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

March 14, 2022

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.

Eton Pharmaceuticals, Inc. and XGen Pharmaceuticals DJB Inc. announced the commercial availability of Rezipres® (ephedrine hydrochloride) injection which is approved for the treatment of clinically important hypotension occurring in the setting of anesthesia. 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 March 14, 2022

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: March 14, 2022

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

Exhibit 99.1

Eton Pharmaceuticals and XGen Pharmaceuticals DJB Announce Commercial Launch of Rezipres® (ephedrine hydrochloride), a Ready-to-Use Formulation of Injectable Ephedrine (4.7 mg/mL)

DEER PARK, Ill., Mar. 14, 2022 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc. (Nasdaq: ETON) and XGen Pharmaceuticals DJB, Inc. today announced the commercial availability of Rezipres® (ephedrine hydrochloride) injection. Rezipres (4.7 mg/mL) is a ready-to-use[1] formulation of injectable ephedrine hydrochloride that is approved for the treatment of clinically important hypotension occurring in the setting of anesthesia.

“We are excited to announce yet another new product launch. The availability of Rezipres will provide hospitals with an FDA-approved, ready-to-use ephedrine injection product as an alternative to compounded formats which are not approved by the FDA. We look forward to partnering with XGen DJB given their extensive track record of successfully commercializing injectable products in the hospital setting,” said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

“We are delighted to be teaming up with Eton as the commercial partner in introducing their ready-to-use Rezipres product, which is the first FDA-approved hydrochloride-based ephedrine injectable formulation,” added Edmund Vanderbeck, President of XGen Pharmaceuticals DJB. “This product will provide doctors with a new option in treating clinically important hypotension occurring in the setting under anesthesia.”

XGen DJB’s seasoned hospital sales force will be responsible for commercializing the product, and Eton will continue to retain ownership of the product’s New Drug Application on file with the FDA.

Based on IQVIA data, the market for ephedrine injections grew 24% in 2021 to $86 million and 5.9 million units, up from $69 million and 4.7 million units in 2020.

Rezipres® is being made available in a 5mL ampule with a strength of 23.5mg/5mL (4.7 mg/mL), equivalent to 19mg/5mL (3.8 mg/mL) ephedrine base. The product can be stored at room temperature and does not contain any preservatives or sulfites. The product is now available for ordering through wholesalers McKesson, AmerisourceBergen, and Cardinal Health. For additional ordering and product information, visit www.xgenpharmadjb.com.

About Rezipres®(ephedrine hydrochloride)

Rezipres (ephedrine hydrochloride) is an alpha- and beta-adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

IMPORTANT SAFETY INFORMATION
Contraindications
None

Warnings and Precautions

- Serious postpartum hypertension can occur in patients also receiving both a vasopressor and an oxytocic. Some patients experienced a stroke.
- Repeated administration of ephedrine can result in tachyphylaxis. An alternative pressor may be needed to mitigate unacceptable responsiveness.
- When used to prevent hypotension, ephedrine can cause an increased incidence of hypertension compared to when used to treat hypotension.

Adverse Reactions

Most common adverse reactions during treatment: nausea, vomiting, dizziness, restlessness, palpitations, tachycardia, reactive hypertension, bradycardia, ventricular ectopics, and R-R variability. To report **SUSPECTED ADVERSE REACTIONS**, contact Eton Pharmaceuticals at 855-224-0233 or FDA at 1-800-FDA-1088.

Drug Interactions

- Agonistic Effects (increase in Rezipres blood pressure effect) can occur with clonidine, oxytocin and oxytocic drugs, monoamine oxidase inhibitors (MAOI), and atropine.
- Antagonistic Effects (decrease in Rezipres blood pressure effect) can occur with α-adrenergic antagonists, β-adrenergic antagonists, reserpine, quinidine, mephentermine.
- Inhibition of the neuron blockage produced by guanethidine can occur resulting in loss of antihypertensive effectiveness.
- Reduction in the onset time of neuromuscular blockade can occur when used for intubation with rocuronium if administered simultaneously with anesthetic induction.
- The efficacy of epidural blockade can be decreased by hastening the regression of sensory analgesia.
- Concomitant use of theophylline may increase the frequency of nausea, nervousness, and insomnia.
- Concomitant use of a cardiac glycoside, such as digitalis, may increase the possibility of arrhythmias.

For more information, please see **Rezipres Full Prescribing Information** at www.xgenpharmadjb.com.

[1]Rezipres [Package Insert]. Deer Park, IL: Eton Pharmaceuticals; 2022

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 XGen Pharmaceuticals DJB

XGen Pharmaceuticals DJB, Inc. is a family-owned pharmaceutical company spanning three generations, located in Horseheads, New York with a 50-year tradition in the pharmaceutical industry.. XGen DJB is extraordinarily proud to be woman-owned and operated, holding the National Women’s Business Enterprise Certification (NWBEC). Building on our legacy of success, XGen DJB’s primary focus is in forging rich and lasting partnerships that enhance and accelerate the development, manufacture and delivery of specialty pharmaceutical products, creating improved patient access and outcomes. XGen DJB’s portfolio centers on acute care, critical need injectable products targeted to the hospital, clinical and specialty markets, predominantly focused on meeting US demand.

Eton's 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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