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): March 28, 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.)**

19900 MacArthur Blvd. Suite 550 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 March 28, 2024, Eledon Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter and year ended December 31, 2023. 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 No.	**Description**
99.1	Press Release Issued on March 28, 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 thereunto duly authorized.

Eledon Pharmaceuticals, Inc.

Date: March 28, 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 Fourth Quarter and Full Year 2023 Operating and Financial Results

Enrolled 12 participants in Phase 2 BESTOW trial evaluating tegoprubart for the prevention of kidney rejection

Tegoprubart used as a component of the immunosuppressive treatment regimen following the first-ever transplant of a kidney from a genetically modified pig to a human

Additional data from 11 participants in Phase 1b trial in kidney transplantation demonstrated that tegoprubart was generally safe and well tolerated, successfully prevented rejection and permitted above historical average post-transplant kidney function

IRVINE, Calif., Mar. 28, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (Nasdaq: ELDN) today reported its fourth quarter and full year 2023 operating and financial results and reviewed recent business highlights.

"Eledon continues to execute on time and as promised towards our goal of extending the functional life of transplanted organs", said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "Our latest Phase 1b data further support the potential of tegoprubart to significantly reduce the risk of rejection as well as harmful side effects associated with current standard of care in immunosuppression. In addition to our clinical development progress, tegoprubart was used for immunosuppression in historical kidney and heart pig-to-human xenotransplant procedures. As we advance our clinical program to assess the use of tegoprubart in kidney transplant procedures, we remain committed to supporting groundbreaking advancements that can lead to broader organ availability for patients around the world."

"Looking ahead, we anticipate completing enrollment of our Phase 2 BESTOW study by the end of the year as we also continue to enroll participants in the second cohort of our Phase 1b study and open-label extension study designed to provide additional insights into tegoprubart's long-term effectiveness," continued Dr. Gros. "We look forward to providing updated interim clinical data from both the Phase 1b and open-label studies in the second quarter of this year."

Fourth Quarter 2023 and Recent Corporate Developments

- Announced the use of tegoprubart as a component of the immunosuppressive treatment regimen following the first-ever transplant of a kidney from a genetically modified pig to a human. The procedure was completed on March 16, 2024, at Massachusetts General Hospital on a 62-year-old man with end-stage kidney disease.

- Announced 12th participant enrolled in the Phase 2 BESTOW trial assessing tegoprubart head-to-head with tacrolimus for the prevention of rejection in kidney transplantation.

- Reported updated safety and efficacy data from the ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of rejection in patients undergoing kidney transplant. Data from 11 participants demonstrated that tegoprubart was generally safe and well-tolerated in patients undergoing kidney transplantation, with aggregate mean estimated glomerular filtration rate (eGFR) above 70 mL/min/1.73m^2 at all reported time points after 90 days post-transplant. Results were presented at the American Society of Nephrology Kidney Week 2023 Annual Meeting held in Philadelphia, PA in November 2023.

- Amended Phase 1b trial protocol to add a second cohort, now allowing enrollment of up to 24 trial participants who are undergoing kidney transplantation.

- Enrolled first patient in a Phase 2 open-label extension (OLE) study, which will evaluate the long-term safety, pharmacokinetics, and efficacy of tegoprubart in participants who have completed one year of treatment in either the ongoing Phase 1b or Phase 2 BESTOW study. The participant completed the Phase 1b study with an eGFR of 91 at one year (day 374).

- Partnered with the University of Chicago Transplantation Institute to secure financing from the Juvenile Diabetes Research Foundation (JDRF) and The Cure Alliance to fund an investigator sponsored study in pancreatic islet cell transplantation in participants with type 1 diabetes. Tegoprubart treatment will be evaluated for the prevention of transplant rejection.

- Strengthened leadership team with appointment of Eliezer Katz, M.D., FACS as Chief Medical Officer and strengthened board of directors with appointment of Allan Kirk, M.D., Ph.D. and James Robinson.

Anticipated 2024 Milestones

- Second quarter 2024: Report updated interim clinical data from the ongoing Phase 1b trial of tegoprubart in kidney transplantation.

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

- 2024: Dose the first islet cell transplant participant for the treatment of type 1 diabetes at the University of Chicago Transplantation Institute.

Fourth Quarter 2023 Financial Results

The Company reported a net loss of $9.6 million, or $0.32 per share, for the three months ended December 31, 2023, compared to a net loss of $58.4 million, or $4.09 per share, for the same period in 2022. The net loss for the three months ended December 31, 2022 includes a non-cash goodwill impairment charge totaling $48.6 million. Excluding the non-cash impairment charge, net loss would be $9.7 million, or $0.68 per share.

Research and development expenses were $7.1 million for the three months ended December 31, 2023, compared to $7.3 million for the comparable period in 2022, a decrease of $0.2 million.

General and administrative expenses were $3.3 million for the three months ended December 31, 2023, compared to $2.8 million for the comparable period in 2022, an increase of $0.5 million.

Full Year 2023 Financial Results

The Company reported a net loss of $40.3 million, or $1.64 per share, for the year ended December 31, 2023, compared to a net loss of $88.0 million, or $6.16 per share, in 2022. The net loss for the year ended December 31, 2022 includes a non-cash goodwill impairment charge totaling $48.6 million. Excluding the non-cash impairment charge, net loss would be $39.3 million, or $2.75 per share.

Research and development expenses were $30.3 million for the year ended December 31, 2023, compared to $27.1 million for the year ended December 31, 2022, an increase of $3.2 million.

General and administrative expenses were $12.7 million for the year ended December 31, 2023, compared to $12.7 million for the year ended December 31, 2022.

The Company ended the year with approximately $51.1 million in cash and cash equivalents and short-term investments, compared to $56.4 million in cash and cash equivalents as of December 31, 2022.

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, 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-CD40 Ligand biology to conduct preclinical and clinical studies in kidney allograft 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 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-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.

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Source: Eledon Pharmaceuticals

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

	December 31,	
	2023	2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,612	$ 56,409
Short-term investments	46,490	—
Prepaid expenses and other current assets	5,027	3,109
Total current assets	56,129	59,518
Operating lease asset, net	365	739
In-process research and development	32,386	32,386
Other assets	186	150
Total assets	$ 89,066	$ 92,793
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 967	$ 2,200
Current operating lease liability	383	363
Accrued expenses and other liabilities	2,545	3,912
Total current liabilities	3,895	6,475
Deferred tax liability	1,752	1,752
Non-current operating lease liability	—	383
Total liabilities	5,647	8,610
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized at December 31, 2023 and 2022:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 110,086 and 117,970 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	—
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 and 6,204 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2023 and 2022; 24,213,130 and 13,776,788 shares issued and outstanding at December 31, 2023 and 2022, respectively	24	14
Additional paid-in capital	326,586	287,034
Accumulated deficit	(243,191)	(202,865)
Total stockholders' equity	83,419	84,183
Total liabilities and stockholders' equity	$ 89,066	$ 92,793

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

	Year Ended December 31,	
	2023	2022
Operating expenses		
Research and development	$ 30,312	$ 27,080
General and administrative	12,688	12,700
Goodwill impairment	—	48,648
Total operating expenses	43,000	88,428
Loss from operations	(43,000)	(88,428)
Other income, net	2,674	462
Loss before income taxes	(40,326)	(87,966)
Income taxes	—	—
Net loss and comprehensive loss	$ (40,326)	$ (87,966)
Net loss per share, basic and diluted	$ (1.64)	$ (6.16)
Weighted-average common shares outstanding, basic and diluted	24,619,197	14,285,254