

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 13, 2021

Date of Report
(Date of earliest event reported)

Eledon Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36620
(Commission
File Number)

20-1000967
(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 13, 2021, Eledon Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the period ended March 31, 2021. 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 13, 2021

* **

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 13, 2021

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



Eledon Pharmaceuticals Reports First Quarter 2021 Operating and Financial Results

Continued enrollment in Phase 2 clinical trial of AT-1501 in amyotrophic lateral sclerosis (ALS)

Strengthens senior leadership team with four key additions

IRVINE, Calif., May 13, 2021 — Eledon Pharmaceuticals, Inc., (“Eledon”) (NASDAQ: ELDN), a clinical stage biopharmaceutical company focused on developing targeted medicines for persons living with autoimmune disease, requiring an organ or cell-based transplant, or living with amyotrophic lateral sclerosis (ALS), today reported its first quarter 2021 operating and financial results.

“We have made valuable progress advancing AT-1501 during the first quarter, including with our Phase 2 clinical trial in ALS with top line data readout expected in first half 2022,” stated David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon Pharmaceuticals, Inc. “At the same time, we remain on track to initiate a Phase 2 trial of AT-1501 in islet cell transplantation, giving us two important programs in the clinic in the near term. With what I regard as a world class team in place, and a strong balance sheet, we believe we are well positioned to deliver on important clinical milestones this year and next.”

First Quarter 2021 and Recent Corporate Developments

- Announced updated development strategy for AT-1501 in renal transplantation based on discussions with the U.S. Food and Drug Administration (“FDA”). As a result, Eledon plans to initiate an evaluation of AT-1501 in a standard non-human primate model of renal transplantation which is expected to be completed late 2022. In parallel, the company will continue to explore potentially conducting a renal transplantation clinical trial outside the United States.
- Announced appointments of seasoned biopharmaceutical executives - Jeff Bornstein, M.D. as Chief Medical Officer, Paul Little as Chief Financial Officer, David Hovland, Ph.D., as Chief Regulatory Officer and Bryan Smith, J.D. as General Counsel, Corporate Secretary, and Chief Compliance Officer.

Upcoming Anticipated Milestones

- Deliver two posters and two oral presentations, including pre-clinical data showing the effectiveness of AT-1501 in preventing islet allograft rejection in nonhuman primate models, at the American Society of Transplantation annual meeting, which is being held virtually June 4 – June 9.
 - Enroll first patient in Phase 2 trial of AT-1501 in islet cell transplantation for type 1 diabetes with interim data readout expected in first half 2022.
 - Initiate Phase 2 trial of AT-1501 in an autoimmune nephritis indication in late 2021.
-

Financial Results for the Three Months Ended March 31, 2021

The company reported a net loss of \$8.5 million, or \$0.57 per share, for the three months ended March 31, 2021, compared to a net loss of \$8.2 million, or \$8.52 per share, for the same period in 2020.

- Research and development expenses were \$5.6 million for the three months ended March 31, 2021, compared to \$1.6 million for the comparable period in 2020, an increase of \$4.0 million.
- General and administrative expenses were \$3.3 million for the three months ended March 31, 2021, compared to \$1.7 million for the comparable period in 2020, an increase of \$1.6 million.
- The company had approximately \$108.6 million in cash and cash equivalents as of March 31, 2021, compared to \$114.2 million in cash and cash equivalents as of December 31, 2020. The Company believes that it has sufficient financial resources to fund operations as currently planned well into 2023.

Conference Call

Eledon will hold a conference call today, May 13, 2021 at 4:30 pm Eastern Time to discuss first quarter results. The dial-in numbers are 800-709-0218 for domestic callers and 212-231-2926 for international callers. The conference ID is 21994011. 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 AT-1501

Eledon Pharmaceuticals is a clinical stage biotechnology company using its expertise in targeting the CD40L pathway to develop potential treatments for patients living with an autoimmune disease, patients requiring an organ or cell-based transplant, and for patients living with ALS. The company's lead compound in development is AT-1501, an anti-CD40L antibody with high affinity for CD40 ligand (CD40L, also called CD154), a well-validated biological target with broad therapeutic potential. AT-1501 is a humanized IgG1 antibody engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. The CD40L/CD40 pathway is widely recognized for its prominent role in immune regulation. CD40L is primarily expressed on activated CD4+ T cells, platelets and endothelial cells while the CD40 receptor is constitutively expressed on antigen presenting cells such as B cells, macrophages, and dendritic cells. By blocking CD40L and not the CD40 receptor, AT-1501 inhibits both the CD40 and CD11 costimulatory signaling pathways, providing the potential for improved efficacy compared to anti-CD40 receptor approaches. Blocking CD40L also increases polarization of CD4+ lymphocytes to Tregs, a specialized subpopulation of T cells that act to suppress an immune response, thus creating a more tolerogenic environment, which may also play a therapeutic role for autoimmune diseases and in the transplant setting. 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: [@Eledon Pharma](#) and [LinkedIn](#).

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 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.

Investor Contact:

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Source: Eledon Pharmaceuticals

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

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 108,579	\$ 114,15
Prepaid expenses and other current assets	1,662	1,43
Total current assets	110,241	115,63
Operating lease asset, net	92	13
Goodwill	48,648	48,64
In-process research and development	32,386	32,38
Other assets	315	38
Total assets	\$ 191,682	\$ 197,18
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,514	\$ 1,36
Current operating lease liability	97	14
Accrued severance	5	1
Accrued expenses and other liabilities	2,590	96
Total current liabilities	4,206	2,48
Deferred tax liabilities	3,605	4,10
Total liabilities	7,811	6,58
Commitments and contingencies		
Stockholders' equity:		
Series X ¹ non-voting convertible preferred stock, \$0.001 par value, 515,000 shares authorized; 108,070 shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Series X preferred stock, \$0.001 par value, 10,000 shares authorized; 6,204 and no shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 14,306,614 and 15,160,397 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	14	1
Additional paid-in capital	272,749	270,97
Accumulated deficit	(88,892)	(80,35)
Total stockholders' equity	183,871	190,58
Total liabilities and stockholders' equity	\$ 191,682	\$ 197,18

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

	For the Three Months Ended March 31,	
	2021	2020
Operating expenses		
Research and development	\$ 5,653	\$ 1,648
General and administrative	3,352	1,730
Total operating expenses	9,005	3,378
Loss from operations	(9,005)	(3,378)
Other income, net	5	30
Warrant inducement expense	—	(4,829)
Loss before income tax benefit	(9,000)	(8,177)
Income tax benefit	501	—
Net loss and comprehensive loss	\$ (8,499)	\$ (8,177)
Net loss per share, basic and diluted	\$ (0.57)	\$ (8.52)
Weighted-average common shares outstanding, basic and diluted	14,831,049	959,285