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

December 17, 2024
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 60010-7208
(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 December 17, 2024, Eton Pharmaceuticals, Inc. (the "Company") issued a press release announcing the full readout and compelling results from the clinical trial evaluating PKU GOLIKE as a protein substitute for the treatment of phenylketonuria (PKU) in patients during prolonged fasting periods. The study demonstrated that PKU GOLIKE, administered as the last daily dose and compared to standard amino acid protein substitutes, improved metabolic control by reducing harmful phenylalanine (Phe) levels and increasing beneficial tyrosine (Tyr) levels, both essential for brain function and metabolic health.

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 December 17, 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.

Date: December 17, 2024

By: */s/ James R. Gruber*
James R. Gruber
Chief Financial Officer and Secretary
(Principal Financial Officer)

Exhibit 99.1

Eton Pharmaceuticals Announces Final Readout of PKU GOLIKE® Clinical Trial

Clinical Trial Demonstrates Clinical and Statistical Improvement in Metabolic Control During Prolonged Fasting in PKU Patients - Results Expected to Promote Awareness and Adoption of PKU GOLIKE®

DEER PARK, Ill., December 17, 2024 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc. ("Eton" or the "Company") (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases announced the full readout and compelling results from the clinical trial evaluating PKU GOLIKE as a protein substitute for the treatment of phenylketonuria (PKU) in patients during prolonged fasting periods. The study demonstrated that PKU GOLIKE, administered as the last daily dose and compared to standard amino acid protein substitutes, improved metabolic control by reducing harmful phenylalanine (Phe) levels and increasing beneficial tyrosine (Tyr) levels, both essential for brain function and metabolic health.

PKU patients often experience significant fluctuations in blood Phe levels during prolonged fasting periods, particularly at night, when protein breakdown causes Phe concentrations to peak in the early morning. These fluctuations are associated with cognitive difficulties and overall health impacts, making nighttime metabolic control an important focus in PKU management.

The study was sponsored by Relief Therapeutics Holding SA, and was a randomized, crossover, controlled clinical study conducted by the Inherited Metabolic Disorders Unit at Birmingham Children's Hospital, UK, on pediatric patients with classical PKU, the condition's most severe form. The trial compared PKU GOLIKE to standard amino acid protein substitutes in managing metabolic parameters during overnight fasting, the longest fasting period within 24 hours.

At the end of the one-week treatment period, patients receiving PKU GOLIKE as the last daily protein substitute dose showed a statistically significant reduction in blood Phe levels compared to those receiving standard amino acid substitutes (P=0.0002) and a statistically significant increase in blood Tyr levels (P=0.0113). Compared to baseline levels measured prior to the start of treatment, the PKU GOLIKE group achieved an average 17.8% reduction in blood Phe levels (P=0.0484) and an average 33.8% increase in blood Tyr levels (P=0.0008) upon awakening after the overnight fasting period. In comparison, when treated with standard amino acid protein substitutes, the same patients experienced an average 27.6% increase in blood Phe levels (P=0.0063) and no significant improvement in blood Tyr levels. Blood sample analysis at three early morning time points across the two groups revealed no significant differences in peak Phe levels upon reawakening in either group.

Highlighting the clinical significance of the findings, Prof. Anita MacDonald, principal investigator and leading dietitian in inherited metabolic disorders at Birmingham Children's Hospital, stated: "Giving one dose of PKU GOLIKE as the final daily dose of protein substitute resulted in consistently better metabolic control in our cohort of patients with PKU. They all had classical PKU and were a particularly challenging group to control."

These results confirm that PKU GOLIKE's prolonged-release profile provides clinically and statistically significant improvements in metabolic control during extended fasting periods compared to standard amino acid protein substitutes. Eton expects these findings to support the adoption of PKU GOLIKE among healthcare providers and within the PKU community.

The study findings will be presented in a poster titled A Prolonged-Release Formula Has a Positive Impact on Morning Phenylalanine and Tyrosine Fluctuations in Patients with Classical Phenylketonuria at the 2025 American College of Medical Genetics and Genomics (ACMG) Annual Clinical Genetics Meeting, March 18- 22, 2025, in Los Angeles, California.

Eton promotes PKU GOLIKE with its existing metabolic sales force, which also promotes Eton's Carglumic Acid, Betaine, and Nitisinone products. PKU patients' care is typically overseen by metabolic geneticists and their support staff of nurse practitioners and registered dieticians. Medical formulas for PKU are frequently covered by insurance and are regulated by the FDA as medical food products. Patients and healthcare professionals seeking additional information or requesting a product sample can visit pkugolike.com.

For more information on this study (NCT05487378), please visit clinicaltrials.gov.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has five commercial rare disease products: ALKINDI SPRINKLE®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has three additional product candidates in late-stage development: ET-400, ET-600, and ZENEO® hydrocortisone autoinjector. For more information, please visit our website at etonpharma.com.

About Phenylketonuria (PKU)

Phenylketonuria (PKU) is caused by a defect of the enzyme needed to break down phenylalanine (Phe), leading to a toxic buildup of Phe from the consumption of foods containing protein or aspartame. Untreated PKU can result in global developmental delay or severe irreversible intellectual disability, as well as growth failure, hypopigmentation, motor deficits, ataxia and seizures. Living with PKU requires a limited diet and very careful management. If left unmanaged, PKU can lead to devastating consequences, such as brain damage. People living with PKU do not have the ability to metabolize Phe, which is found in many foods, and they require supplementation of amino acid-based phenylalanine-free medical formulas as part of an effort to prevent protein deficiency and optimize metabolic control. Medical formulas used in PKU are challenged to provide a range of amino acids slowly and without a medicinal aftertaste.

About PKU GOLIKE®

PKU GOLIKE® products are foods for special medical purposes (FSMPs) for the dietary management of PKU in both children and adults for use under medical supervision. Developed with Relief's proprietary, patent-protected Physiomimic Technology™ drug delivery platform, PKU GOLIKE® products are the first prolonged-release amino acid FSMPs, characterized by a special coating that ensures physiological absorption of the amino acids mirroring that of natural proteins. The special coating also masks the unpleasant taste, odor, and aftertaste of the amino acids. PKU GOLIKE PLUS® granules are flavorless and can be mixed with many foods. PKU GOLIKE® products contain all 19 amino acids that people with PKU need to maintain neurological and muscular health and PKU GOLIKE PLUS® granules are fortified with 27 essential vitamins and minerals, including ones normally found in protein-rich foods like iron, calcium and vitamin B12. The PKU GOLIKE® line of products are available in convenient packets (PKU GOLIKE PLUS® 3-16 and 16+) and medical formula bars (PKU GOLIKE BAR®). PKU GOLIKE® products have been commercially available in the U.S. since October 2022. For more information, visit pkugolike.com. (Please note this site is intended for U.S. audiences only).

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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Source: Eton Pharmaceuticals, Inc.