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

November 12, 2021 (November 11, 2021)
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 November 11, 2021, Eledon Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the period ended September 30, 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 November 11, 2021
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: November 12, 2021

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

Eledon Pharmaceuticals Reports Third Quarter 2021 Operating and Financial Results

Nearing full enrollment in ALS Phase 2 Study; topline data expected 1H 2022

Received Investigational New Drug ("IND") clearance from the FDA for AT-1501 in islet cell transplantation in the U.S.

Announced renal transplantation research collaboration with CareDx, Inc.

Initiated AT-1501 monotherapy non-human primate renal transplant study; topline data expected 1H 2022

Conference call today at 4:30 PM ET

November 11, 2021

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

"We made significant progress across our three therapeutic areas: transplantation focusing on kidney and islet cell transplantation, autoimmunity focused on IgA Nephropathy (IgAN), and neurodegeneration focusing on ALS," stated David-Alexandre C. Gros, M.D., Chief Executive Officer. "In ALS, we completed enrollment in the first three cohorts of our phase 2 study and anticipate completing enrollment in the fourth and final cohort by year-end. In renal transplantation, we are in the process of opening our first clinical site in Canada and our non-human primate study in the U.S. is well underway. We recently announced IgAN as the next indication for development of AT-1501 and are still on track to initiate a Phase 2 trial by the end of this year. Finally, we received IND clearance for AT-1501 to initiate a clinical trial for the prevention of islet cell rejection in the U.S. We remain focused on continued execution across our three therapeutic areas in 2021 and building momentum as we prepare for multiple data readouts in 2022."

"In addition, we recently announced our research collaboration with CareDx, the leader in precision medicine for transplant patients and caregivers," said Steven Perrin, Ph.D., President and Chief Scientific Officer of Eledon. "This multi-year and multi-trial collaboration provides us with access to CareDx's best-in-class technologies for our renal transplantation studies. Our partner's extensive experience with biomarkers and predictive algorithms will allow us to gather important insights on the potential for product differentiation and long-term allograft survival rates as we advance AT-1501 through clinical development."

Third Quarter 2021 and Recent Corporate Developments

- Received a “No Objection” Letter from Health Canada, allowing Eledon to initiate a Canadian clinical trial of AT-1501 for the prevention of kidney transplant rejection.
- Announced selection of IgAN as next indication for clinical development of AT-1501; initiation of Phase 2 study expected by year-end.
- Completed enrollment of the first three cohorts of a Phase 2 study of AT-1501 in ALS; fourth and final cohort enrollment is nearing completion with full enrollment expected by year-end.
- Initiated preclinical renal transplant study evaluating AT-1501 monotherapy in at least four non-human primates.
- Announced renal transplant research collaboration with CareDx providing Eledon access to CareDx’s best-in-class biomarker and predictive algorithm technologies.
- Received IND clearance from the U.S. Food & Drug Administration for AT-1501 in islet cell transplantation in the United States.
- Presented data at the 2021 Northeast Amyotrophic Lateral Sclerosis Consortium and the International Pancreas and Islet Transplantation World Congress.

Upcoming Anticipated Milestones

- Q4 2021: initiation of Phase 1b clinical trial of AT-1501 in kidney transplantation.
- Q4 2021: initiation of Phase 2 clinical trial of AT-1501 in IgAN.
- 1H 2022: topline data from Phase 2 trial of AT-1501 in ALS.
- 1H 2022: completion of non-human primate study with AT-1501.
- 2H 2022: initial data from Phase 1b trial of AT-1501 in kidney transplantation.
- 2H 2022: initial data from Phase 2 trial of AT-1501 in IgAN.
- 2022: initial data from Phase 2 trial of AT-1501 in islet cell transplantation.

Financial Results for the Three Months Ended September 30, 2021

- The company reported a net loss of $9.8 million, or $0.66 per share, for the three months ended September 30, 2021, compared to a net loss of $6.1 million, or $5.51 per share, for the same period in 2020.
- Research and development expenses were $7.7 million for the three months ended September 30, 2021, compared to $0.6 million for the comparable period in 2020, an increase of $7.1 million. The increase in research and development spend primarily reflects clinical and formulation costs associated with increased activity for our lead asset AT-1501.
- General and administrative expenses were $2.8 million for the three months ended September 30, 2021, compared to $3.7 million for the comparable period in 2020, a decrease of $0.9 million.
- The company had approximately $94.0 million in cash and cash equivalents as of September 30, 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, November 11, 2021 at 4:30 pm Eastern Time to discuss third quarter results. The dial-in numbers are 877-407-9039 for domestic callers and 201-689-8470 for international callers. The conference ID is 13723561. 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 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 AT-1501, 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: @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 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

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 94,041	$ 114,195
Prepaid expenses and other current assets	1,517	1,435
Total current assets	95,558	115,630
Operating lease asset, net	222	138
Goodwill	48,648	48,648
In-process research and development	32,386	32,386
Other assets	356	383
Total assets	$ 177,170	$ 197,185
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,598	$ 1,366
Current operating lease liability	177	144
Accrued expenses and other liabilities	2,271	973
Total current liabilities	4,046	2,483
Deferred tax liabilities	2,331	4,106
Non-current operating lease liability	45	—
Total liabilities	6,422	6,589
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Series X1 non-voting convertible preferred stock, $0.001 par value, 515,000 shares authorized; 108,070 shares issued and outstanding at September 30, 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 September 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2021 and December 31, 2020; 14,306,788 and 15,160,397 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	14	15
Additional paid-in capital	276,827	270,974
Accumulated deficit	(106,093)	(80,393)
Total stockholders' equity	170,748	190,596
Total liabilities and stockholders' equity	$ 177,170	$ 197,185

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,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 7,658	$ 615	$ 17,553	$ 3,095
General and administrative	2,848	3,731	9,929	6,730
Restructuring expense	—	1,802	—	2,292
Total operating expenses	10,506	6,148	27,482	12,117
Loss from operations	(10,506)	(6,148)	(27,482)	(12,117)
Other income, net	3	4	7	39
Warrant inducement expense	—	—	—	(4,829)
Loss before income tax benefit	(10,503)	(6,144)	(27,475)	(16,907)
Income tax benefit	686	—	1,775	—
Net loss and comprehensive loss	$ (9,817)	$ (6,144)	$ (25,700)	$ (16,907)
Net loss per share, basic and diluted	$ (0.66)	$ (5.51)	$ (1.73)	$ (16.81)
Weighted-average common shares outstanding, basic and diluted	14,815,852	1,114,133	14,820,822	1,006,008