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 22, 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 1.01: Entry into a Material Definitive Agreement

On November 22, 2024, Eton Pharmaceuticals, Inc. (the "Company") entered into a Licensing Agreement (the "Licensing Agreement") with AMMTeK. (the "Seller"), pursuant to which the Company has agreed to acquire the U.S. rights to Amglidia (glyburide oral suspension) from the Seller. Amglidia is being developed for the treatment of neonatal diabetes mellitus, a rare condition estimated to impact approximately 300 patients in the U.S. The product was approved by the European Medicines Agency in 2018 and has been granted Orphan Drug Designation by the U.S. FDA. The Seller has conducted a post-approval study tracking five years of real-world safety and efficacy in European patients, which will be used to support Eton's New Drug Application ("NDA") submission.

The Company intends to hold a meeting with the FDA in the first quarter of 2025 and retains the option to terminate the licensing agreement within 30 days of receiving FDA meeting minutes without liability for any milestone payments to the Seller. Under the terms of the Licensing Agreement, the Company will not make any upfront payments to Seller and could pay up to $2.35 million as follows:

- $0.50 million following the receipt of FDA meeting minutes
- $0.55 million upon NDA acceptance for review by the FDA
- $1.30 million upon NDA approval by the FDA and first commercial sale

In addition, the Company would pay a royalty of 14% of net sales to the Seller.

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 25, 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 25, 2024

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

Exhibit 99.1

Eton Pharmaceuticals Announces Acquisition of U.S. Rights to Amglidia (Glyburide Oral Suspension)

- Amglidia® has been approved by the European Medicines Agency (EMA) and is commercially available in Europe
- Strong strategic fit with Eton's existing pediatric endocrinology focus
- Amglidia has been granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA)
- Potential New Drug Application (NDA) submission in 2026

DEER PARK, Ill., November 25, 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 it has acquired the U.S. rights to Amglidia (glyburide oral suspension, known as glibenclamide in Europe) for the treatment of neonatal diabetes mellitus from AMMTeK.

"This exciting transaction adds another attractive, patented product candidate to our growing pediatric endocrinology portfolio. In addition, the product aligns with Eton's expertise and wealth of experience in bringing to market liquid and precision dose formulations for pediatric patients," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

"Currently, there are no FDA-approved oral treatments for neonatal diabetes mellitus. Amglidia has been used successfully to treat European patients for years, and families and pediatric endocrinologists have expressed to us the significant need for this treatment in the United States. We look forward to working with AMMTeK to bring the product to U.S. patients as quickly as possible," concluded Brynjelsen.

Amglidia is a proprietary, patented liquid product that was developed for the treatment of neonatal diabetes mellitus by AMMTeK, a French biotechnology company. The product was approved by the EMA in 2018. The product has already been granted Orphan Drug Designation by the U.S. FDA. Neonatal diabetes mellitus is a rare condition estimated to impact approximately 300 patients in the United States. Currently, there are no FDA-approved oral treatment options and as a result, U.S. patients frequently either rely on compounded products that are not FDA-approved or administer products off-label by making homemade suspensions.

AMMTeK has conducted a post-approval study tracking five years of real-world safety and efficacy in European patients, which will be used to support Eton's NDA submission. Eton plans to hold a meeting with the FDA in the first quarter of 2025 and anticipates submitting an NDA for the product in 2026.

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.

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