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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

**June 13, 2019**

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:

<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.

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**Item 8.01 Other Events.**

On June 13, 2019, Eton Pharmaceuticals, Inc. (the “Company”) issued a press release announcing entering into an agreement to acquire U.S. marketing rights to ET-105, a patent-pending formulation of lamotrigine to be delivered to patients as an oral liquid, from Aucta Pharmaceuticals and also containing an update on the Company’s pipeline product candidates. 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 June 13, 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: June 13, 2019

By: /s/ W. Wilson Troutman

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



## **Eton Pharmaceuticals Announces Licensing of Lamotrigine New Drug Application and Provides Pipeline Update**

- *Unique patent-pending formulation of lamotrigine addresses significant unmet need in pediatric epilepsy patients*
- *NDA was submitted in May 2019; product launch anticipated in 1H 2020*
- *Lamotrigine market currently exceeds \$700 million annually*

DEER PARK, Ill., June 13, 2019 (GLOBE NEWSWIRE) – Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced that the Company has entered into an agreement with Aucta Pharmaceuticals, Inc to acquire U.S. marketing rights for ET-105.

ET-105 is an innovative patent-pending formulation of lamotrigine that will be delivered to patients as an oral liquid. Aucta submitted the product's New Drug Application (NDA) to the FDA in May 2019 and is seeking approval as an epilepsy treatment to be used as an adjunct therapy for partial seizures, primary generalized tonic-clonic seizures, and generalized seizures of Lennox-Gastaut syndrome in patients two years of age and older. Lamotrigine is currently only approved in tablet formulations, and Eton believes ET-105 will fulfill a significant unmet need for pediatric patients requiring precision dosing.

Lamotrigine is one of the most widely used anti-epilepsy drugs with sales exceeding \$700 million annually. Initiation of epilepsy treatment with lamotrigine requires multi-week titration based on patient weight, and pediatric patients often require doses that are a fraction of the currently available tablet strengths. ET-105's precision dosing delivery system allows for accurate measurements down to 1.0mg whereas the lowest strength tablet available on the market is 5.0mg.

The addition of ET-105 brings Eton's emerging neurology franchise to a total of four high-value product candidates, two of which are now expected to launch in 2020. Eton plans to establish its neurology-focused sales force in early 2020 to support the anticipated launches of ET-105 in the first half of 2020, ET-104 in the second half of 2020, and ET-101 and ET-102 in 2021.

"We are excited to add ET-105 to our growing pipeline of near-term product launches and further strengthen our neurology franchise. There remains a significant unmet medical need for precision dosing for pediatric patients, and we believe that ET-105 has the potential to fill the need," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "We look forward to working with Aucta to bring this important product to market as we gear up for its potential launch in the first half of next year."

"Aucta is excited to be partnering with Eton. We look forward to working closely with Eton's dedicated commercial team to bring this innovative treatment forward and to address the unmet medical need in epilepsy," said Shoufeng Li, Chief Executive Officer of Aucta Pharmaceuticals.

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Closing of the transaction is contingent upon Aucta's NDA receiving an acceptance for review letter from the FDA. Under the terms of the agreement, Eton will pay to Aucta licensing milestones of up to \$5 million, including \$2 million upon closing of the transaction, \$2 million upon FDA approval and product launch, and \$1 million upon issuance of an Orange-book listed patent. Aucta will receive a low double-digit royalty on net sales and will be entitled to receive milestone payments of up to \$18 million based on commercial success of the product, including:

- \$1 million when net sales exceed \$10 million in a calendar year
- \$2 million when net sales exceed \$20 million in a calendar year
- \$5 million when net sales exceed \$50 million in a calendar year
- \$10 million when net sales exceed \$100 million in a calendar year

#### **Pipeline Update**

Eton also provided an update on its pipeline product candidates:

**EM-100.** EM-100, Eton's preservative-free ophthalmic solution for allergic conjunctivitis has been assigned a target action date of July 11, 2019. Bausch Health will be responsible for all remaining regulatory and commercial activities surrounding the product. Eton is entitled to a milestone payment upon product launch and a royalty on commercial sales.

**ET-202.** Eton has initiated launch preparations for ET-202, Eton's ready-to-use injectable formulation of phenylephrine. If approved on its PDUFA date of October 21, 2019, Eton anticipates launching the product in the fourth quarter of 2019. Eton believes the addressable phenylephrine market for ET-202 is more than 10 million units annually.

**DS-300.** Due to a third-party approval of another NDA product containing DS-300's active ingredient, the FDA has notified Eton's development partner that DS-300 no longer qualifies for the NDA regulatory pathway and will be required to follow the ANDA regulatory pathway. Eton is pursuing the FDA's process to appeal the decision. If the appeal is unsuccessful, Eton plans to re-submit DS-300 as an ANDA later this year.

**ET-203.** The NDA for ET-203, a ready-to-use formulation of a high-volume injectable product, is expected to be submitted by Eton's partner by the end of the third quarter of 2019.

**DS-200.** The FDA notified Eton that a third party received approval for an NDA product containing DS-200's active ingredient in a different formulation and was granted New Chemical Entity (NCE) exclusivity. As a result, the third party is entitled to five years of market exclusivity, and the FDA will not approve any products containing the molecule during the period, regardless of formulation or dosage form. Eton is in discussions with the FDA to understand the status of its DS-200 application.

**ET-104.** The bioequivalence study for ET-104, a patent-pending oral suspension pursuing a neurological indication, is ongoing. Eton expects study results in September and, if successful, plans to submit the NDA in the fourth quarter of 2019.

**ET-103.** The bioequivalence study for ET-103, a liquid formulation of levothyroxine, is ongoing. Eton expects study results in September and, if successful, plans to submit the NDA in the fourth quarter of 2019.

**DS-100.** Eton has an FDA meeting scheduled for August 2019 to discuss DS-100's clinical pathway. If successful, Eton anticipates submitting the product's NDA in 2020.

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**ET-101.** Development activities are ongoing for ET-101, an innovative oral liquid neurology product. Eton currently expects to submit the product's NDA in 2020

**ET-102.** Development activities are ongoing for ET-102, an innovative oral liquid neurology product. Eton currently expects to submit the product's NDA in 2020

**ET-201.** Development activities are ongoing for ET-201, an injectable product currently approved in Europe. Eton expects to submit the product's NDA in 2020.

#### **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 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 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.

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