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

May 7, 2020
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 Select 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 [X]

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. [X]

Item 8.01 Other Events.

On May 7, 2020, Eton Pharmaceuticals, Inc. (“Eton”) issued a press release announcing that Eton has been confirmed as the first filer of a patent challenge against Exela Pharma Science’s Elcys product (cysteine hydrochloride injection). 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 May 7, 2020

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: May 7, 2020

By: */s/ W. Wilson Troutman*

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

Exhibit 99.1

Eton Pharmaceuticals Confirms First-to-File Patent Challenge on Elcys (Cysteine Hydrochloride Injection)

-Eton confirms first-to-file ANDA referencing Exela Pharma Sciences' Elcys product

-Eton plans to file Post Grant Reviews in the U.S. Patent & Trademark Office challenging the validity of Exela's listed patents, which, if successful, could allow Eton to launch in 2021

-Eton believes Exela Pharma Sciences is improperly stifling competition on a decades-old drug

DEER PARK, Ill., May 7, 2020 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today disclosed that it has been confirmed as the first filer of an Abbreviated New Drug Application (ANDA) against Exela Pharma Science's Elcys (cysteine hydrochloride injection).

Eton's Paragraph IV certifications challenge the validity of U.S. Patent Nos. 10,478,453 and 10,583,155, which were issued to Exela Pharma Sciences in 2019 and 2020, respectively.

Eton is the first company to have filed a substantially complete abbreviated new drug application (ANDA) containing a Paragraph IV certification with the U.S. Food and Drug Administration (FDA). If successful, this would entitle Eton to 180 days of generic exclusivity.

Cysteine hydrochloride injection is an old molecule that was sold in the United States for decades as an unapproved product before Exela's New Drug Application (NDA) approval in 2019. Exela did not conduct any new clinical studies to support its NDA filing, and instead relied on historic published literature to support its safety and efficacy claims. Eton's own development partner had manufactured and commercialized cysteine hydrochloride injection over fifteen years ago in the same formulation that was claimed to be novel by Exela Pharma Sciences, and as a result, Eton is highly confident that the Exela Pharma Science patents will be invalidated.

In addition, Eton expects to file Post Grant Reviews (PGRs) with the U.S Patent and Trademark Office (USPTO) later this month. The PGR process is an abbreviated pathway to challenge the validity of patents issued by the USPTO. The USPTO is generally required to make a final ruling on a PGR challenge within eighteen months of a challenger's PGR submission, which would allow for Eton to potentially launch its product as early as November 2021.

"Cysteine injection has been sold in the United States in its current form since at least 1990. These baseless patents are an attempt by Exela to stifle competition on a decades-old product and jack-up the price," said Sean Brynjelsen, CEO of Eton Pharmaceuticals. "We look forward to overturning Exela's patents related to Cysteine injection and providing a lower cost alternative to patients."

Formerly known as Eton's DS-300 project, cysteine hydrochloride is an injectable product used as an additive to amino acid solutions to meet the nutritional requirements of newborn infants. Currently, Exela is the only supplier of the product in the United States and the market is estimated to be more than $50 million annually. Eton's ANDA was submitted in December 2019 and was assigned a Generic Drug User Fee Act date in October 2020.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing, acquiring, and commercializing innovative products. Eton is primarily focused on hospital injectable and pediatric rare disease products. The company's first commercial product, Biorphen, is the only FDA approved ready-to-use formulation of phenylephrine injection and was launched in December 2019. The company's lead pediatric product is the orphan drug Alkindi® Sprinkle, which is currently under review with the FDA. The company has an additional eight products under development, including three that are under review with the FDA.

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 Contact:
David Krempa
dkrempa@etonpharma.com
612-387-3740