
**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

August 1, 2019
Date of Report (Date of earliest event reported)

ETON PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State of
incorporation)

001-38738
(Commission
File Number)

37-1858472
(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:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
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

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 August 1, 2019, Eton Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the U.S. Food & Drug Administration (“FDA”) had accepted for review Aucta Pharmaceuticals’ (“Aucta”) New Drug Application for ET-105 and assigned a target Prescription Drug User Fee Act (“PDUFA”) date of March 17, 2020. Eton acquired the U.S. marketing rights to ET-105, an innovative form of lamotrigine, from Aucta in June 2019. 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 August 1, 2019](#)

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: August 1, 2019

By: /s/ W. Wilson Troutman

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

Eton Pharmaceuticals Announces FDA Acceptance of New Drug Application for ET-105

-ET-105 assigned Prescription Drug User Fee Act (PDUFA) target action date of March 17, 2020

DEER PARK, Ill., August 1, 2019 (GLOBE NEWSWIRE) – Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced that Aucta Pharmaceuticals' New Drug Application for ET-105, an innovative formulation of lamotrigine which Eton acquired the U.S. marketing rights to in June 2019, has been accepted for review by the U.S. Food and Drug Administration (FDA). The FDA has assigned the application a Prescription Drug User Fee Act (PDUFA) target action date of March 17, 2020.

“The NDA acceptance of ET-105 marks an important milestone for Eton as this strengthens our growing pipeline of near-launch products. We are very excited about the potential for ET-105 to address a significant unmet need in this large and growing market,” said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. “Our team looks forward to working with Aucta and the FDA over the coming months as we prepare for a potential commercial launch in the first half of 2020.”

ET-105 is a patent-pending formulation of lamotrigine for which Aucta is seeking approval as an adjunct therapy for partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome in patients two years of age and older. Lamotrigine is one of the most widely used anti-epilepsy medications in the U.S with sales exceeding \$700 million and 1 billion tablets annually but is only FDA-approved in tablet formulations. ET-105's innovative formula will be delivered to patients as an oral liquid and has been developed specifically to address the significant unmet need in patients with dysphagia and pediatric patients requiring precision dosing at levels below the currently available tablet strengths.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Eton is primarily focused on liquid dosage forms including injectables, oral liquids and ophthalmics. Eton has a diversified pipeline of high-value product candidates in various stages of development and therapeutic areas, including multiple product candidates currently pending regulatory approval 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 and its partner to undertake certain activities and accomplish certain goals and objectives. These statements include but are not limited to statements regarding the expected impact of the FDA's Complete Response Letter, the timing of a response to such letter, the ability to resolve the issues raised by the letter and the timing of such resolution, the approvability of the product in light of this letter and the timing of such approval and launch. 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 business, development programs, and financial condition 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.

Company Contact:

David Krempa
dkrempa@etonpharma.com
847-805-1077

Investor Contact:

Julie Seidel
Stem Investor Relations, Inc.
Julie.Seidel@stemir.com
212-362-1200
