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

April 11, 2022
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.

Eton Pharmaceuticals, Inc. announced that it has received final approval from the U.S. Food and Drug Administration ("FDA") for its cysteine hydrochloride abbreviated new drug application ("ANDA"). 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 April 11, 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: April 11, 2022

By: */s/ W. Wilson Troutman*

W. Wilson Troutman
Chief Financial Officer and Secretary
(Principal Financial Officer)

Exhibit 99.1

Eton Pharmaceuticals Announces FDA Approval of Cysteine Hydrochloride Injection

DEER PARK, Ill., April 11, 2022 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced that it has received final approval from the U.S. Food and Drug Administration (FDA) for its cysteine hydrochloride abbreviated new drug application (ANDA), a bioequivalent generic of Exela Pharma Sciences' Elcys™. Eton was granted 180 days of generic exclusivity as a result of being the first ANDA submitted against the reference product. The 180-day exclusivity period will begin upon Eton's commercialization of the product.

"We are pleased to see another one of our products receive FDA approval. Despite Exela's attempts to monopolize a decades old treatment with patents that we believe to be frivolous, we are eager to provide a lower cost product to newborn infants that need cysteine," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Cysteine is indicated for use as an additive to amino acid solutions to meet the nutritional requirements of newborn infants. Prior to 2019, cysteine was sold in the United States as a "grandfathered" or "unapproved" product. In 2019, Exela Pharma Sciences received FDA approval of its product, which contains the same formulation as the "grandfathered" versions, and Exela Pharma Sciences more than tripled the price of the product to its current price of $82 per vial from the "grandfathered" product price of $22. Eton's partner has manufactured the product in its current formulation as far back as 2003, well before Exela Pharma Sciences began working on its product or filed its patent, and as a result, Eton believes Exela's patents are invalid and should not have been issued by the United States Patent and Trademark Office.

Eton is currently engaged with Exela in paragraph IV litigation regarding the validity of Exela's cysteine patents. The trial was held in March 2022 and the company expects a decision from the judge in the third quarter of 2022.

Based on IQVIA data, the current market for cysteine injection is more than $50 million annually.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The company currently owns or receives royalties from seven FDA-approved products, including ALKINDI SPRINKLE®, Carglumic Acid, Biorphen®, Alaway® Preservative Free, Rezipres®, Eprontia™, and cysteine injection, and has three additional products that have been submitted to the FDA.

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