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 15, 2021
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 15, 2021, Eton Pharmaceuticals, Inc. issued a press release announcing that it has entered into a multi-year agreement with Tolmar Pharmaceuticals, Inc. to co-promote ALKINDI SPRINKLE®. 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 November 15, 2021

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 15, 2021

By: */s/ W. Wilson Troutman*

W. Wilson Troutman
Chief Financial Officer and Secretary
(Principal Financial Officer)

Exhibit 99.1

Eton Pharmaceuticals Announces Co-Promotion Agreement with Tolmar Pharmaceuticals for ALKINDI SPRINKLE®

- Tolmar's 62-person sales force will co-promote ALKINDI SPRINKLE® to pediatric endocrinologists -

DEER PARK, Ill., Nov. 15, 2021 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON) today announced that it has entered into a multi-year agreement with Tolmar Pharmaceuticals, Inc. to co-promote ALKINDI SPRINKLE®. Eton will leverage Tolmar's 62-person sales force and their existing relationships in the pediatric endocrinology specialty. Tolmar currently promotes FENSOLVI® (leuprolide acetate) for injectable suspension, indicated for pediatric patients 2 years of age and older with Central Precocious Puberty (CPP).

"It's clear that physicians see the need for ALKINDI SPRINKLE's accurate dosing when treating adrenal insufficiency, however, we have found that changing the decades old prescribing habits of pediatric endocrinologists is often requiring multiple face-to-face interactions. With this partnership, our reach will be increasing more than 10-fold and we will drastically increase the number of face-to-face interactions. We believe this will translate to significantly faster adoption of ALKINDI SPRINKLE and accelerate the time to reach peak conversion," said Sean Brynjelsen, CEO of Eton Pharmaceuticals. "We are confident Tolmar is the right partner for ALKINDI SPRINKLE. Their FENSOLVI® launch results speak for themselves and highlight their team's ability to drive treatment change in pediatric endocrinology," added Brynjelsen.

"We are excited to co-promote ALKINDI SPRINKLE," said Tolmar CEO Anil D'Souza. "This agreement will further enhance Tolmar's commitment to the pediatric endocrinology space. It allows Tolmar to continue providing therapies with optimal delivery mechanisms that improve patient and caregiver experience."

Tolmar's pediatric endocrinology sales force currently promotes the specialty drug FENSOLVI® for CPP, a rare disease that impacts roughly one in 5,000-10,000 children in the United States. FENSOLVI® was launched in May 2020 and has already reached more than 1,500 patients.

Under terms of the agreement, Tolmar's sales force will promote ALKINDI SPRINKLE® to their pediatric endocrinology targets alongside FENSOLVI®. Tolmar will receive a royalty on net sales growth above ALKINDI SPRINKLE®'s current baseline sales. Eton's sales force will continue to promote the product and Eton will maintain responsibility for all non-sales force related commercial activities.

The companies expect Tolmar's sales force to start promoting ALKINDI SPRINKLE® in December. In tandem with the co-promotion launch, Eton plans to introduce an expanded digital marketing campaign targeted at raising awareness among patients and caregivers.

About ALKINDI SPRINKLE®

ALKINDI® SPRINKLE (hydrocortisone) oral granules is FDA-approved as replacement therapy for Adrenocortical Insufficiency (AI) in children under 17 years of age. ALKINDI SPRINKLE is the first and only FDA-approved granular hydrocortisone formulation for the treatment of adrenocortical insufficiency specifically designed for use in children. The approval of ALKINDI SPRINKLE was supported by six clinical studies, including the first and only interventional open-label Phase III study of oral hydrocortisone for Pediatric AI in neonates to children under eight years of age. Prior to the approval of ALKINDI SPRINKLE, oral hydrocortisone was only FDA-approved in tablet formulations of 5mg and stronger. Many pediatric patients require significantly lower doses and the flexibility of precise titration. ALKINDI SPRINKLE is available in 0.5mg, 1mg, 2mg, and 5mg strengths, allowing clinicians greater flexibility to individualize dosing based on each patient's needs in accordance with the instructions for dosage and administration. Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain.

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The company currently owns or receives royalties from six FDA-approved products, including ALKINDI® SPRINKLE, carglumic acid, Biorphen®, Alaway® Preservative Free, Rezipres®, and Eprontia™, and has four additional products that have been submitted to the FDA.

About Tolmar

Tolmar is a fully integrated pharmaceutical company focused on the innovative development, approval, manufacturing, and commercialization of specialty pharmaceuticals. "Tolmar" refers to Tolmar Holding, Inc. and its wholly owned operating subsidiaries, Tolmar Inc., Tolmar Therapeutics, Inc., and Tolmar Pharmaceuticals, Inc. Tolmar global headquarters, product development and manufacturing facilities are based in northern Colorado, while Tolmar Pharmaceuticals' U.S. commercial business is based in Buffalo Grove, Illinois. For more information about the company, please visit www.tolmar.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.

Important Safety Information for ALKINDI SPRINKLE® (hydrocortisone) Oral Granules

Adrenal Crisis: Undertreatment or sudden discontinuation of therapy may lead to symptoms of adrenal insufficiency, adrenal crisis, and death. Adrenal crisis may also be induced by stressor events, such as infections or surgery. Monitor patients closely when switching from other forms of hydrocortisone to ALKINDI SPRINKLE. Increase the dose during periods of stress. Switch patients who are vomiting, severely ill, or unable to take oral medications to parenteral corticosteroid formulations.

Infections: Excessive doses may increase the risks of new infections or exacerbation of latent infections with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic infections. Monitor patients for signs and symptoms of infections. Treat all infections seriously, and initiate stress dosing of steroids early.

Growth Retardation: Long-term use in excessive doses may cause growth retardation. Use the minimum dosage of ALKINDI SPRINKLE to achieve desired clinical response and monitor the patient's growth.

Cushing's Syndrome Due to Use of Excessive Doses of Corticosteroids: Prolonged use with supraphysiologic doses may cause Cushing's syndrome. Monitor patients for signs and symptoms of Cushing's syndrome every 6 months; pediatric patients under one year of age may require more frequent monitoring.

Decrease in Bone Mineral Density: Corticosteroids decrease bone formation and increase bone resorption, which may lead to inhibition of bone growth and development of osteoporosis. Use the minimum dosage of ALKINDI SPRINKLE to achieve desired clinical response.

Psychiatric Adverse Reactions: Use may be associated with severe psychiatric adverse reactions, such as euphoria, mania, psychosis with hallucinations and delirium, or depression. Symptoms typically emerge within a few days or weeks of starting the treatment. Most reactions resolve after either dose reduction or withdrawal, although specific treatment may be necessary. Monitor patients for behavioral and mood disturbances during treatment. Instruct caregivers and/or patients to seek medical advice if psychiatric symptoms develop.

Ophthalmic Adverse Reactions: Cataracts, glaucoma, and central serous chorioretinopathy have been reported with prolonged use of high doses. Monitor patients for blurred vision or other visual disturbances, and if they occur, refer them to an ophthalmologist.

Gastrointestinal Adverse Reactions: There is an increased risk of gastrointestinal perforation in patients with certain gastrointestinal disorders. Signs of gastrointestinal perforation, such as peritoneal irritation, may be masked in patients receiving corticosteroids. Corticosteroids should be used with caution if there is a probability of impending perforation, abscess, or other pyogenic infections; diverticulitis; fresh intestinal anastomoses; and active or latent peptic ulcer.
Concurrent administration of corticosteroids with nonsteroidal anti-inflammatory drugs (NSAIDs) may increase the risk of gastrointestinal adverse reactions. Monitor patients receiving corticosteroids and concomitant NSAIDs for gastrointestinal adverse reactions.

Adverse Reactions

Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite, and weight gain.

INDICATION

ALKINDI SPRINKLE is a corticosteroid indicated for replacement therapy in pediatric patients with adrenocortical insufficiency.

Please see full Prescribing Information for more information.

Important Safety Information for FENSOLVI® (leuprolide acetate) for injectable suspension

FENSOLVI® (leuprolide acetate) for injectable suspension is a gonadotropin releasing hormone (GnRH) agonist used to treat patients 2 years of age and older with central precocious puberty (CPP). CPP may be diagnosed when signs of sexual maturity begin to develop in girls under the age of 8 or in boys under the age of 9.

FENSOLVI is contraindicated in individuals with hypersensitivity to any drug that is in the same class as FENSOLVI, in individuals who are allergic to any of the ingredients in FENSOLVI, or in individuals who are pregnant. FENSOLVI may cause fetal harm when administered to a pregnant patient.

During the first few weeks of treatment, increases in gonadotropins and sex steroids above baseline may result in an increase in signs and symptoms of puberty including vaginal bleeding in girls.

Psychiatric events have been reported in patients taking GnRH agonists. Events include emotional lability, such as crying, irritability, impatience, anger, and aggression. Patients should be monitored for development or worsening of psychiatric symptoms.

Convulsions have been observed in patients treated with GnRH agonists with or without a history of seizures, epilepsy, cerebrovascular disorders, central nervous system anomalies or tumors, and in patients on concomitant medications that have been associated with convulsions such as bupropion and SSRIs.

The most common adverse events seen with FENSOLVI were: injection site pain, nasopharyngitis, pyrexia, headache, cough, abdominal pain, injection site erythema, nausea, constipation, vomiting, upper respiratory tract infection, bronchospasm, productive cough and hot flush.

Please see Full Prescribing Information for additional important safety information.

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