
**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 27, 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 27, 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 orphan drug Dehydrated Alcohol Injection. 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 27, 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 27, 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 Orphan Drug Dehydrated Alcohol Injection (DS-100)

-Granted Orphan Drug Designation by the FDA for the Treatment of Methanol Poisoning

-Since the Start of COVID-19, the FDA has Recalled More Than 75 Contaminated Hand Sanitizers Due to Risk of Methanol Poisoning

-DS-100 is Eton's Fifth Drug Application Under FDA Review and Second Orphan Application

DEER PARK, Ill., July 27, 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 dehydrated alcohol injection, previously known as the company's DS-100 product candidate, to the U.S. Food & Drug Administration (FDA) for the treatment of methanol poisoning.

"We are very excited to add another orphan drug NDA submission to our late-stage pipeline. Our team and our partners have worked tirelessly to complete DS-100's extensive clinical and development activities, which has allowed us to submit this application ahead of schedule," said Sean Brynjelsen, CEO of Eton Pharmaceuticals. "If approved by the FDA, we look forward to launching the product in the near future."

Eton's product has been granted orphan drug designation for the treatment of methanol poisoning, and as a result, the product is expected to receive seven years of market exclusivity upon its approval. The incidence of methanol poisoning has increased significantly in 2020 due to COVID-19, as unprecedented demand for hand sanitizers has led some manufacturers to improperly use methanol in their products. Earlier this month, the FDA recommended manufacturers recall more than 75 different hand sanitizers that were found to contain methanol despite being labeled as ethanol. Methanol, or wood alcohol, is a substance that can be toxic when absorbed through the skin or ingested. The FDA has reported cases of adults and children suffering from adverse events including blindness, hospitalization and death, due to methanol poisoning caused by methanol-based sanitizers.¹

The DS-100 NDA represents Eton's second orphan drug candidate and fifth total drug candidate under review with the FDA. Alkindi® Sprinkle, the company's other orphan drug product, is currently under FDA review as a replacement therapy for pediatric adrenal insufficiency (AI) and has been assigned a Prescription Drug User Fee Act date of September 29, 2020. Eton's EM-100 (preservative-free ketotifen ophthalmic solution) product candidate has an August 10, 2020 target action date.

¹ <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-methanol>

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 four 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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