
**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

December 2, 2019

Date of Report (Date of earliest event reported)

ETON PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of
incorporation)

001-38738
(Commission
File Number)

37-1858472
(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:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
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

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 December 2, 2019, Eton Pharmaceuticals, Inc. issued a press release announcing that 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, is now commercially available. 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 December 2, 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: December 3, 2019

By: /s/ W. Wilson Troutman

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

Eton Pharmaceuticals Announces Commercial Availability of Biorphen® (phenylephrine HCl) Injection

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

~ Biorphen is Now Available for Order Through Major Wholesalers ~

~ Biorphen is Eton Pharmaceuticals' First Commercially Available Product ~

DEER PARK, Ill., Dec. 2, 2019 (GLOBE NEWSWIRE) — Eton Pharmaceuticals, Inc. (Nasdaq: ETON), a specialty pharmaceutical company focused on developing and commercializing innovative drug products, today announced that 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, is now commercially available. Biorphen is available in a 5mL ampule containing 500mcg of phenylephrine. The product is now available for ordering through wholesalers McKesson, AmerisourceBergen, and Cardinal Health.

“Since Biorphen’s approval, we have seen strong interest from both physicians and hospital pharmacy directors and we are excited to begin supplying the product. The availability of Biorphen reduces the need for hospitals to rely on compounders to provide unapproved compounded phenylephrine,” said Sean Brynjelsen, President and Chief Executive Officer of Eton. “In addition, Biorphen’s three-year shelf life allows hospitals to more easily stock the product in operating rooms, emergency rooms, and crash carts. We are well prepared for the commercial success of Biorphen with a strong and experienced sales team that is fully trained and deployed promoting Biorphen to hospitals throughout the US.”

“The teams at Eton and Sintetica have worked closely together to ensure that Biorphen is ready for launch and to assuredly supply the United States healthcare system from day one with the first and only FDA-approved ready-to-use injectable formulation of phenylephrine,” said Pasquale Mitidieri, Corporate Director of Sintetica’s Global Division.

Eton estimates the total addressable market for Biorphen is more than 20 million units annually. In tandem with its manufacturing partner Sintetica, Eton expects to have the capacity to supply this market as necessary. Eton’s sales force currently includes a team of field representatives and inside sales representatives that will be initially targeting the institutions with the highest phenylephrine usage.

For ordering and product information visit www.Biorphen.com.

About Biorphen

Biorphen[®] (phenylephrine HCl) 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. Ready-to-use Biorphen can be standardized and stocked in operating rooms, emergency departments and intensive care units, as well as in crash carts throughout the hospital. With a three-year shelf life, Biorphen can be stocked throughout hospitals without frequent restocking.

Indications and 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

Contraindications

None.

Warnings and Precautions: BIORPHEN can precipitate angina in patients with severe arteriosclerosis or history of angina, exacerbate underlying heart failure, and increase pulmonary arterial pressure. Can also cause excessive peripheral and visceral vasoconstriction and ischemia to vital organs. Extravasation during intravenous administration may cause necrosis or sloughing of tissue. Can cause severe bradycardia and decreased cardiac output, renal toxicity, augmented pressor effect in patients with autonomic dysfunction and pressor effect with concomitant oxytocic drugs.

Adverse Reactions

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

To report **SUSPECTED ADVERSE REACTIONS**, contact Eton Pharmaceuticals, Inc. at 1-888-450-0568 or FDA at 1-800-FDA-1088.

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.

About Eton Pharmaceuticals, Inc.

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.

Company Contact:

David Krempa
dkrempa@etonpharma.com
847-805-1077

Media Contact:

Lindsay Rocco
Elixir Health PR
lrocco@elixirhealthpr.com
862-596-1304
