# 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 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 60010-7278**
**(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 June 15, 2021, Eton Pharmaceuticals, Inc., the U.S. marketer of ALKINDI SPRINKLE®, a treatment for adrenocortical insufficiency in pediatric patients, issued a press release announcing that it has acquired U.S. and Canadian rights to Crossject's ZENEO® hydrocortisone needleless autoinjector, which is under development as a rescue treatment for adrenal crisis. 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 15, 2021**

**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 15, 2021

By: */s/ W. Wilson Troutman*
W. Wilson Troutman
Chief Financial Officer and Secretary
(Principal Financial Officer)

**Exhibit 99.1**

**Eton Pharmaceuticals Acquires U.S. and Canadian Rights to ZENEO® Hydrocortisone Autoinjector**

- Expands Eton's Adrenal Insufficiency Orphan Drug Portfolio
- ZENEO® Hydrocortisone is Expected to be the First and Only Hydrocortisone Autoinjector for Patients Requiring Emergency Hydrocortisone
- Proprietary ZENEO® Needleless Device is Covered by 24 U.S. Patents Extending as Far as 2037

DEER PARK, Ill., June 15, 2021 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc (Nasdaq: ETON), the U.S. marketer of ALKINDI SPRINKLE®, a treatment for adrenocortical insufficiency in pediatric patients, today announced that it has acquired U.S. and Canadian rights to Crossject's ZENEO® hydrocortisone needleless autoinjector, which is under development as a rescue treatment for adrenal crisis.

"The ZENEO autoinjector is a revolutionary delivery system, and this product is a terrific strategic fit with our current adrenal insufficiency business. Patients, advocacy groups, and physicians in the adrenal insufficiency community have repeatedly expressed to us the need for a hydrocortisone autoinjector, so we are excited to be partnering with Crossject to bring this product to patients in need," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Patrick Alexandre, CEO of Crossject, added: ''We are proud to announce a sound commercial agreement for ZENEO® Hydrocortisone in the US and Canada with an American leader in adrenal insufficiency. ETON has successfully established strong relations with the patient communities and medical specialists that are its core focus. ZENEO® Hydrocortisone answers a medical need. This strong partnership will contribute to saving lives by bringing to patients and their families a modern autoinjection possibility.''

"We are delighted about Eton Pharmaceuticals' plans to partner with Crossject to bring this incredibly needed product to patients in the U.S.", said Dina Matos, Executive Director of CARES Foundation, a leading North American advocacy foundation for patients with congenital adrenal hyperplasia, the most common presentation of adrenal insufficiencies in children. "The challenge for patients and caregivers facing an adrenal crisis is serious; an easy-to-use needleless autoinjector of hydrocortisone will be a game changer for our patients. We welcome this advancement."

ZENEO® is a proprietary needleless device developed and manufactured by Crossject. The pre-filled, single-use device propels medication through the skin in less than a tenth of a second. The device's compact form factor, simple two-step administration, and needle-free technology make it an ideal delivery system for emergency medications that need to be administered in stressful situations by non-healthcare professionals. Crossject holds more than 400 global patents on the device, including 24 issued in the United States that extend as far as 2037, and has successfully completed bioequivalence and human factor studies with the ZENEO device using various medications.

Crossject has developed a proprietary, room-temperature stable liquid formulation of hydrocortisone to be delivered via the ZENEO device. ZENEO hydrocortisone is expected to be the first and only hydrocortisone autoinjector available for patients that require a rescue dose of hydrocortisone. Currently, injectable hydrocortisone is only available in the United States in a lyophilized powder formulation that must be reconstituted and manually delivered via a traditional syringe.

Eton expects to submit a New Drug Application for the product to the U.S. Food and Drug Administration in 2023 and plans to request Orphan Drug Designation. In the United States, it is estimated that approximately 100,000 patients currently suffer from adrenocortical insufficiency and are at risk for adrenal crisis.

Under the terms of the agreement, Crossject will receive development and regulatory milestone payments from Eton of up to $5.0 million, commercial milestones of up to $6.0 million, and a 10% royalty on net sales of the product. Crossject will be responsible for the management and expense of development, clinical, and manufacturing activities. Eton will be responsible for all regulatory and commercial activities.

**About Adrenal Crisis**

Patients with adrenal insufficiency can go into adrenal crisis if their cortisol levels are too low. Adrenal crisis is typically caused by missed doses of maintenance hydrocortisone, trauma, surgery, illness, fever, or major psychological distress. Signs of adrenal crisis include hyperpigmentation, severe weakness, nausea, abdominal pain, and confusion. It is estimated that approximately 8% of adrenal insufficiency patients will report an adrenal crisis in any given year and more than 6% of cases result in death.

**About Crossject**

Crossject (ISIN: FR0011716265; Ticker: ALCJ; LEI: 969500W1VTFNL2D85A65) is developing and is soon to market a portfolio of drugs dedicated to emergency situations: epilepsy, overdose, allergic shock, severe migraine and asthma attack. The company's portfolio currently contains eight products in advanced stages of development, including 7 emergency treatments, 5 of which are intended for life-threatening situations. Thanks to its patented needle-free self-injection system, Crossject aims to become the world leader in self-administered emergency drugs. The company has been listed on the Euronext Growth market in Paris since 2014, and benefits from Bpifrance funding.

**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 three FDA-approved products, including ALKINDI® SPRINKLE, Biorphen®, and Alaway Preservative Free®, and has six additional products that have been submitted to the FDA.

**Company Contact:**

David Krempa
dkrempa@etonpharma.com
612-387-3740