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 19, 2024
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 2.01: Completion of Acquisition or Disposition of Assets

On December 19, 2024, Eton Pharmaceuticals, Inc. (the "Company") completed its previously announced asset purchase of Increlex® (mecasermin injection) from Ipsen S.A. ("Ipsen"). Increlex® is a biologic product used to treat children and adolescents from two- to 18-years-old who suffer from severe primary insulin-like growth factor 1 deficiency (SPIGFD).

Under the terms of the purchase agreement, the Company acquired Increlex® for $22.5 million at closing, plus an additional $8.7 million for product inventory. The Company will also make payments to seller of $2.5 million on each of the first and second anniversaries of closing. In addition, the Company will be obligated to purchase additional inventory over 30 months, in an amount not to exceed €15.0 million.

As previously disclosed, the Company also entered into an amendment to its existing credit agreement with SWK Holdings that was contingent upon the closing of the purchase agreement. Under the terms of the amendment, the Company expanded its existing credit facility by $25.7 million to $30.0 million, extended the facility's maturity to three years from closing, and reduced the facility's annual interest rate to Secured Overnight Financing Rate (SOFR) plus 6.75%. In connection with the closing of Increlex®, the Company issued a warrant to the lender for the purchase of up to 289,736 shares of common stock at a price of $5.32 per share.

A copy of the press release announcing the transaction dated December 20, 2024 is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01: Financial Statements and Exhibits

Exhibit No.	Description
Exhibit 99.1	Press Release dated December 20, 2024
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: December 20, 2024

By: */s/ James R. Gruber*
James R. Gruber
Chief Financial Officer and Secretary
(Principal Financial Officer)

Eton Pharmaceuticals Closes Acquisition of Increlex® (mecasermin injection)

- Acquisition bolsters Eton's commercial pediatric endocrinology portfolio
- Product is now available through AnovoRx, a specialty pharmacy dedicated to serving patients with rare and chronic conditions

DEER PARK, Ill., December 20, 2024 (GLOBE NEWSWIRE) -- Eton Pharmaceuticals, Inc ("Eton" or "the Company") (Nasdaq: ETON), an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced that it has completed its previously announced asset purchase of Increlex® (mecasermin injection) from Ipsen S.A. ("Ipsen"). Increlex® is a biologic product used to treat pediatric patients 2 years of age and older who suffer from severe primary insulin-like growth factor 1 deficiency (SPIGFD).

"We are excited to close this transformational acquisition and add another important treatment to our commercial portfolio. Increlex® is perfectly aligned with our expertise and strong relationships in pediatric endocrinology and we're well-positioned to leverage our existing sales team to increase awareness of SPIGFD, an underdiagnosed and undertreated condition," said Sean Brynjelsen, CEO of Eton Pharmaceuticals. "In the U.S., Increlex® is now available through a specialty pharmacy dedicated to rare and chronic conditions and we are proud to be able to continue supplying this crucial product worldwide without disruption."

Increlex® is a biologic product used to treat pediatric patients 2 years of age and older who suffer from severe primary insulin-like growth factor 1 deficiency (SPIGFD) because their bodies do not make enough insulin-like growth factor 1 (IGF-1). The medicine is approved in 41 territories, including the United States (U.S.) and the European Union (EU). It is estimated that approximately 200 patients in the United States and 900-1,000 patients in Europe live with SPIGFD. Increlex® is the only treatment approved by the U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) for SPIGFD.

Increlex® is now available in the United States exclusively through AnovoRx, a specialty pharmacy dedicated to serving patients with rare and chronic conditions. AnovoRx will administer the Eton Cares Program in partnership with Eton Pharmaceuticals. The program provides prescription fulfillment, insurance benefits investigation, educational support, financial assistance for qualified patients, and other services designed to help patients access treatment. Eton Cares will offer co-pay assistance to allow for $0 co-pays for qualifying patients.

Outside the U.S., Ipsen will continue distributing Increlex® during a six-month transition period, after which Eton will take over commercialization. The transaction was financed by Eton's cash on hand and an expansion of the Company's existing credit facility with SWK Holdings.

Clinicians seeking to prescribe Increlex® can e-prescribe by selecting AnovoRx #5 or fax in a patient referral form to 855-831-2039. Additional product details can be found on the product website, https://www.increlex.com/en-us.

For questions regarding prescription fulfillment, please contact AnovoRx at 1-833-343-2500.

Important Safety Information

Contraindications

- **Hypersensitivity** to mecasermin (rhIGF-1), any of the inactive ingredients in INCRELEX®, or who have experienced a severe hypersensitivity to INCRELEX®. Allergic reactions have been reported, including anaphylaxis requiring hospitalization.
- **Intravenous Administration.**
- **Closed Epiphyses.**
- **Benign and malignant Neoplasia** in pediatric patients with active or suspected neoplasia or medical history with an increased risk of benign or malignant neoplasia.

Warnings and Precautions

- **Hypoglycemia**: INCRELEX® should be administered 20 minutes before or after a meal or snack and should not be administered when the meal or snack is omitted. Glucose monitoring and INCRELEX® dose titration are recommended until a well-tolerated dose is established and as medically indicated.
- **Intracranial Hypertension**: Funduscopic examination is recommended at the initiation of and periodically during the course of therapy.
- **Lymphoid Tissue Hypertrophy**: Patients should have periodic examinations to rule out potential complications.
- **Slipped Capital Femoral Epiphysis**: Carefully evaluate any pediatric patient with the onset of a limp or hip/knee pain during INCRELEX® therapy.
- **Progression of Scoliosis**: Patients with a history of scoliosis, treated with INCRELEX®, should be monitored.
- **Cardiomegaly:** An echocardiogram is recommended before initiation and at termination of mecasermin treatment in all patients
- Benign and malignant neoplasms: There have been postmarketing reports of malignant neoplasia in pediatric patients who received treatment with INCRELEX®. The tumors were observed more frequently in patients who received INCRELEX® at higher than recommended doses or at doses that produced serum IGF-1 levels above the normal reference ranges for age and sex. Monitor all patients receiving INCRELEX® carefully for development of neoplasms. If malignant neoplasia develops, discontinue INCRELEX® treatment.
- **Risk of Serious Adverse Reactions in Infants due to Benzyl Alcohol Preserved Solution:** Serious and fatal adverse reactions including "gasping syndrome" can occur in neonates and infants treated with benzyl alcohol-preserved drugs. Use of INCRELEX® in infants is not

recommended as well as in children below 3 years old.

Adverse Reactions

Common adverse reactions include hypoglycemia, local and systemic hypersensitivity, and tonsillar hypertrophy.

U.S. Indication

INCRELEX® (mecasermin) is indicated for the treatment of growth failure in pediatric patients aged 2 years and older with severe primary IGF-1 deficiency* (IGFD), or with hormone (GH) gene deletion who have developed neutralizing antibodies to GH.

Limitations of use: INCRELEX® is not a substitute to GH for approved GH indications. INCRELEX® is not indicated for use in patients with secondary forms of IGFD, such as GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids.

*Severe primary IGF-1 deficiency (IGFD) is defined by height standard deviation score ≤ -3.0 and basal IGF-1 standard deviation score ≤ -3.0 and normal or elevated GH.

Full U.S. Prescribing Information for Increlex® is available at: **http://increlex.com/pdf/hcp-full-prescribing-information.pdf**

You are encouraged to report negative effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call 1-800-FDA-1088.

EU Indication

In the European Union, INCRELEX is indicated for the long-term treatment of growth failure in children and adolescents from 2 to 18 years with confirmed severe primary insulin-like growth factor 1 deficiency (Primary IGFD). Severe Primary IGFD is defined by: height standard deviation score <– 3.0 and basal IGF-1 levels below the 2.5th percentile for age and gender and GH sufficiency. Exclusion of secondary forms of IGF 1 deficiency, such as malnutrition, hypopituitarism, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory steroids.
Severe Primary IGFD includes patients with mutations in the GH receptor (GHR), post-GHR signaling pathway, and IGF 1 gene defects; they are not GH deficient, and therefore, they cannot be expected to respond adequately to exogenous GH treatment. In some cases, when deemed necessary, the physician may decide to assist in the diagnosis by performing an IGF-I generation test.

Detailed information on this medicinal product is available on the website of the European Medicines Agency: http://www.ema.europa.eu

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has six commercial rare disease products: INCRELEX®, ALKINDI SPRINKLE®, PKU GOLIKE®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has three additional product candidates in late-stage development: ET-400, ET-600, and ZENEO® hydrocortisone autoinjector. For more information, please visit our website at www.etonpharma.com.

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.

Investor Relations:
Lisa M. Wilson, In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com