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

June 28, 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 June 28, 2023, Eton Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) in response to its New Drug Application (NDA) for dehydrated alcohol injection for the treatment of methanol poisoning. The issues raised in the CRL relate primarily to Chemistry Manufacturing and Controls (CMC). The Company believes all issues in the CRL are addressable and will develop a comprehensive action plan to address the FDA's concerns.

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 June 28, 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: June 28, 2023

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

Exhibit 99.1

Eton Pharmaceuticals Receives Complete Response Letter (CRL) for Dehydrated Alcohol Injection

DEER PARK, Ill., June 28, 2023 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (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) issued a Complete Response Letter (CRL) in response to its New Drug Application (NDA) for dehydrated alcohol injection for the treatment of methanol poisoning. The issues raised in the CRL relate primarily to Chemistry Manufacturing and Controls (CMC). The Company believes all issues in the CRL are addressable and will develop a comprehensive action plan to address the FDA's concerns.

"While we are disappointed with the FDA's decision, our commercial business remains strong, and we are pleased that our momentum in product revenue growth has continued. We expect to once again report record product revenue in the second quarter of 2023. With the recent addition of Betaine Anhydrous for Oral Solution to our commercial product portfolio, we are well positioned for continued sustainable long-term growth," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

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 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 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