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

November 8, 2021
Date of Report (Date of earliest event reported)

ETON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38738**	**37-1858472**
(State of incorporation)	**(Commission File Number)**	**(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:

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 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 November 8, 2021, Eton Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration has approved EPRONTIA™ (topiramate) oral solution, 25mg/mL. 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 November 8, 2021

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 8, 2021

By: */s/ W. Wilson Troutman*
W. Wilson Troutman
Chief Financial Officer and Secretary
(Principal Financial Officer)

Exhibit 99.1

Eton Pharmaceuticals, Inc. and Azurity Pharmaceuticals, Inc. Announce FDA Approval of EPRONTIA™ (topiramate) oral solution

The first and only FDA-approved ready-to-use liquid topiramate

DEER PARK, Ill, and WOBURN, MA, Nov. 8, 2021 (GLOBE NEWSWIRE)—Eton Pharmaceuticals, Inc (Nasdaq: ETON) and Azurity Pharmaceuticals, Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved EPRONTIA™ (topiramate) oral solution, 25mg/mL.

EPRONTIA™ has been approved as a monotherapy for treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; an adjunctive therapy for treatment of partial-onset seizures, primary generalized tonic-clonic seizures or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older; and as a preventive treatment of migraine in patients 12 years of age and older.

“This is a transformative day for patients living with epileptic seizures and migraines and their families and caregivers,” said Amit Patel, Chairman and CEO of Azurity Pharmaceuticals. “We take great pride in developing therapies that give healthcare practitioners the ability to treat patients whose needs are not served by available medicines.”

EPRONTIA™ is the first oral liquid formulation of topiramate to be approved by the FDA. Azurity will be responsible for commercializing the product and anticipates product availability before year end. Eton will receive a $5 million milestone payment upon EPRONTIA’s commercial launch, a royalty on net sales, and potential commercial milestones.

“We are proud to see the approval of EPRONTIA™ and we believe it will address a critical unmet need for patients requiring adherence, compliance and precision dosing with a liquid formulation. We look forward to continuing to work with Azurity to achieve additional approvals from our CNS portfolio partnership,” added Sean Brynjelsen, CEO of Eton Pharmaceuticals.

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 six FDA-approved products, including ALKINDI® SPRINKLE, carglumic acid, Biorphen®, Alaway® Preservative Free, Rezipres®, and Eprontia™, and has four additional products that have been submitted to the FDA.

About Azurity Pharmaceuticals Inc.

Azurity Pharmaceuticals is a privately held specialty pharmaceutical company that focuses on innovative products that meet the needs of patients with underserved conditions. As an industry leader in providing unique, accessible, and high-quality medications, Azurity leverages its integrated capabilities and vast partner network to continually expand its broad commercial product portfolio and robust late-stage pipeline. The company’s patient-centric products span the cardiovascular, neurology, endocrinology, gastro-intestinal, institutional, and orphan markets, and have benefited millions of patients. For more information, visit www.azurity.com.

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