# 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**

**December 20, 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 December 20, 2021, Eton Pharmaceuticals, Inc. issued a press release announcing the launching of its Carglumic Acid tablets product. 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 | Description |
|---|---|
| 99.1 | Press Release dated December 20, 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: December 20, 2021

By: */s/ W. Wilson Troutman*

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

**Exhibit 99.1**

**Eton Pharmaceuticals and ANI Pharmaceuticals Announce Commercial Availability of Carglumic Acid Tablets, the First and Only FDA-Approved Generic Version of Carbaglu® (carglumic acid)**

- Product is now available exclusively through Anovo specialty pharmacy
- Product is stable at room temperature while Carbaglu® requires refrigeration
- Eton Cares patient support program will offer $0 co-pays to commercial insurance patients

DEER PARK, Ill., Dec. 20, 2021 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases and ANI Pharmaceuticals, Inc (Nasdaq: ANIP), a bio-pharmaceutical company serving patients in need through the development and manufacturing of high-quality generic and branded medicines, today announced the commercial launch of Carglumic Acid tablets.

The product will be marketed by Eton Pharmaceuticals and is the first and only FDA-approved generic version of Carbaglu®. It was approved by the FDA for the treatment of acute and chronic hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency. The product is AB-rated and is bioequivalent and therapeutically equivalent to Carbaglu®, which allows pharmacies to substitute it in place of Carbaglu® prescriptions. The product application is owned by Novitium Pharmaceuticals, a subsidiary of ANI Pharmaceuticals.

“We are excited to offer patients a convenient Carglumic Acid product that does not require refrigeration and to provide it at a lower price than the existing Carbaglu®. We believe the adoption of our product will result in significant financial savings to the U.S. healthcare system and to many patients through lower co-pay and co-insurance costs,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

The product application was granted Competitive Generic Therapy (CGT) designation by the FDA, and as a result, the product is expected to receive 180 days of generic exclusivity. “This approval further strengthens ANI’s focus on niche opportunities and maintains our leadership position in Competitive Generic Therapy approvals,” said Nikhil Lalwani, CEO Of ANI Pharmaceuticals.

Carglumic Acid tablets are available exclusively through Anovo, a specialty pharmacy dedicated to serving patients with rare and chronic conditions. Anovo will administer the Eton Cares Program in partnership with Eton Pharmaceuticals. The program will provide prescription fulfillment, insurance benefits investigation, educational support, aid qualified patients to obtain financial assistance along with other services designed to help patients access treatment. Eton Cares will offer co-pay assistance to allow for $0 co-pays for qualifying patients.

Clinicians seeking to prescribe Carglumic Acid tablets can e-prescribe by selecting Anovo #5 or fax in a patient referral form. Additional product details can be found on the product website, www.carglumicacid.com.

For questions regarding prescription fulfillment, please contact Anovo at 1-888-991-1330.

**IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about Carglumic Acid?**

- Carglumic Acid tablets are for oral suspension and must be mixed in water before taking. Carglumic Acid should **not be** mixed in any food or liquid other than water.
- **Do not** swallow Carglumic Acid tablets whole.
- **Do not** crush Carglumic Acid tablets.
- Take Carglumic Acid right before meals or feedings.

**What are the possible side effects of Carglumic Acid?**

- The most common side effects of Carglumic Acid include vomiting, abdominal pain, fever, tonsillitis, anemia, diarrhea, ear infection, infections, inflammation of the throat and nasal passages, decreased hemoglobin in the red blood cells, and headache.
- This is not a complete list of all possible side effects. Tell your doctor if you have any side effect that bothers you or that does not go away.

**Please visit** www.carglumicacid.com **for more information.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/safety/medwatch, or call the FDA at 1-800-FDA-1088.**

Please see the **Full Prescribing Information**, including Instructions for Use, for Carglumic Acid.

**USE**

- Carglumic Acid is for pediatric and adult patients as supplemental therapy to standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency.
- Carglumic Acid is for pediatric and adult patients as maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency.

Carbaglu® is a registered trademark of Recordati Rare Disease Inc.

**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 ANI Pharmaceuticals**

ANI Pharmaceuticals is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. For more information, please visit www.anipharmaceuticals.com.

**Eton's 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 after the date on which they were made.

**ANI's Forward-Looking Statements**

To the extent any statements made in this release deal with information that is not historical, these are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, those relating to the development, manufacturing and commercialization of the product and any additional product launches from the Company's generic pipeline, other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words and the use of future dates.

Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that the Company may face with respect to importing raw materials; competition from other products; acquisitions; contract manufacturing arrangements; delays or failure in obtaining product approval from the U.S. Food and Drug Administration; general business and economic conditions; market trends; products development; regulatory and other approvals and marketing.

More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission ("SEC"), including its most recent annual report on Form 10-K and quarterly reports on Form 10-Q, as well as other filings with the SEC. All forward-looking statements in this news release speak only as of the date of this news release and are based on the Company's current beliefs, assumptions, and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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