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

September 29, 2020
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 [X]

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. [X]

Item 8.01 Other Events.

On September 29, 2020, Eton Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration had approved Alkindi Sprinkle® (hydrocortisone) for the treatment of adrenocortical insufficiency in pediatric patients. 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 September 29, 2020

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: September 29, 2020

By: */s/ W. Wilson Troutman*

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

Exhibit-99.1

Eton Pharmaceuticals Announces FDA Approval of Orphan Drug ALKINDI® SPRINKLE (hydrocortisone) as Replacement Therapy in Pediatric Patients with Adrenocortical Insufficiency

-ALKINDI SPRINKLE is the first and only FDA-approved granular hydrocortisone formulation for adrenocortical insufficiency specifically designed for children

-Eton expects ALKINDI SPRINKLE to be available in the fourth quarter of 2020

DEER PARK, Ill., Sept. 29, 2020 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative treatments for rare pediatric diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved ALKINDI® SPRINKLE (hydrocortisone) oral granules 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 FDA approval of ALKINDI SPRINKLE is a breakthrough for patients and caregivers treating pediatric adrenocortical insufficiency. We are excited to offer an FDA-approved product that enables low dosing and administration of hydrocortisone to pediatric patients,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals. “We look forward to making the product available to patients in the coming months.”

“For years, we heard from parents about their struggle to provide the right dose to their child,” said Dina M. Matos, Executive Director of the CARES Foundation. “We are thrilled the FDA has approved ALKINDI SPRINKLE for pediatric patients with Adrenocortical Insufficiency including patients with Congenital Adrenal Hyperplasia, a type of Adrenocortical Insufficiency.”

The FDA approval of ALKINDI SPRINKLE was supported by six clinical studies, including the first and only interventional 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 precision titration. ALKINDI SPRINKLE will be 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.

Eton expects ALKINDI SPRINKLE to be commercially available in the fourth quarter of 2020.

About Pediatric Adrenocortical Insufficiency

Pediatric adrenocortical Insufficiency (AI) is a rare disease characterized by an inability to synthesize and release cortisol, and sometimes aldosterone. This causes excessive androgens (abnormal sexual development in females, premature puberty, premature growth termination and short stature). The most common form of pediatric AI is Congenital Adrenal Hyperplasia (CAH), which is caused by a genetic defect. Patients with primary or central (secondary and tertiary) AI lack appropriate levels of cortisol in their system. Diminished cortisol in the system may result in deadly consequences like adrenal crisis. To survive, patients with AI must replace the missing cortisol daily. Eton estimates that pediatric AI effects between 5,000 and 11,000 children in the United States.

About ALKINDI SPRINKLE

ALKINDI SPRINKLE is an immediate-release oral hydrocortisone granule preparation that has been specifically designed to meet the dosing needs of pediatric patients with adrenocortical insufficiency. Prior to ALKINDI SPRINKLE's approval, parent caregivers had to cut or split higher strength hydrocortisone tablets to achieve the lower doses required for small children, which could result in inaccurate dosing. ALKINDI SPRINKLE is manufactured using commercially proven technology in four strengths: 0.5mg, 1mg, 2mg and 5mg, to give greater dosing flexibility to clinicians. Taste-masking excipients that are acceptable for pediatric use eliminate the bitter taste of hydrocortisone. ALKINDI SPRINKLE has a shelf life of three years at ambient temperature and does not require refrigeration.

Indications and Usage

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

Important Safety Information

Contraindications

ALKINDI SPRINKLE is contraindicated in patients with hypersensitivity to hydrocortisone or to any of the ingredients in ALKINDI SPRINKLE. Anaphylactic reactions have occurred in patients receiving corticosteroids.

Warning and Precautions

- **Adrenal Crisis**: Undertreatment or sudden discontinuation of therapy may lead to adrenal insufficiency, adrenal crisis and death. Adrenal crisis may also be induced by stress events such as infections or surgery. 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**: increased risk in patients with certain gastrointestinal disorders. Signs and symptoms may be masked.

Adverse Reactions

The most 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 a specialty pharmaceutical company focused on developing and commercializing innovative treatments for rare pediatric diseases. Eton is primarily focused on hospital injectable and pediatric rare disease products. The company currently owns or receives royalties from three FDA-approved approved products, including ALKINDI® SPRINKLE, Biorphen®, and Alaway® Preservative Free, and has six additional products in its late-stage pipeline, including four that have been submitted to the FDA.

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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