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

March 22, 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 March 22, 2024, Eton Pharmaceuticals, Inc. issued a press release announcing that it has entered into an agreement to acquire U.S. rights to PKU GOLIKE® from Relief Therapeutics Holding SA ("Relief").

Under the terms of the agreement, Eton will pay the seller $2.2 million for the acquisition and could pay up to $2 million in additional commercial milestones, consisting of one-time $500,000 payments when net sales in a year reach $4 million, $8 million, $15 million, and $20 million. Eton will pay the seller a royalty of 30% of net sales, which will include the cost of the product.

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 99.1	Press Release dated March 22, 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: March 22, 2024

By: */s/ James R. Gruber*

James R. Gruber
Chief Financial Officer and Secretary
(Principal Financial Officer)

Exhibit 99.1

Eton Pharmaceuticals Announces Acquisition of PKU GOLIKE® for Phenylketonuria

- PKU GOLIKE® is a commercial ultra-rare disease medical formula complementary to Eton's existing metabolic franchise and specialty call point
- Transaction is expected to be accretive to 2024 earnings
- Estimated peak sales of more than $10 million annually
- U.S. phenylketonuria ("PKU") medical formula market estimated to be $100 million annually

DEER PARK, Ill., March 22, 2024 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals ("Eton" or the "Company") (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced that it has acquired U.S. rights to PKU GOLIKE® from RELIEF THERAPEUTICS Holding SA ("Relief") (SIX: RLF, OTCQB: RLFTF, RLFTY).

"We are excited to be partnering with Relief on PKU GOLIKE in the United States. After extensive discussions with metabolic geneticists, dieticians, and PKU patients, we believe PKU GOLIKE is the best product in the estimated $100 million U.S. PKU medical formula market. With our sales force and existing relationships in the metabolic community, we believe we can significantly increase the awareness, education, and adoption of this important product," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

"We are very pleased to gain this partnership with Eton for PKU GOLIKE patients in the US as it is aligned with RELIEF's strategy to enhance patient access to our innovative products," said Michelle Lock, interim CEO of Relief. "Eton brings valuable know-how in the metabolic space as well as commercialization expertise for products in rare diseases."

PKU is a rare inherited disorder caused by a defect in the enzyme needed to break down phenylalanine, leading to a toxic buildup of phenylalanine when eating foods that contain proteins. Treatment of PKU requires patients to follow a strict diet that severely limits phenylalanine content and typically requires low protein foods supplemented by phenylalanine-free medical formulas. Excessive levels of phenylalanine in the blood accumulate in the brain and inhibit proper brain development. It is estimated that 8,000 PKU patients in the U.S. utilize medical formulas to manage their diet.

PKU GOLIKE® is a next generation medical formula product engineered with the patent protected, pharmaceutical grade Physiomimic™ technology for the dietary management of PKU under medical supervision. PKU GOLIKE's taste-masked, odor-free coating technology is designed to provide a better taste and a superior experience compared to alternative PKU medical formulas. In addition, PKU GOLIKE's delayed amino acid release formulation is designed to keep patients full for a longer period of time. Relief launched PKU GOLIKE Granules in the United States in the fourth quarter of 2022 and the PKU GOLIKE Tropical Bar in the second quarter of 2023. Only a few months into the product's launch, PKU GOLIKE's fourth quarter net sales in the U.S. were at an annual run rate of more than $1 million. Relief, through its subsidiary APR, has commercialized PKU GOLIKE in Europe since 2019 and seen strong adoption.

Eton plans to promote PKU GOLIKE with its existing metabolic sales force, which currently 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. PKU GOLIKE is exclusively distributed in the United States by Pentec Health. Patients and healthcare professionals seeking additional information on the product can visit www.PKUGOLIKE.com.

The transaction is expected to be accretive to Eton's 2024 earnings and the company expects peak sales of more than $10 million annually. As part of the transaction, Eton also received U.S. rights to Relief's GOLIKE medical formulas line extensions under development for the management of the metabolic conditions tyrosinemia and homocystinuria, which are expected to launch in 2025 and 2026, respectively. Eton has also been granted a right of first negotiation for Relief's RLF-OD032 development candidate. RLF-OD032 is an innovative drug product candidate under development for the treatment of PKU and is expected to be filed with the FDA in the second half of 2025 as a 505(b)(2) New Drug Application. Relief will continue to own PKU GOLIKE rights outside the United States.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has four FDA-approved rare disease products, ALKINDI SPRINKLE®, 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 www.etonpharma.com.

About RELIEF THERAPEUTICS Holding SA

Relief is a commercial-stage biopharmaceutical company committed to advancing treatment paradigms and delivering improvements in efficacy, safety, and convenience to benefit the lives of patients living with select specialty and rare diseases. Relief's portfolio offers a balanced mix of marketed, revenue-generating products, proprietary, globally patented Physiomimic™ and TEHCLO™ platform technologies and a targeted clinical development pipeline consisting of risk-mitigated assets focused in three core therapeutic areas: rare metabolic disorders, rare skin diseases and rare respiratory diseases. In addition, Relief is commercializing several legacy products via licensing and distribution partners. Relief's mission is to provide therapeutic relief to those suffering from rare diseases and is being advanced by an international team of well-established, experienced biopharma industry leaders with extensive research, development and rare disease expertise. Relief is headquartered in Geneva, with additional offices in Balerna, Switzerland, Offenbach am Main, Germany and Monza, Italy. Relief is listed on the SIX Swiss Exchange under the symbol RLF and quoted in the U.S. on OTCQB under the symbols RLFTF and RLFTY. For more information, visit www.relieftherapeutics.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® 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 is 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 www.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.