

**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

May 10, 2023

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:

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 May 10, 2023, Eton Pharmaceuticals, Inc. issued a press release announcing the commercial availability of Betaine Anhydrous for Oral Solution 180 grams for the treatment of homocystinuria.

Betaine Anhydrous is available exclusively through Optime Care, a specialty pharmacy dedicated to helping patients with rare diseases manage their conditions. Optime Care will administer the Eton Cares Program in partnership with Eton Pharmaceuticals. The program will provide prescription fulfillment, insurance benefits investigation, educational support, and will provide qualified patients financial assistance along with other services designed to help eligible patients access treatment.

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 May 10, 2023](#)

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: May 10, 2023

By: /s/ James R. Gruber

James R. Gruber
Chief Financial Officer and Secretary
(Principal Financial Officer)

Eton Pharmaceuticals Announces Commercial Availability of Betaine Anhydrous for Oral Solution

— Eton Cares patient support program offers \$0 co-pay to eligible, commercially insured patients* —

— Product is now available exclusively through Optime Care —

DEER PARK, Ill., May 10, 2023 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced the commercial availability of Betaine Anhydrous for Oral Solution 180grams for the treatment of homocystinuria.

“We are excited to be offering a lower cost alternative¹ to Cystadane® while still providing full patient and provider support services. We believe the adoption of our product will result in significant financial savings to the U.S. healthcare system and many patients,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Betaine Anhydrous is available exclusively through Optime Care, a specialty pharmacy dedicated to helping patients with rare diseases manage their conditions. Optime Care will administer the Eton Cares Program in partnership with Eton Pharmaceuticals. The program will provide prescription fulfillment, insurance benefits investigation, educational support, and will provide qualified patients financial assistance along with other services designed to help eligible patients access treatment. Eton Cares will also offer co-pay assistance to allow for \$0 co-pays for qualifying patients.*

Clinicians seeking to prescribe Betaine Anhydrous can e-prescribe by selecting Optime Care as the pharmacy or fax in a patient referral form to 866-318-2990. Additional product details can be found on the product website, www.betaineus.com.

For questions regarding prescription fulfillment, please contact Optime Care at 1-888-673-0039.

¹ <https://www.analysource.com/products/active/>

* Restrictions, limitations, and/or eligibility requirements may apply

Cystadane is a registered trademark of Recordati Orphan Drugs SAS

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hypermethioninemia in Patients with CBS Deficiency: Betaine Anhydrous may worsen high methionine blood levels and accumulation of excess fluid in the brain has been reported. If you have been told you have CBS deficiency, your doctor will be monitoring your methionine blood levels to see if changes in your diet and dosage are necessary.

Adverse Reactions

Most common side effects were nausea and gastrointestinal distress, based on a survey of doctors.

To report a suspected adverse event related to Betaine Anhydrous, contact Eton Pharmaceuticals, Inc. at 1-855-224-0233 or the U.S. Food and Drug Administration (FDA) at <http://www.fda.gov/MedWatch> or call 1-800-FDA-1088.

INDICATIONS AND USAGE

Betaine anhydrous for oral solution is indicated in children and adults for the treatment of homocystinuria to decrease high homocysteine blood levels. Homocystinuria is a rare genetic disorder in which there is an abnormal accumulation of the amino acid homocysteine in the blood and urine. The following are considered to be homocystinuria disorders:

- Cystathionine beta-synthase (CBS) deficiency
- 5,10-methylenetetrahydrofolate reductase (MTHFR) deficiency
- Cobalamin cofactor metabolism (cbl) defect

Please see full **Prescribing Information** for more information.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has three FDA approved products in ALKINDI SPRINKLE®, Carglumic Acid tablets for oral suspension 200mg, and Betaine Anhydrous, and four late-stage pipeline candidates under development with dehydrated alcohol injection, ZENEO® hydrocortisone autoinjector, ET-400, and ET-600. In addition, the Company receives royalties on three FDA-approved products and is entitled to receive milestone payments on other products. For more information, please visit our website at www.etonpharma.com.

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Source: Eton Pharmaceuticals
