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 5, 2024
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 7, 2024, Eton Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the United States Patent and Trademark Office (USPTO) has granted the Company U.S. Patent Application No. 18/443,889, now U.S. Patent No. 12,133,914, for ET-400, a proprietary patented formulation of liquid hydrocortisone. The patent, which expires in 2043, covers a method of using hydrocortisone oral liquid formulations and is expected to be listed in the U.S. Food and Drug Administration's (FDA) Orange Book upon the product's approval. Eton received its first patent (US 11,904,046) for ET-400 in February 2024 and the Company has an additional U.S. patent application under review related to the 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 No.	Description
Exhibit 99.1	Press Release dated November 7, 2024
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 7, 2024

By: */s/ James R. Gruber*
James R. Gruber
Chief Financial Officer and Secretary
(Principal Financial Officer)

Exhibit 99.1

Eton Pharmaceuticals Awarded Second Patent for ET-400 (Hydrocortisone Oral Solution)

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

DEER PARK, Ill., November 7, 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 that the United States Patent and Trademark Office (USPTO) has granted the Company U.S. Patent Application No. 18/443,889, now U.S. Patent No. 12,133,914, for ET-400, a proprietary patented formulation of liquid hydrocortisone. The patent, which expires in 2043, covers a method of using hydrocortisone oral liquid formulations and is expected to be listed in the U.S. Food and Drug Administration's (FDA) Orange Book upon the product's approval. Eton received its first patent (US 11,904,046) for ET-400 in February 2024 and the Company has an additional U.S. patent application under review related to the product.

"We are thrilled to have been granted a second patent for ET-400, further strengthening the IP protection of this important asset. Through our interactions with the patient community, we've seen firsthand the extensive need and desire for an FDA-approved liquid formulation of hydrocortisone.," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

The FDA has accepted the Company's New Drug Application (NDA) for ET-400 and has assigned the application a PDUFA target action date of February 28, 2025. If approved, ET-400 would be the only FDA-approved liquid formulation of hydrocortisone.

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.

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, Inc.