
**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 12, 2019
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:

<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 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 July 12, 2019, Eton Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the U.S Food and Drug Administration (FDA) had provided Eton’s partner with a Complete Response Letter relating to the application for the EM-100 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**(d) Exhibits**

Exhibit 99.1 [Press Release dated July 12, 2019](#)

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 12, 2019

By: /s/ W. Wilson Troutman

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

Eton Pharmaceuticals Provides Update on EM-100 Program

DEER PARK, ILL., July 12, 2019 (GLOBE NEWSWIRE) – Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced that the U.S Food and Drug Administration (FDA) provided Eton’s partner with a Complete Response Letter relating to the application for EM-100. No concerns were raised about the clinical data in the application, so it is not anticipated that any additional clinical work will be required. A response to this letter is expected shortly, and the Company remains confident in the approvability of the product.

“We believe the issues cited in the CRL can be addressed in the coming months, and we remain confident that EM-100 will be available to patients as quickly as possible,” said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA’s 505(b)(2) regulatory pathway. Eton is primarily focused on liquid dosage forms including injectables, oral liquids and ophthalmics. Eton has a diversified pipeline of high-value product candidates in various stages of development and therapeutic areas, including multiple product candidates currently pending regulatory approval 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 and its partner to undertake certain activities and accomplish certain goals and objectives. These statements include but are not limited to statements regarding the expected impact of the FDA’s Complete Response Letter, the timing of a response to such letter, the ability to resolve the issues raised by the letter and the timing of such resolution, the approvability of the product in light of this letter and the timing of such approval and launch. 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 business, development programs, and financial condition 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.

Company Contact:

David Krempa
dkrempa@etonpharma.com
847-805-1077

Investor Contact:

Julie Seidel
Stem Investor Relations, Inc.
Julie.Seidel@stemir.com
212-362-1200
