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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

February 19, 2020

Date of Report (Date of earliest event reported)

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**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)

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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 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.

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**Item 8.01 Other Events.**

On February 19, 2020, Eton Pharmaceuticals, Inc. issued a press release which provided an update on its ET-105 product candidate, which is currently under review with the U.S Food and Drug Administration (FDA). 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 February 19, 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: February 19, 2020

By: */s/ W. Wilson Troutman*

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



## **Eton Pharmaceuticals Provides Update on ET-105 Program**

DEER PARK, Ill., February 19, 2020 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today provided an update on its ET-105 product candidate, which is currently under review with the U.S. Food and Drug Administration (FDA).

In a review correspondence and a teleconference held yesterday, the FDA requested that Eton and its development partner make changes to the Dosage and Administration section of the product's Prescribing Information to simplify the dosing information for intended users. The FDA has requested that the company conduct a human factors validation study with the revised labeling to demonstrate that the intended users can prepare and administer the oral suspension safely and effectively. Eton remains confident that it can successfully complete the requested human factors validation study, however, the study is unlikely to be completed by the product's March 17, 2020 Prescription Drug User Fee Act date. The company expects the study and its final report to be completed and submitted to the FDA in the coming months. Eton is not aware of any other non-labeling related deficiencies outstanding with the FDA's review and believes the NDA will be approved in 2020.

### **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 oral liquid 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 has an additional eight products under development, including three 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 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:**

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