

**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

July 15, 2024

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 July 15, 2024, Eton Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the acceptance of a New Drug Application (NDA) from the U.S. Food and Drug Administration (FDA) for its submission of ET-400, the Company's proprietary patented formulation of hydrocortisone oral solution.

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**

<b>Exhibit No.</b>	<b>Description</b>
Exhibit 99.1 104	<a href="#">Press Release dated July 15, 2024</a> 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: July 15, 2024

By: /s/ James R. Gruber

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

**Eton Pharmaceuticals Announces FDA Acceptance of New Drug Application for ET-400 (Hydrocortisone Oral Solution)**

- Prescription Drug User Fee Act (PDUFA) target action date is February 28, 2025
- Product has patent protection through 2043

DEER PARK, Ill., July 15, 2024 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc (“Eton” or the “Company”) (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced the Company’s New Drug Application (NDA) for ET-400, a proprietary patented formulation of hydrocortisone oral solution, has been accepted by the U.S. Food and Drug Administration (FDA) and has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of February 28, 2025.

“The acceptance of our NDA is a significant milestone toward our efforts of bringing this important and highly in-demand liquid formulation to children. Once approved, we believe ET-400 will allow us to capture a greater percentage of the oral hydrocortisone market and, together with ALKINDI SPRINKLE®, achieve combined peak sales of more than \$50 million annually. We look forward to working with the FDA and preparing for a potential launch in early 2025,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

ET-400 is a proprietary room temperature stable formulation of oral hydrocortisone solution. The Company has been issued a patent related to the product by the U.S. Patent and Trademark Office that expires in 2043 and has additional patent applications currently under review.

**About Eton Pharmaceuticals**

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has five commercial rare disease products: ALKINDI SPRINKLE®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has three additional product candidates in late-stage development: ET-400, ET-600, and ZENEO® hydrocortisone autoinjector. For more information, please visit our website at [www.etonpharma.com](http://www.etonpharma.com).

**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.

**Investor Relations:**

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Source: Eton Pharmaceuticals.