# 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**

**March 24, 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 March 24, 2022, Eledon Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended December 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 March 24, 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: March 24, 2022

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

# Eledon Pharmaceuticals Reports Fourth Quarter and Full-Year 2021 Operating and Financial Results

*Topline data from Phase 2a trial of tegoprubart in ALS expected in 2Q 2022*

*Ongoing clinical studies evaluating tegoprubart in kidney transplantation, IgA nephropathy, and islet cell transplantation with initial readouts anticipated in late 2022*

*Cash balance of $84.8M, sufficient to fund operations into 2024*

*Conference call today at 4:30 PM ET*

**IRVINE, Calif., March 24, 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 fourth quarter and full-year 2021 operating and financial results.

"In 2021, our first full year following the acquisition of the rights to tegoprubart, we fully enrolled our ALS trial, initiated several other pre-clinical and clinical trials across four programs, and created momentum heading into 2022," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "We now enter a pivotal year for Eledon, and we look forward to sharing the results beginning with topline readout from our Phase 2a study in ALS in the second quarter, followed by initial clinical readouts in our other tegoprubart programs anticipated by year-end."

**Fourth Quarter 2021 and Recent Corporate Developments**

- Completed enrollment of all four cohorts in ongoing Phase 2a study with tegoprubart in Amyotrophic Lateral Sclerosis (ALS).
- Received regulatory clearance to initiate a Phase 1b clinical trial in the United Kingdom in addition to Canada, evaluating tegoprubart as a replacement for tacrolimus as an immunosuppressive regimen component in patients undergoing kidney transplantation.
- Received regulatory clearance to initiate a Phase 2a clinical trial in Australia, New Zealand and Malaysia, evaluating tegoprubart for the treatment of IgA Nephropathy, with plans to expand the study in up to eight additional countries in 2022.
- Obtained FDA clearance to initiate a Phase 2a U.S. clinical trial in islet cell transplantation utilizing tegoprubart to prevent allograft rejection for the treatment of Type 1 diabetes.

- Presented pre-clinical data showing the effectiveness of tegoprubart in preventing islet cell allograft rejection resulting in improved metabolic control in a nonhuman primate model of diabetes at the International Pancreas and Islet Transplantation Association (IPITA) Congress.
- Announced a collaborative research agreement to incorporate CareDx's biomarker and predictive algorithm technologies to assess longer-term allograft survival into Eledon's clinical trials of tegoprubart in renal transplantation.
- Successfully completed non-human primate kidney transplantation study with tegoprubart as monotherapy for the prevention of kidney allograft rejection.

**Upcoming Anticipated 2022 Milestones**

- 2Q 2022: topline data from Phase 2a trial of tegoprubart in ALS.
- 4Q 2022: initial open label data from Phase 1b trial of tegoprubart in kidney transplantation.
- 4Q 2022: initial open label data from Phase 2a trial of tegoprubart in IgAN.
- 4Q 2022: initial open label data from Phase 2a trial of tegoprubart in islet cell transplantation.

**Financial Results for the Three Months Ended December 31, 2021**

The company reported a net loss of $8.8 million, or $0.59 per share, for the three months ended December 31, 2021, compared to a net loss of $5.9 million, or $2.13 per share, for the same period in 2020.

- Research and development expenses were $6.2 million for the three months ended December 31, 2021, compared to $3.0 million for the comparable period in 2020, an increase of $3.2 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 December 31, 2021, compared to $3.3 million for the comparable period in 2020, a decrease of $0.1 million.

**Financial Results for the Year Ended December 31, 2021**

The company reported a net loss of $34.5 million, or $2.33 per share, for the year ended December 31, 2021, compared to a net loss of $22.8 million, or $15.72 per share, for the year ended December 31, 2020.

- Research and development expenses were $23.7 million for the year ended December 31, 2021, compared to $6.1 million for the year ended December 31, 2020, an increase of $17.6 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 $13.1 million for the year ended December 31, 2021, compared to $10.1 million for the year ended December 31, 2020, an increase of $3.0 million. The increase in general and administrative spend primarily reflects an increase in stock-based

compensation costs and other personnel costs associated with increased headcount, and an increase in general operating expenses. This was partially offset by a decrease in merger related costs of $2.9 million that were incurred for the year ended December 31, 2020, as a result of the Anelixis acquisition. No merger related expenses were recorded for the year ended December 31, 2021.

**Cash Position**

The company had approximately $84.8 million in cash and cash equivalents as of December 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 operating activities into 2024.

**Conference Call**

Eledon will hold a conference call today, March 24, 2022 at 4:30 pm Eastern Time to discuss fourth quarter and full-year 2021 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 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 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.**
**CONSOLIDATED BALANCE SHEETS**
**(In thousands, except share data)**

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 84,833 | $ 114,195 |
| Prepaid expenses and other current assets | 3,513 | 1,435 |
| Total current assets | 88,346 | 115,630 |
| Operating lease asset, net | 768 | 138 |
| Goodwill | 48,648 | 48,648 |
| In-process research and development | 32,386 | 32,386 |
| Other assets | 400 | 383 |
| Total assets | $ 170,548 | $ 197,185 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,813 | $ 1,366 |
| Current operating lease liability | 369 | 144 |
| Accrued expenses and other liabilities | 2,219 | 973 |
| Total current liabilities | 4,401 | 2,483 |
| Deferred tax liability | 1,752 | 4,106 |
| Non-current operating lease liability | 400 | — |
| Total liabilities | 6,553 | 6,589 |
| | | |
| 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 December 31, 2021 and 2020 | — | — |
| Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares authorized; 6,204 and no shares issued and outstanding at December 31, 2021 and 2020, respectively | — | — |
| Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2021 and 2020; 14,306,788 and 15,160,397 shares issued and outstanding at December 31, 2021 and 2020, respectively | 14 | 15 |
| Additional paid-in capital | 278,880 | 270,974 |
| Accumulated deficit | (114,899) | (80,393) |
| Total stockholders' equity | 163,995 | 190,596 |
| Total liabilities and stockholders' equity | $ 170,548 | $ 197,185 |

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

| | Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| **Operating expenses** | | |
| Research and development | $ 23,735 | $ 6,131 |
| General and administrative | 13,132 | 10,052 |
| Restructuring expense | — | 2,282 |
| Total operating expenses | 36,867 | 18,465 |
| Loss from operations | (36,867) | (18,465) |
| Other income, net | 7 | 79 |
| Warrant inducement expense | — | (4,829) |
| Loss before income tax benefit | (36,860) | (23,215) |
| Income tax benefit | 2,354 | 404 |
| Net loss and comprehensive loss | $ (34,506) | $ (22,811) |
| Net loss per share, basic and diluted | $ (2.33) | $ (15.72) |
| Weighted-average common shares outstanding, basic and diluted | 14,819,582 | 1,451,432 |