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

January 11, 2023
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 January 11, 2023, Eton Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application (NDA) response for dehydrated alcohol injection for the proposed indication of methanol poisoning. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 27, 2023.

Eton's application has previously been granted orphan drug designation for the indication of methanol poisoning and if approved, the Company expects the FDA to grant the application seven years of orphan drug exclusivity. Based on IQVIA data, trailing twelve month sales for dehydrated alcohol injection were $74 million.

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 January 11, 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: January 11, 2023

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

Exhibit 99.1

Eton Pharmaceuticals Announces FDA Acceptance of NDA Response for Dehydrated Alcohol Injection

— Product previously granted orphan drug designation for methanol poisoning —

— Application assigned a PDUFA date of June 27, 2023 —

DEER PARK, Illinois – January 11, 2023 – Eton Pharmaceuticals ("Eton" or "the Company") (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Company's New Drug Application (NDA) response for dehydrated alcohol injection for the proposed indication of methanol poisoning. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 27, 2023.

"We are excited to be one step closer to bringing this much needed product to patients and we have begun working with our commercial partner to prepare for a potential near-term launch," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Eton's application has previously been granted orphan drug designation for the indication of methanol poisoning and if approved, the Company expects the FDA to grant the application seven years of orphan drug exclusivity. Based on IQVIA data, trailing twelve month sales for dehydrated alcohol injection were $74 million.

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, and Betaine Anhydrous for oral solution, and three late-stage pipeline candidates under development with dehydrated alcohol injection, ZENEO® hydrocortisone autoinjector, and ET-400. 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