
**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 19, 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 19, 2019, Eton Pharmaceuticals, Inc. issued a press release announcing positive results from bioequivalence studies of ET-104, Eton's proprietary oral liquid formulation of a molecule frequently used to treat a severe neurological condition. Eton acquired the U.S. and Canada marketing rights to ET-104 in January 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 19, 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 19, 2019

By: /s/ W. Wilson Troutman

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

Eton Pharmaceuticals Announces Positive Results from Clinical Study Report of ET-104

ET-104 Successfully Demonstrated Bioequivalence to Currently Approved Oral Solid Formulation

New Drug Application (NDA) Submission Expected in Fourth Quarter of 2019

DEER PARK, Ill., August 19, 2019 (BUSINESSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products today announced positive results from bioequivalence studies of ET-104, Eton's proprietary oral liquid formulation of a molecule frequently used to treat a severe neurological condition.

In bioequivalence studies conducted in 35 human subjects under both fed and fasting conditions, ET-104 demonstrated pharmacokinetic equivalence to a currently FDA-approved oral solid product of the same active ingredient. The 90% confidence intervals for ET-104's area-under-the-curve and peak concentration measurements were within the 80 to 125 percent-range that is commonly used to define bioequivalence. Based on these successful trial results, Eton anticipates submitting an NDA with the U.S Food and Drug Administration (FDA) for the product in the fourth quarter of 2019.

"We are pleased to report positive results for ET-104, which we believe has the potential to meet a significant unmet need for patients," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "We expect to submit the NDA for ET-104 later this year, further growing our near-approval pipeline and strengthening our neurology liquid franchise."

ET-104 is an innovative patent-pending oral liquid formulation of a molecule frequently used to treat a severe neurological condition. ET-104's active ingredient is currently FDA-approved in oral solid form but not as a liquid. ET-104 was developed to address the significant unmet need for patients that require precision dosing or have difficulty swallowing tablets. In oral solid form, ET-104's active ingredient sells over 200 million tablets and capsules annually.

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 two products currently filed 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.

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
