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 5, 2026
Date of Report (Date of earliest event reported)

ETON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38738**	**37-1858472**
(State of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

21925 W. Field Parkway, Suite 235
Deer Park, Illinois 60010-7278
(Address of principal executive offices) (Zip code)

(847) 787-7361
(Registrant's telephone number, including area code)

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, par value $0.001 per share	**ETON**	**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 8.01: Other Events

On November 5, 2026, Eton Pharmaceuticals, Inc. (the "Company") issued a press release announcing preliminary results from a randomized, double-blind, placebo-controlled pilot study evaluating ET-700, its investigational extended-release zinc acetate formulation being developed for Wilson disease.

The study demonstrated improved gastrointestinal tolerability with ET-700 compared to GALZIN®, with treatment-related adverse events reported in 1 of 12 participants receiving ET-700 compared to 8 of 12 participants receiving GALZIN. The study also evaluated copper absorption inhibition, with hepatic copper uptake decreasing by 12% with ET-700 compared to 46% with GALZIN and an 11% increase with placebo in the prespecified primary analysis.

Based on these preliminary findings, the Company is already advancing additional formulations and intends to evaluate these faster-release formulations of ET-700 in additional study arms in 2027 to seek to improve copper absorption inhibition while preserving its favorable tolerability profile.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01: Financial Statements and Exhibits

Exhibit No.	Description
Exhibit 99.1	Press Release dated November 5, 2026
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.

Date: November 5, 2026

By: */s/ Judith M. Matthews*
Judith M. Matthews
Chief Financial Officer and Secretary
(Principal Financial Officer)

Eton Pharmaceuticals Announces Preliminary ET-700 Pilot Study Results Evaluating Copper Absorption Inhibition and Gastrointestinal Tolerability

- *Treatment-related adverse events occurred in 1 of 12 ET-700 participants compared with 8 of 12 GALZIN® participants*
- *Hepatic copper uptake decreased 12% with ET-700, compared with a 46% decrease with GALZIN, and an 11% increase with placebo*
- *Company plans additional study arms in 2027 evaluating faster-release formulations to seek to improve copper absorption inhibition while preserving favorable safety profile*

DEER PARK, Ill., November 5, 2026 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc ("Eton" or "the Company") (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced preliminary results from a randomized, double-blind, placebo-controlled pilot study evaluating ET-700, its investigational extended-release zinc acetate formulation being developed to treat Wilson disease.

ET-700 demonstrated a lower rate of drug related adverse events than GALZIN, with participants who received ET-700 reporting a single gastrointestinal-related adverse event. In comparison, 8 out of 12 participants receiving GALZIN reported 17 adverse events. Participants who received placebo reported 3 treatment related adverse events in 3 of the 12 participants. No serious adverse events were reported in the study. The estimated rate of treatment related gastrointestinal side effects was 0.30 per 100 participant-days for ET-700, compared with 5.35 for GALZIN and 0.89 for the placebo.

"The tolerability findings are exciting and reinforce our belief that a slower release zinc can improve tolerability, which is a notorious issue with zinc treatment," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "We are encouraged by the initial results, which showed a benefit over placebo, and our next objective is to improve ET-700's effect on copper absorption. We believe faster release formulations, which we've previously developed, can improve efficacy while preserving an attractive safety profile and we intend to test that hypothesis through additional study arms in the coming months. Our goal is to combine effective copper control, favorable tolerability, and twice-daily dosing."

"Gastrointestinal side effects are a well-known problem with zinc therapy in Wilson disease, so the clear difference in tolerability with ET-700 is clinically relevant. Its effect on copper absorption was more modest than that of standard zinc acetate, but the study has taught us a great deal about how the release profile matters. With copper-64 PET/CT, we now have a precise way to test whether an adjusted formulation can combine better tolerability with effective copper blocking," said Thomas Damgaard Sandahl, MD, PhD, Clinical Professor, Aarhus University and Aarhus University Hospital.

The study used copper-64 PET/CT imaging before and after treatment to assess hepatic copper uptake as a measure of intestinal copper absorption. The prespecified primary analysis included 29 participants who met per-protocol criteria.

Based on the median individual post-treatment-to-baseline uptake ratios, hepatic copper uptake decreased by 12% with ET-700 and 46% with GALZIN, compared with an 11% increase with placebo.

The supportive intention-to-treat analysis of 35 participants showed the same directional pattern, with reductions of 18% for ET-700 and 58% for GALZIN, compared with an 11% increase for placebo. In that analysis, GALZIN demonstrated a greater effect than ET-700 (p=0.023).

Tolerability Results

The safety population included 36 healthy participants, with 12 participants in each treatment group. Over four weeks:

Safety measure	ET-700	GALZIN	Placebo
Participants with at least one treatment-related adverse event	1 (8%)	8 (67%)	3 (25%)
Total treatment-related adverse events	1	17	3
Participants with at least one adverse event, regardless of relatedness	2 (17%)	9 (75%)	7 (58%)
Serious adverse events	0	0	0

Planned Evaluation of Faster-Release Formulations

Eton believes the findings support further evaluation of ET-700's release characteristics. The Company's working hypothesis is that a faster release profile could increase zinc exposure in the upper intestine, where copper absorption predominantly occurs, and improve inhibition of copper uptake.

Eton is currently advancing additional formulations with faster-release formulations and intends to evaluate additional study arms in 2027. These evaluations will assess whether greater activity can be achieved while preserving the favorable gastrointestinal tolerability observed to date.

About the Study

The investigator-initiated study was sponsored and conducted by Aarhus University Hospital in Denmark, with funding and study medication provided by Eton Pharmaceuticals. Healthy participants were randomized to four weeks of GALZIN 50 mg three times daily, ET-700 75 mg twice daily plus a matching placebo dose, or placebo three times daily. Both active regimens provided 150 mg of elemental zinc daily.

Thirty-six participants contributed safety data, 35 completed both PET/CT scans, and 29 met per-protocol criteria. The primary endpoint was the post-treatment-to-baseline ratio of hepatic copper-64 uptake.

The findings are preliminary and reflect a small, four-week study in healthy volunteers. They do not establish clinical efficacy in patients with Wilson disease or long-term comparative safety.

Important Safety Information for GALZIN®

INDICATION

GALZIN® (zinc acetate) is indicated for maintenance treatment of patients with Wilson's disease who have been initially treated with a chelating agent.

IMPORTANT SAFETY INFORMATION

Contraindication

Hypersensitivity to zinc acetate or any of the ingredients in GALZIN.

Warnings and Precautions

Copper Deficiency: Several post-marketing cases reported that zinc acetate taken over extended periods of time may result in decreased enteral copper absorption and copper deficiency. If a patient develops signs and/or symptoms of copper deficiency, interrupt zinc treatment and measure zinc, 24-hr urinary copper, and non-ceruloplasmin bound copper (NCC) levels.

Gastric Ulcer: Gastric ulcers including complications of anemia and gastric ulcer perforation with peritonitis have been reported with long-term use of zinc acetate.

General: GALZIN is not recommended for the initial therapy of symptomatic patients because of the delay required for zinc-induced increase in enterocytic metallothionein and blockade of copper uptake. Symptomatic patients should be treated initially, using chelating agents. During initial therapy, neurological deterioration may occur as stores of copper are mobilized.

Information for Patients: GALZIN should be administered on an empty stomach, at least one hour before or two to three hours after meals. Capsules should be swallowed whole, not opened or chewed. Patients must be clinically monitored to determine the adequacy of zinc acetate therapy.

Monitoring Patients: Existing signs and symptoms of Wilson's disease and 24-hour urine copper should be monitored. Neuropsychiatric evaluations including speech as well as liver function tests including bilirubin and aminotransferases, should be done as appropriate. In all treated patients,

24--hour urinary zinc levels may be a useful measure of compliance with the zinc acetate regimen.

Adverse Reactions

The most common adverse reactions are gastric irritation, elevations of serum alkaline phosphatase, amylase, and lipase suggesting pancreatitis.

To report a suspected adverse event related to GALZIN, contact Eton Pharmaceuticals, Inc. at 1-855- 224-0233 or the U.S. Food and Drug Administration (FDA) at www.fda.gov/safety/Medwatch or call 1-800-FDA-1088.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has twelve rare disease products: KHINDIVI ®, INCRELEX®, ALKINDI SPRINKLE®, DESMODA™, GALZIN®, HEMANGEOL®, PKU GOLIKE®, IMPAVIDO®, LIBERVANT®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has six additional product candidates in late-stage development: ASN-001, AMGLIDIA®, ET-700, ET-800, ET-900, and ZENEO® hydrocortisone autoinjector. For more information, please visit our website at www.etonpharma.com.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements associated with the expected ability of Eton to undertake certain activities and accomplish certain goals and objectives. These statements include but are not limited to statements regarding Eton's business strategy, Eton's plans to develop and commercialize its product candidates, the safety and efficacy of Eton's product candidates, Eton's plans and expected timing with respect to regulatory filings and approvals, and the size and growth potential of the markets for Eton's product candidates. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "goal," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Eton's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. These and other risks concerning Eton's development programs and financial position are described in additional detail in Eton's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Eton undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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