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 2, 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 1.01: Entry into a Material Definitive Agreement

On October 2, 2024, Eton Pharmaceuticals, Inc. (the "Company") entered into an Asset Purchase Agreement (the "Purchase Agreement") with Ipsen Biopharmaceuticals, Inc. (the "Seller"), a subsidiary of Ipsen S.A., pursuant to which the Company has agreed to acquire Increlex® (mecasermin injection) from Seller. Increlex is a biologic product used to treat children 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 product is approved in 40 territories, including the United States and the European Union.

Under the terms of the Purchase Agreement, the Company will purchase Increlex for $22.5 million at closing and will pay an additional $7.5 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.

The acquisition is structured as an all-cash purchase without any financing contingencies and is expected to close near year-end 2024, subject to customary closing conditions. Each of the Company and Seller have made customary representations, warranties, covenants and indemnities in the Purchase Agreement. As part of the acquisition, the parties have entered into a transition services agreement, whereby Seller will continue to distribute the product in markets outside the United States for a period of six months following the closing. The Company will immediately commercialize the product within the United States upon closing.

The Company also entered into an amendment to its existing credit agreement with SWK Holdings that is contingent upon the closing of the Purchase Agreement. Under the terms of the amendment, the Company will expand its existing credit facility by $25.7 million to $30.0 million, extend the facility's maturity to 3 years from closing, and reduce the facility's annual interest rate to Secured Overnight Financing Rate (SOFR) plus 6.75%. In connection with and contingent upon the closing of the Purchase Agreement, the Company agreed to issue 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 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 October 3, 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: October 3, 2024

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

Exhibit 99.1

Eton Pharmaceuticals, Inc to Acquire Increlex® (mecasermin injection) from Ipsen

- **Aligns with Eton's Mission to Develop and Distribute Medicines that Have a Life Changing Impact for Patients with Ultra-rare Conditions**
- **Acquisition to Bolster Eton's Commercial Pediatric Endocrinology Portfolio**

DEER PARK, Ill., Oct. 03, 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 entered into an asset purchase agreement to acquire Increlex® (mecasermin injection) from Ipsen S.A. ("Ipsen"). The acquisition is expected to close near year-end 2024.

"Eton's mission is to develop and distribute medicines that make a life changing impact for patients with the rarest of conditions. Increlex, a critical medication for patients with the ultra-rare condition of severe IGF-1 deficiency, aligns perfectly with our mission and our significant expertise in serving extremely rare patient populations," said Sean Brynjelsen, CEO of Eton Pharmaceuticals. "Leveraging our strong presence in the pediatric endocrinology community, we aim to raise awareness of this underdiagnosed and undertreated condition. We look forward to collaborating with Ipsen to ensure continuity of care and long-term supply for patients globally."

Increlex is a biologic product used to treat children and adolescents from 2- to 18-years-old 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 40 territories, including the United States and the European Union. 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.

Post closing, Eton will immediately commercialize the product in the U.S. without disruption to patient supply. Outside the U.S., Ipsen will continue distributing the product during a six-month transition period to ensure no disruption to patient supply, after which the commercialization will be continued by Eton.

The transaction will be financed by Eton's cash on hand and an expansion of the Company's existing credit facility with SWK Holdings. Ipsen reported global sales for Increlex of €17.3 million in 2023.

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

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has five commercial rare disease products: 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.

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