# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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

December 17, 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)

] Soliciting material pursuant to Rule 14a-12 under the Ex	xchange Act (17 CFR 240.14a-12)	
] Pre-commencement communications pursuant to Rule 1	4d-2(b) under the Exchange Act (1	7 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 1	3e-4(c) under the Exchange Act (1	7 CFR 240.13e-4(c))
Securitie	es registered pursuant to Section 12	(b) of the Act:
Title of each class	Trading symbol(s)	Name of each exchange on which registered

Emerging growth company [X]

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. [X]

## Item 8.01 Other Events.

On December 17, 2020, Eton Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration has accepted for filing its new drug application for topiramate oral suspension. 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 December 17, 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: December 17, 2020 By: /s/ W. Wilson Troutman

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

3

#### Eton Pharmaceuticals Announces Acceptance for Filing of New Drug Application for Topiramate Oral Solution

- Application Assigned a PDUFA Date of August 6, 2021

DEER PARK, Ill., December 17, 2020 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative treatments for rare pediatric diseases, today announced the U.S. Food and Drug Administration (FDA) has accepted for filing the company's new drug application (NDA) for topiramate oral solution. The application has been assigned a Prescription Drug User Fee Act (PDUFA) date of August 6, 2021.

The application was submitted for three indications, including: monotherapy for treatment of partial-onset or primary general tonic-clonic seizures in patients two years age and older; adjunctive therapy for treatment of partial-onset seizures, including seizures associated with Lennox-Gastaut syndrome in patients two years of age and older; and as preventative treatment of migraine in patients 12 years of age and older. Topiramate is one of Eton's three neurology-focused oral liquid product candidates that have been submitted to the FDA, and all three product candidates are expected to be approved and launched in 2021.

#### **About Eton Pharmaceuticals**

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative treatments for rare pediatric diseases. The company currently owns or receives royalties from three FDA-approved approved products, including ALKINDI<sup>®</sup> SPRINKLE, Biorphen<sup>®</sup>, and Alaway Preservative Free<sup>®</sup>, 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

## **Company Contact:**

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