinical programs, highlighted by the recent Phase 2a trial initiation in IgAN, and are well positioned to announce meaningful clinical results throughout the remainder of the year."

First Quarter 2022 and Recent Corporate Developments

- Completed enrollment of all four cohorts in ongoing Phase 2a study with tegoprubart in ALS and remain on track to deliver topline results in June 2022.
- Dosed the first patient in a Phase 2a clinical trial evaluating tegoprubart for the treatment of IgA Nephropathy. The ongoing trial currently has received regulatory clearances in Australia, New Zealand, Malaysia, and Spain, and the company plans to expand the study in up to seven additional countries in 2022.
- Successfully completed non-human primate study evaluating tegoprubart monotherapy in the prevention of kidney allograft rejection.

- Continued progress in two other clinical studies evaluating tegoprubart in kidney transplantation and islet cell transplantation with initial readouts anticipated in late 2022.
- Hosted first-ever Company R&D Day highlighting tegoprubart with four leading experts on ALS, renal transplantation, islet cell transplantation, and IgA Nephropathy (IgAN).
- Published meta-analysis comparing the efficacy of historical anti-CD40 and anti-CD40L approaches in the prevention of kidney transplant rejection in nonhuman primates.

Upcoming Anticipated Milestones

- 2Q 2022: topline data from Phase 2a trial of tegoprubart in ALS.
- 2H 2022: initial open label data from Phase 1b trial of tegoprubart in kidney transplantation.
- 2H 2022: initial open label data from Phase 2a trial of tegoprubart in IgAN.
- 2H 2022: initial open label data from Phase 2a trial of tegoprubart in islet cell transplantation.

Financial Results for the Three Months Ended March 31, 2022

The company reported a net loss of $9.9 million, or $0.69 per share, for the three months ended March 31, 2022, compared to a net loss of $8.5 million, or $0.57 per share, for the same period in 2021.

- Research and development expenses were $6.6 million for the three months ended March 31, 2022, compared to $5.7 million for the comparable period in 2021, an increase of $0.9 million. The increase in research and development spend primarily reflects an increase in clinical development costs and costs related to the production of clinical trial materials as we advance tegoprubart into global phase 1 and 2 clinical trials.

- General and administrative expenses were $3.2 million for the three months ended March 31, 2022, compared to $3.4 million for the comparable period in 2021, a decrease of $0.2 million.

- The company had approximately $76.7 million in cash and cash equivalents as of March 31, 2022, compared to $84.8 million in cash and cash equivalents as of December 31, 2021. The company believes that it has sufficient financial resources to fund operating activities into 2024.

Conference Call

Eledon will hold a conference call today, May 12, 2022, at 4:30 pm Eastern Time to discuss first quarter 2022 results. The dial-in numbers are 877-407-9039 for domestic callers and 201-689-8470 for international callers. The conference ID is 13729260. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at www.eledon.com. The webcast will be archived on the website following the completion of the call.

About Eledon Pharmaceuticals and tegoprubart (formerly AT-1501)

Eledon Pharmaceuticals is a clinical stage biotechnology company using its expertise in targeting the CD40 Ligand (CD40L, also called CD154) pathway to develop potential treatments for persons requiring an organ or cell-based transplant, living with autoimmune disease, or living with ALS. The company's lead compound in development is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target with broad therapeutic potential. Eledon is headquartered in Irvine, Calif. 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 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-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

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

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 76,677	$ 84,833
Prepaid expenses and other current assets	2,648	3,513
Total current assets	79,325	88,346
Operating lease asset, net	675	768
Goodwill	48,648	48,648
In-process research and development	32,386	32,386
Other assets	344	400
Total assets	$ 161,378	$ 170,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,026	$ 1,813
Current operating lease liability	328	369
Accrued expenses and other liabilities	1,604	2,219
Total current liabilities	2,958	4,401
Deferred tax liability	1,752	1,752
Non-current operating lease liability	350	400
Total liabilities	5,060	6,553
Commitments and contingencies		
Stockholders' equity:		
Series X[1] non-voting convertible preferred stock	—	—
Series X non-voting convertible preferred stock	—	—
Common stock	14	14
Additional paid-in capital	281,067	278,880
Accumulated deficit	(124,763)	(114,899)
Total stockholders' equity	156,318	163,995
Total liabilities and stockholders' equity	$ 161,378	$ 170,548

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 March 31,	
	2022	2021
Operating expenses		
Research and development	$ 6,635	$ 5,653
General and administrative	3,224	3,352
Total operating expenses	9,859	9,005
Loss from operations	(9,859)	(9,005)
Other income/(expense), net	(5)	5
Loss before income tax benefit	(9,864)	(9,000)
Income tax benefit	—	501
Net loss and comprehensive loss	$ (9,864)	$ (8,499)
Net loss per share, basic and diluted	$ (0.69)	$ (0.57)
Weighted-average common shares outstanding, basic and diluted	14,330,693	14,831,049