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

October 4, 2023

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 October 4, 2023, Eton Pharmaceuticals, Inc. issued a press release announcing that it has entered into an agreement to acquire an abbreviated new drug application for Nitisinone Capsules.

Under the terms of the agreement, Eton paid the seller $0.15 million for the acquisition and assumed $0.5 million of cure amounts owed to the manufacturer. Eton will retain 80% of product profit and will pay 20% of product profit to the manufacturer.

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 October 4, 2022
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: October 4, 2023

By: */s/ James R. Gruber*

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

Exhibit 99.1

Eton Pharmaceuticals Announces Acquisition of FDA-Approved Ultra-Rare Disease Product Nitisinone

- Expect Q1 2024 product launch
- Nitisinone market estimated to be more than $50 million annually
- Eton will offer Eton Cares support program to all patients

DEER PARK, Ill., Oct. 4, 2023 (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 it has entered into an agreement to acquire an abbreviated new drug application for Nitisinone Capsules via Oakrum Pharma, LLC's Chapter 11 bankruptcy proceeding. The transaction has been approved by the bankruptcy court and is expected to be effective on October 12, 2023. The acquired product was approved by the U.S. Food and Drug Administration (FDA) in May of 2023 for the treatment of hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. It is estimated that less than 500 patients in the United States suffer from this ultra-rare condition.

"With a patient population of less than 500, Nitisinone is another opportunity for Eton to deliver on its mission of providing medicines to and supporting patients and families with rare conditions. Nitisinone is our fourth FDA-approved product, and further advances us toward our goal of having ten commercial rare disease products on the market by the end of 2025. Nitisinone also shares the same metabolic geneticist prescriber base as our Carglumic Acid and Betaine products, so this is an attractive opportunity to leverage our existing sales force and relationships with prescribers," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Eton expects to launch the product in the first quarter of 2024 and plans to offer its Eton Cares support program to all patients. The program is designed to help patients access treatment, providing prescription fulfillment services, insurance benefits investigation, educational support, and help in obtaining financial assistance for qualified patients, among other services. The current Nitisinone market is estimated to be over $50 million annually, and Eton believes the Company's commercial advantages, including its Eton Cares program, existing relationships with prescribers, and experienced sales force should allow it to capture a meaningful percentage of the market.

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 refer to the full Prescribing 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 three commercial rare disease products, ALKINDI SPRINKLE® for the treatment of pediatric adrenocortical insufficiency, Carglumic Acid for the treatment of hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency, and Betaine Anhydrous for the treatment of homocystinuria. The Company has four additional product candidates in late-stage development: dehydrated alcohol injection, which has received Orphan Drug Designation for the treatment of methanol poisoning, ZENEO® hydrocortisone autoinjector for the treatment of adrenal crisis, ET-400 for the treatment of adrenocortical insufficiency, and ET-600 for the treatment of diabetes insipidus. 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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Source: Eton Pharmaceuticals.