
**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

March 17, 2020

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:

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

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 March 17, 2020, Eton Pharmaceuticals, Inc. issued a press release which provided an update for results on its ET-101 product candidate. 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 March 17, 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: March 17, 2020

By: */s/ W. Wilson Troutman*

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

Eton Pharmaceuticals Reports Positive Study Results for ET-101 (Topiramate Oral Solution)

-Results Demonstrated Bioequivalence to the Currently Approved Oral Solid Formulation

-Market for Topiramate in Oral Form is Greater than \$800 million Annually

DEER PARK, Ill., March 17, 2020 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced positive bioequivalence study results for ET-101, its proprietary oral solution formulation of topiramate.

A bioequivalence study was conducted in healthy male subjects under fasting conditions, of Eton's ET-101 oral solution compared to the existing FDA-approved topiramate oral solid product. The 90% confidence intervals for all pharmacokinetic (PK) parameters were within the 80 to 125% BE criteria, demonstrating that ET-101 is bioequivalent to the comparator product under fasting conditions. Further, a food effect study was conducted on ET-101 under fed conditions, which demonstrated that the bioavailability of the product is not impacted by food.

"We are pleased to report positive results for ET-101, which brings the product one step closer to the market. ET-101 represents a very large market opportunity and is an important part of our growing pediatric neurology portfolio," said Sean Brynjelsen, CEO of Eton Pharmaceuticals. "We believe our proprietary oral liquid formulation will address a critical unmet need for pediatric epilepsy patients and we look forward to bringing the product to them as quickly as possible".

Eton anticipates submitting a New Drug Application for ET-101 in the third quarter of 2020, which would allow for Food and Drug Administration (FDA) approval as early as the second quarter of 2021.

ET-101 is expected to be the first oral solution of topiramate approved by the FDA. The current market for topiramate in oral form is greater than \$800 million annually according to IQVIA data. Eton's product is specifically designed to offer patients precision dosing and an ease of administration that is not available from existing FDA-approved treatment options. Due to this current unmet need, topiramate is one of the most frequently compounded neurology oral liquids. ET-101 is the third product in Eton's pediatric neurology pipeline, along with ET-105, its lamotrigine for oral suspension product candidate, and ET-104.

ET-101's unique proprietary formulation is stable at room temperature storage. Eton is seeking approval of ET-101 for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older, as adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older, and for the preventive treatment of migraine in patients 12 years of age and older.

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 oral liquid 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 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.

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