
**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

October 6, 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 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 October 6, 2020, Eton Pharmaceuticals, Inc. issued a press release announcing that it has submitted a New Drug Application for Topiramate Oral Solution to the U.S. Food and Drug Administration. 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 October 6, 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: October 6, 2020

By: */s/ W. Wilson Troutman*

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

Eton Pharmaceuticals Submits New Drug Application to the FDA for Topiramate Oral Solution (ET-101)

- Application Submitted for the Treatment of Partial-Onset Seizures and Migraine
- Eton's Patent-Pending Product Addresses Significant Unmet Need for a Liquid Formulation of Topiramate
- Topiramate Oral Solution is Eton's Third Neurology Product Candidate Submitted to the FDA

DEER PARK, Ill., October 6, 2020 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative treatments for rare pediatric diseases, today announced that in tandem with its development and manufacturing partner Tulex Pharmaceuticals, it has submitted a new drug application (NDA) for topiramate oral solution to the U.S. Food & Drug Administration (FDA). The product candidate, formerly known as ET-101, was submitted for three indications, including: monotherapy for treatment of partial-onset or primary general tonic-clonic seizures in patients two years age and older; adjunctive therapy for treatment of partial-onset seizures, including seizures associated with Lennox-Gastaut syndrome in patients two years of age and older; and as preventative treatment of migraine in patients 12 years of age and older.

“Topiramate is one of the most widely compounded oral liquids, and our product addresses the unmet need for pediatric-friendly formulations of the molecule. We look forward to working with the FDA to bring a safe, effective, FDA-approved product to patients and caregivers as quickly as possible,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Eton's product is expected to be the first and only FDA-approved liquid formulation of topiramate. The company's patent-pending liquid formulation addresses the significant unmet need for patients with dysphagia and patients that require the precision dosing that a liquid can offer. Topiramate is currently FDA-approved only in tablet and capsule form. Based on IQVIA data, the market for oral topiramate is more than \$800 million annually.

ET-101 is Eton's third neurology-focused liquid product candidates to be submitted to the FDA. Eton expects all three of the neurology product candidates to be approved and launched in 2021.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative treatments for rare pediatric diseases. The company currently owns or receives royalties from three FDA-approved approved products, including ALKINDI® SPRINKLE, Biorphen®, and Alaway® Preservative Free, and has six additional products in its late-stage pipeline, including five that have been submitted to 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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