

**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

July 30, 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 July 30, 2020, Eton Pharmaceuticals, Inc. issued a press release announcing that it had submitted a New Drug Application to the U.S. Food and Drug Administration for Zonisamide Oral Suspension. 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 July 30, 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: July 30, 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 Zonisamide Oral Suspension (ET-104)

- Application Submitted for the Treatment of Partial Seizures in Epilepsy Patients
- Eton's Patent-Pending Product Addresses Significant Unmet Need for a Liquid Formulation of Zonisamide
- Application is Eton's Sixth Drug Application Under FDA Review

DEER PARK, Ill., July 30, 2020 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced it has submitted a new drug application (NDA) for zonisamide oral suspension, previously known as the company's ET-104 product candidate, to the U.S. Food & Drug Administration (FDA) for the treatment of partial seizures in patients with epilepsy.

"We know there is strong demand for liquid zonisamide from neurologist and patients, and we look forward to working with the FDA to get the product approved and available to patients as soon as possible," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Zonisamide is widely used as a capsule to treat partial seizures, but the molecule is not FDA approved in liquid form. Eton's patent-pending liquid formulation addresses the significant unmet need for patients with dysphagia and patients that require the precision dosing that a liquid product offers. Based on IQVIA data, more than 150,000 prescriptions of zonisamide are written annually for the treatment of epilepsy.

ET-104 is one of Eton's three neurology-focused liquid product candidates, along with ET-105 (lamotrigine oral suspension) and ET-101 (topiramate oral solution). The company expects all three product candidates to be approved and launched in 2021.

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 seven products under development, including five 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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