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): October 29, 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.)**

19800 MacArthur Blvd. Suite 250 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 7.01 Regulation FD Disclosure.

On October 29, 2024, Eledon Pharmaceuticals Inc. (the "Company") issued a press release announcing initial data from subjects with type 1 diabetes treated with tegoprubart, the Company's investigational anti-CD40L antibody, as part of an immunosuppression regimen following islet transplantation in an investigator-initiated trial at the University of Chicago Medicine's Transplantation Institute. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

Also, on October 29, 2024, the Company updated its investor presentation, which is posted on the Company's website at https://ir.eledon.com/news-and-events/publications-and-presentations.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) 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, or be deemed, incorporated by reference in any filings under the Securities Act of 1933, as amended (the "Securities Act"), unless the Company specifically states that the information is to be considered "filed" under the Exchange Act or incorporates it by reference into a filing under the Securities Act or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release, dated October 29, 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 hereunto duly authorized.

Eledon Pharmaceuticals, Inc.

Date: October 29, 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 Announces Positive Initial Data from Subjects with Type 1 Diabetes Treated with Tegoprubart as Part of an Immunosuppression Regimen Following Islet Transplantation in Investigator-Initiated Trial at UChicago Medicine

- *First two out of three subjects treated with tegoprubart as part of immunosuppression regimen to prevent transplant rejection achieved insulin independence and remain insulin free, with glucose control in the normal range; Third subject was recently transplanted and is on trajectory for insulin independence*

- *Islet engraftment in the first two subjects with tegoprubart estimated three to five times higher than engraftment in three comparable subjects receiving standard of care tacrolimus-based immunosuppression*

- *Treatment with tegoprubart was generally well tolerated*

- *Study data to be presented by UChicago Medicine's team in oral presentation at the 5th IPITA/HSCI/Breakthrough T1D Stem Cells Summit*

IRVINE, Calif., October 29, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today announced positive data for the first three islet transplant recipients treated with an immunosuppression regimen that includes tegoprubart, the Company's investigational anti-CD40L antibody, for prevention of islet transplant rejection in subjects with type 1 diabetes (T1D). The investigator-initiated trial, conducted by the research team at the University of Chicago Medicine's Transplantation Institute, demonstrated potentially the first human cases of insulin independence achieved using an anti-CD40L monoclonal antibody therapy without the use of tacrolimus, the current standard of care for prevention of transplant rejection. The first two subjects achieved insulin independence and normal hemoglobin A1C (HbA1c) levels, a measure of average blood glucose, post-transplant. The third subject, who recently received an islet transplant, decreased insulin use by more than 60% three days following the procedure and continues on an insulin independence trajectory.

Subjects on study received islet transplants combined with induction therapy, mycophenolate mofetil (MMF), and tegoprubart, given every third week by intravenous (IV) infusion. The first two subjects achieved insulin independence and presented stable islet graft function at approximately three months and six months post-transplant, respectively. Islet engraftment, measured by graft

function standardized to the number of islets infused, was three to five times higher than three comparable subjects outside this study who received tacrolimus-based immunosuppression, suggesting treatment with tegoprubart is less toxic to transplanted islets resulting in improved graft survival and function. Treatment was generally well tolerated in all subjects with no unexpected adverse events or hypoglycemic episodes. After initial islet transplant, the first participant reduced insulin requirements by over 60% and normalized blood glucose control. The first patient then achieved insulin independence approximately two weeks after the second islet transplantation procedure.

The data are being featured in an oral presentation at the International Pancreas and Islet Transplantation Association (IPITA), Harvard Stem Cell Institute (HSCI), and Breakthrough T1D (formerly JDRF) 5th Annual Summit on Stem Cell Derived Islets on Tuesday, October 29, 2024.

“We are very pleased that tegoprubart played a pivotal role in yet another landmark advance in transplantation research through the work of Dr. Witkowski, Dr. Fung and their team at UChicago Medicine,” said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “Following promising results in kidney allotransplant procedures as well as heart and kidney xenograft procedures, these data from subjects following islet transplantation further demonstrate tegoprubart’s potential to protect transplanted organs and cells. Dr. Witkowski’s study also further reinforces prior study results showing that tegoprubart may offer a favorable safety and efficacy profile compared to tacrolimus-based immunosuppression regimens.”

“These data are another step in our quest to achieve a path for functional cures in type 1 diabetes,” said Piotr Witkowski, M.D., Ph.D., Director, Pancreas and Islet Transplant Program, UChicago Medicine and one of the study’s lead investigators. “For more than 30 years, we have been looking for options that can deliver target levels of immunosuppression without the side effects associated with standard of care, including toxicity to the kidneys, central nervous system and islet cells, and increased risk of diabetes and hypertension. These data further support tegoprubart as a novel immunosuppression option that can play a central role in advancing islets transplantation as a potentially transformational alternative for subjects with type 1 diabetes.”

“Breakthrough T1D is proud to fund and support this research and is encouraged by the tegoprubart study showing that subjects who received islet transplants with a tacrolimus-free immunosuppressive regimen are making insulin again," said Breakthrough T1D Chief Scientific Officer Sanjoy Dutta, Ph.D. "Islet replacement therapies are a key priority for Breakthrough T1D, and we’re committed to driving research that moves us toward a world where these therapies are available to the broader T1D community. Achieving this goal requires novel approaches to keep transplanted cells functional with a tolerable immunosuppression regimen. These results are an important step toward that goal, and we look forward to seeing additional data."

Efficacy and Safety Results

The first participant was a 42-year-old female with a baseline weight of 88 kg/194 lbs (BMI of 30). At 90 days post-transplant, the participant’s HbA1c level improved to 6.0% (from 8.4% at baseline)

and daily insulin dose decreased to 16 units per day (from 80 units per day at baseline). After 16 weeks, the participant received a second islet transplant, and approximately two weeks later achieved insulin independence, maintaining improved HbA1c levels of 5.4% afterwards.

The second participant was a 30-year-old female with a baseline weight of 50 kg/110 lbs (BMI of 21). This patient stopped insulin support (from 60 units per day at baseline) four weeks after the islet transplant. Her HbA1c levels improved to 5.8% and below (from 8.5% at baseline) starting at seven weeks after the transplant.

The third participant was a 37-year-old male with a baseline weight of 92 kg/203 lbs (BMI of 30) with a baseline HbA1C of 9.3%. This patient was discharged home on day three post-transplant, requiring 29 units of insulin (from 90 units per day at baseline).

The treatment was generally well tolerated in all subjects with no unexpected adverse events, severe hypoglycemic episodes, or graft rejection.

In January 2024, Eledon announced that it would be supplying tegoprubart for this investigator-led clinical trial with the UChicago Medicine Transplantation Institute for pancreatic islet transplantation in subjects with type 1 diabetes (NCT06305286). Tegoprubart is the cornerstone component of the chronic immunosuppressive regimen for trial participants and is being evaluated for the prevention of transplant rejection in the trial. Funding for the study includes grants from Breakthrough T1D (formerly known as JDRF) and The Cure Alliance.

About Islet Transplantation for Type 1 Diabetes

Pancreatic islet transplantation is a minimally invasive procedure developed to provide blood glucose control for subjects with type 1 diabetes and minimize or eliminate dependence on insulin. During the procedure, pancreatic islets containing insulin-producing beta cells are isolated from the pancreas of a deceased organ donor and infused through a small catheter into the patient’s liver. The islet cells lodge in small blood vessels in the liver and release insulin. Post-procedure, subjects remain on immunosuppression therapy to prevent transplant rejection.

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 the CD40 Ligand, a well-validated biological target that has broad therapeutic potential. 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, expected or future results of tegoprubart trials and its ability to prevent rejection in connection with islet cell transplantation or kidney transplantation, 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; and risks relating to costs of clinical trials and the sufficiency of the company's capital resources to fund planned clinical trials. 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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