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

February 2, 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 February 2, 2024, Eton Pharmaceuticals, Inc. issued a press release announcing the commercial availability of Nitisinone Capsules for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

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 February 2, 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: February 2, 2024

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

Exhibit 99.1

Eton Pharmaceuticals Announces Commercial Availability of Ultra-Rare Disease Product Nitisinone Capsules

- Eton Cares patient support program offers $0 co-pay to eligible, commercially insured patients*
- Current Nitisinone market is estimated to exceed $50 million annually
- Product is now available exclusively through Optime Care

DEER PARK, Ill., Feb. 2, 2024 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals ("Eton" or "the Company") (Nasdaq: ETON), an innovative pharmaceutical company focused on developing, acquiring, and commercializing products to address unmet needs in patients suffering from rare diseases, today announced the commercial availability of Nitisinone Capsules for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. Please see important safety information below. Tyrosinemia type 1 is an ultra-rare condition that is estimated to impact fewer than 500 patients in the United States.

"Eton is committed to serving patients and families with the rarest of conditions. We are proud to make Nitisinone available to the hundreds of patients in the United States and offer full patient and provider support services. We believe that our existing commercial infrastructure and strong patient support services should help us capture a meaningful percentage of the estimated $50 million annual Nitisinone market," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Nitisinone Capsules are available exclusively through Optime Care, a specialty pharmacy dedicated to helping patients with rare diseases manage their conditions. Optime Care will administer the Eton Cares Program in partnership with Eton Pharmaceuticals. The Eton Cares Program will provide $0 co-pays for all commercially insured patients*, as well as prescription fulfillment, insurance benefits investigation, educational support, and financial assistance for qualifying patients.

Clinicians seeking to prescribe Nitisinone Capsules can e-prescribe by selecting Optime Care as the pharmacy or fax in a patient referral form to 866-318-2990. Additional product details can be found on the product website, www.nitisinoneUS.com.

For questions regarding prescription fulfillment, please contact Optime Care at 1-844-397-0541.

*Restrictions, limitations, and/or eligibility requirements may apply

USE and IMPORTANT SAFETY INFORMATION

What is Nitisinone?

Nitisinone is a prescription medicine used to treat adults and children with a hereditary disease called tyrosinemia type 1 (HT-1). Nitisinone should be taken along with a diet limiting tyrosine and phenylalanine.

What is the most important information I should know about Nitisinone?

Tell your doctor or nurse right away if you have any of these symptoms with Nitisinone:

Increased levels of plasma tyrosine, eye symptoms, developmental delay, and skin changes:

- Inadequate restriction of tyrosine and phenylalanine intake can result in raising plasma tyrosine levels.
- Plasma tyrosine levels above 500 micromol/L may lead to eye signs and symptoms like corneal ulcers, corneal cloudiness, inflammation of the cornea (keratitis), pink eye (conjunctivitis), eye pain, and sensitivity to light (photophobia), intellectual disability and developmental delay or painful thickening of the skin (hyperkeratotic plaques) on the soles and palms.
- Your healthcare provider should not adjust Nitisinone dosage in order to lower the levels of tyrosine in the blood.

Changes in blood profile

- You may develop a reduction in the number of white blood cells, which form part of the immune system (leukopenia) and abnormally low levels of platelets, which help the blood to clot (severe thrombocytopenia).

Do not take Nitisinone if:

- you are allergic to Nitisinone or any other ingredients. Stop using Nitisinone and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of the face, lips, tongue, or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; or very rapid heartbeat.

Before taking Nitisinone, tell your doctor if you:

- are pregnant or plan to become pregnant. Nitisinone may harm your unborn baby. Tell your doctor if you become pregnant or suspect you are pregnant during treatment with Nitisinone.
- are breastfeeding or plan to breastfeed. It is not known if Nitisinone passes into your breast milk. Talk to your doctor about the best ways to feed your baby during treatment with Nitisinone.
- are aged 65 and older. Your doctor may need to adjust the dose of Nitisinone based on your requirements.
- are taking other medicines since Nitisinone can interfere with their effect. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, dietary and herbal supplements.

What are the possible side effects of Nitisinone?

The most common side effects of Nitisinone (≥1%) include high tyrosine levels, low platelets (thrombocytopenia) or white cells in the blood (leukopenia), and complaints related to the eyes, including pink eye (conjunctivitis), corneal cloudiness, inflammation of the cornea, eye pain and extreme sensitivity to light (photophobia), nosebleed (epistaxis), itching (pruritus), skin inflammation (exfoliative dermatitis), rash (maculopapular rash), dry skin and hair loss (alopecia).

For more detailed information, please see full Prescribing Information for more information.

To report a suspected adverse event related to Nitisinone, contact Eton Pharmaceuticals, Inc. at: 1-855-224-0233 or the US Food and Drug Administration at www.fda.gov/medwatch or call 1-800-FDA-1088.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing, acquiring, and commercializing products to address unmet needs in patients suffering from 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.

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.

Investor Relations:
Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com

Source: Eton Pharmaceuticals.