

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): May 09, 2024

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.)

1980 MacArthur Blvd.
Suite 250
Irvine, California
(Address of Principal Executive Offices)

92612
(Zip Code)

Registrant's Telephone Number, Including Area Code: 949 238-8090

1990 MacArthur Blvd, Ste 550
Irvine, California 92612
(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 May 9, 2024, Eledon Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2024. 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 May 9, 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: May 13, 2024

By: /s/ David-Alexandre C. Gros, M.D.

Name: David-Alexandre C. Gros, M.D.

Title: Chief Executive Officer



Eledon Pharmaceuticals Reports First Quarter 2024 Operating and Financial Results

Completed oversubscribed \$50 million private placement

First participant dosed in clinical trial at University of Chicago Medicine assessing the use of tegoprubart to prevent islet cell transplant rejection in patients with type 1 diabetes

Reported updated data from ongoing Phase 1b trial evaluating tegoprubart for prevention of rejection in kidney transplantation

Tegoprubart used as part of immunosuppressive treatment following the first-ever kidney xenotransplant

IRVINE, Calif., May 9, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (Nasdaq: ELDN) today reported its first quarter 2024 operating and financial results and reviewed recent business highlights.

"We are pleased with the significant progress made so far this year in the development of tegoprubart for use both in kidney transplantation and in the emerging fields of xenotransplantation and islet cell transplantation. This progress reinforces tegoprubart's potential to become the first-line immunosuppressive treatment option of choice for a broad range of transplant procedures," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon.

First Quarter 2024 and Recent Corporate Developments

- First participant in an investigator-led clinical trial has received an islet cell transplant and is being treated with a novel immunosuppression regimen including tegoprubart, the company's novel anti-CD40L antibody, which is in development for the prevention of pancreatic islet cell transplant rejection in patients with type 1 diabetes. The study is being conducted by the research team at the University of Chicago's Pancreatic and Islet Transplant Program in collaboration with Eledon, the Juvenile Diabetes Research Foundation, and The Cure Alliance.
 - Announced the use of tegoprubart as part of the immunosuppressive treatment regimen used following the first-ever kidney xenotransplant procedure of a genetically modified kidney from a pig to a human.
 - Enrolled the 12th participant in March 2024 in the ongoing Phase 2 BESTOW trial assessing tegoprubart head-to-head with tacrolimus for the prevention of rejection in kidney transplantation.
 - Completed a private placement financing for total gross proceeds of \$50.0 million, before deducting any offering related expenses, to a select group of institutional and accredited investors at a price per share of \$2.37.
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Anticipated 2024 Milestones

- June 2024: Report updated interim clinical data from the ongoing Phase 1b trial and open-label extension study of tegoprubart in kidney transplantation at the American Transplant Congress in Philadelphia, PA.
- End of 2024: Complete enrollment in the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.

First Quarter 2024 Financial Results

The Company reported a net loss of \$10.3 million, or \$0.34 per share, for the three months ended March 31, 2024, compared to a net loss of \$10.8 million, or \$0.75 per share, for the same period in 2023.

Research and development expenses were \$7.4 million for the three months ended March 31, 2024, compared to \$8.1 million for the comparable period in 2023, a decrease of \$0.7 million.

General and administrative expenses were \$3.5 million for the three months ended March 31, 2024, compared to \$3.0 million for the comparable period in 2023, an increase of \$0.5 million.

Eledon ended the first quarter with approximately \$42.9 million in cash, cash equivalents and short-term investments, which excludes the \$50.0 million in gross proceeds received in the recently completed private placement.

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 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-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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)
(Unaudited)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,655	\$ 4,612
Short-term investments	37,207	46,490
Prepaid expenses and other current assets	5,115	5,027
Total current assets	47,977	56,129
Operating lease asset, net	270	365
In-process research and development	32,386	32,386
Other assets	185	186
Total assets	\$ 80,818	\$ 89,066
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,864	\$ 967
Current operating lease liabilities	284	383
Accrued expenses and other liabilities	2,099	2,545
Total current liabilities	4,247	3,895
Deferred tax liabilities	1,752	1,752
Total liabilities	5,999	5,647
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized at March 31, 2024 and December 31, 2023:		
Series X ¹ non-voting convertible preferred stock, \$0.001 par value, 515,000 shares designated; 110,086 shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Series X non-voting convertible preferred stock, \$0.001 par value, 10,000 shares designated; 4,422 shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 24,813,130 and 24,213,130 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	25	24
Additional paid-in capital	328,280	326,586
Accumulated deficit	(253,486)	(243,191)
Total stockholders' equity	74,819	83,419
Total liabilities and stockholders' equity	\$ 80,818	\$ 89,066

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,	
	2024	2023
Operating expenses		
Research and development	\$ 7,410	\$ 8,113
General and administrative	3,459	2,997
Total operating expenses	10,869	11,110
Loss from operations	(10,869)	(11,110)
Other income, net	574	338
Net loss and comprehensive loss	\$ (10,295)	\$ (10,772)
Net loss per share, basic and diluted	\$ (0.34)	\$ (0.75)
Weighted-average common shares outstanding, basic and diluted	29,989,400	14,285,905

