
**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
May 28, 2021

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 60010-7278
(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 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 May 28, 2021, Eton Pharmaceuticals, Inc. (the “Company”) issued a press release reporting that it has received a Complete Response Letter (“CRL”) from the U.S. Food and Drug Administration (“FDA”) in response to the submission of its New Drug Application (“NDA”) for dehydrated alcohol injection for the treatment of methanol poisoning. The CRL indicated the FDA has completed its review of the application and has determined that the application cannot be approved in its present form. 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 May 28, 2021](#)

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: May 28, 2021

By: /s/ W. Wilson Troutman

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

Eton Pharmaceuticals Receives Complete Response Letter from U.S. FDA for Dehydrated Alcohol Injection

DEER PARK, Ill., May 28, 2021 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), today announced that the company has received a Complete Response Letter (CRL) from the U.S. Food & Drug Administration (FDA) in response to the submission of its New Drug Application (NDA) for dehydrated alcohol injection for the treatment of methanol poisoning. The CRL indicated that the FDA has completed its review of the application and has determined that the application cannot be approved in its present form. A Pre-Approval Inspection (PAI) of the product's European contract manufacturer is pending due to what the company believes is COVID-related travel restrictions. The company believes all other FDA questions raised in the letter can be fully addressed in a response in the coming months.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The company currently owns or receives royalties from three FDA-approved products, including ALKINDI® SPRINKLE, Biorphen®, and Alaway Preservative Free®, and has six additional products 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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