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

October 22, 2019
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 Select 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 October 22, 2019, Eton Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food & Drug Administration ("FDA") has approved Biorphen®, the first and only FDA-approved ready-to-use formulation of phenylephrine for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. Eton acquired the U.S. marketing rights to Biorphen® from Sintetica SA in February 2019. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Separately, Sintetica also notified Eton that the NDA for ET-203, Eton's second ready-to-use injectable product, was not yet accepted for review by the FDA due to questions surrounding the potency of ET-203 relative to the reference product. Sintetica plans to hold an FDA meeting within the next 30 days to discuss the topic and believes the FDA's concerns can be adequately addressed with a resubmitted NDA in the near future.

Item 9.01 Financial Statements and Exhibits

Exhibit 99.1 Press Release dated October 22, 2019

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: October 22, 2019

By: */s/ W. Wilson Troutman*

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

Eton Pharmaceuticals Announces U.S. FDA Approval of Biorphen® (phenylephrine HCI) Injection

Biorphen is the First and Only Ready-to-Use FDA-Approved Injectable Formulation of Phenylephrine

Biorphen Eliminates Need for Compounding, Reducing Risks for Unsafe Injection Practices, Medication Administration Errors, Sterility Breaches, and Waste

DEER PARK, Ill., October 22, 2019 — Eton Pharmaceuticals, Inc. (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced that the U.S. Food and Drug Administration (FDA) has approved Biorphen®, the first and only FDA-approved ready-to-use formulation of phenylephrine for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

Prior to the FDA approval of Biorphen, phenylephrine injection was only approved and available as a highly concentrated formulation that required hospitals to manually dilute the concentrate prior to administration, or purchase ready-to-use formulations from 503B compounding pharmacies. Compounded drugs do not have to undergo FDA premarket review for safety, effectiveness and certain controls over manufacturing quality. Due to this lower regulatory standard, compounded drugs are often associated with higher risks of medication error.[1]

“Today’s FDA approval of Biorphen addresses a critical medical need for an approved, ready-to-use standardized formulation of phenylephrine that can potentially reduce medication administration errors and improve patient safety,” said Sean Brynjelsen, chief executive officer of Eton Pharmaceuticals. “The approval of Biorphen represents an important step forward in Eton’s commitment to improving existing medicines to address unmet patient needs. We look forward to working with our manufacturing partner, Sintetica, to make Biorphen available to hospitals across the United States before the end of the year.”

“Operating rooms, emergency departments and intensive care units are fast-paced and time-sensitive environments. Add to that the complexity of caring for patients with a wide range of critical conditions and the use of high-alert medications like phenylephrine – and you have an atmosphere primed for potential medication error,” said Jared Marcucci, M.D., assistant director, Community First Medical Center Department of Emergency Medicine in Chicago. “As a practicing emergency medicine physician, the availability of an FDA-approved, ready-to-use formulation of phenylephrine is a welcome advance, providing physicians and hospital systems with an important new option that does not require compounding and can potentially help reduce the risk of medication errors and minimize harm to patients.”

“Providers at the bedside need reliable, easy to use, safe drugs that have a consistent supply. Many hospitals outsource unapproved ready-to-use phenylephrine from 503B compounders, however often have to navigate supply disruptions through these suppliers,” said Heather Nixon, M.D., Associate Professor Anesthesiology, University of Illinois at Chicago Hospital. “The availability of Biorphen will help address many of the underlying causes for risk and error associated with compounded phenylephrine while also reducing potential for waste associated with overdrawing medications. This will be an important new tool for anesthesiologists, pharmacists and other hospital providers in their efforts to enhance patient safety and prevent patient harm.”

About Biorphen

Biorphen® (phenylephrine HCI) Injection is the first and only FDA-approved ready-to-use formulation of phenylephrine for treating clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia. Designed for patient safety, Biorphen can be administered without diluting, which reduces the risk of medication error in often stressful clinical environments. No compounding also reduces the risk of sterility breach, can assist safe injection practices, and reduces waste. Ready-to-use Biorphen can be standardized and stocked in the operating room, emergency department and intensive care unit, as well as in crash carts throughout the hospital. Biorphen’s three-year shelf life reduces the need for hospital staff to monitor and restock it as frequently as compounded phenylephrine.

INDICATION & USAGE

BIORPHEN injection is an alpha-1 adrenergic receptor agonist indicated for the treatment of clinically important hypotension resulting primarily from vasodilation in the setting of anesthesia.

IMPORTANT SAFETY INFORMATION

Intravenous administration of phenylephrine can precipitate angina in patients with severe arteriosclerosis or history of angina, exacerbate underlying heart failure, and increase pulmonary arterial pressure. BIORPHEN can cause excessive peripheral and visceral vasoconstriction and ischemia to vital organs as well as severe bradycardia and decreased cardiac output.

Extravasation during intravenous administration may cause necrosis or sloughing of tissue. The most common side effects of phenylephrine during treatment are nausea, vomiting, and headache. Interactions with concomitant medications may augment or antagonize the pressor effect.

Contraindications

None.

Warnings and Precautions

- Exacerbation of Angina, Heart Failure, or Pulmonary Arterial Hypertension
- Peripheral and Visceral Ischemia
- Skin and Subcutaneous Necrosis
- Bradycardia

Adverse Reactions

Most common adverse reactions during treatment: nausea, vomiting, and headache.

Drug Interactions

- Agonistic Effects (increase in BIORPHEN blood pressure effect) can occur with monoamine oxidase inhibitors (MAOI), oxytocin and oxytocic drugs, tricyclic antidepressants, angiotensin and aldosterone, atropine, steroids, norepinephrine transporter inhibitors, ergot alkaloids.
- Antagonistic Effects (decrease in BIORPHEN blood pressure effect) can occur with α-adrenergic antagonists, phosphodiesterase Type 5 inhibitors, mixed α- and β-receptor antagonists, calcium channel blockers, benzodiazepines and ACE inhibitors, centrally acting sympatholytic agents.

Overdosage

Overdose of BIORPHEN (phenylephrine hydrochloride) can cause a rapid rise in blood pressure. Symptoms of overdose include headache, vomiting, hypertension, reflex bradycardia, a sensation of fullness in the head, tingling of the extremities, and cardiac arrhythmias including ventricular extrasystoles and ventricular tachycardia.

Please see full Prescribing Information at:

http://www.biorphen.com/wp-content/uploads/full-prescribing-information.pdf

About Eton Pharmaceuticals

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing innovative products utilizing the FDA's 505(b)(2) regulatory pathway. Eton is primarily focused on liquid dosage forms including injectables, oral liquids and ophthalmics. Eton has a diversified pipeline of high-value product candidates in various stages of development and therapeutic areas, including multiple product candidates currently under review by 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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REFERENCES

1. 2018 Compounding Policy Priorities Plan. US Food and Drug Administration. https://www.fda.gov/drugs/human-drug-compounding/2018-compounding-policypriorities-plan. Updated June 21, 2018. Accessed May 14, 2019./para 20/line 2-9