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

November 2, 2026

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 60010-7278
(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

On November 2, 2026, Eton Pharmaceuticals, Inc. (the "Company") announced ET-900, a new development program evaluating mecasermin injection for the treatment of infantile and epileptic spasms. The Company has entered into a license agreement with Baylor College of Medicine covering patent rights related to the use of insulin-like growth factor 1 (IGF-1) for the treatment of spasms. A research Investigational New Drug application has been submitted to the U.S. Food and Drug Administration for an investigator-sponsored Phase 2 clinical study evaluating mecasermin in children with refractory epileptic spasms, with initial enrollment and patient dosing targeted for the first quarter of 2027.

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 November 2, 2026
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: November 2, 2026

By: */s/ Judith M. Matthews*
Judith M. Matthews
Chief Financial Officer and Secretary
(Principal Financial Officer)

Eton Pharmaceuticals Announces Licensing and Initiation of ET-900 Program Evaluating Mecasermin/IGF-1 for Treatment of Infantile and Epileptic Spasms

- ET-900 targets a potential new indication for mecasermin, the active ingredient in Eton's INCRELEX®
- Eton has licensed patent rights from Baylor College of Medicine covering the use of insulin-like growth factor1 (IGF-1) for infantile and epileptic spasms
- Research conducted at Baylor College of Medicine and Texas Children's Hospital and funded by CURE Epilepsy and NIH, showed IGF-1 therapy led to reduction in spasms in the majority of treated animals
- An Investigational New Drug application (IND) has been submitted to the United States Food and Drug Administration (FDA) for an investigator-sponsored Phase 2 study to evaluate mecasermin/IGF-1 in children with refractory epileptic spasms, with first patient dosing planned in Q1 2027
- Eton retains commercial rights to ET-900 and the product candidate would align with the Company's planned entry into the pediatric neurology therapeutic area

DEER PARK, Ill., Nov. 02, 2026 (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 ET-900, a new development program evaluating mecasermin injection for the treatment of infantile and epileptic spasms. Mecasermin is a recombinant form of IGF-1 and the active ingredient in INCRELEX, which Eton markets in the United States. The Company has entered into a license agreement with Baylor College of Medicine covering patent rights related to the use of IGF-1 for the treatment of spasms.

"These spasms can have devastating and lifelong consequences for children and their families, and there remains a significant and urgent need for new therapeutic approaches due to high rates of resistance to current therapies," said Sean Brynjelsen, Chief Executive Officer of Eton Pharmaceuticals. "The Baylor research provides a compelling scientific rationale for evaluating IGF-1 therapy for use with this condition. With an IND now submitted, we are excited to help translate this research into meaningful clinical advancement."

Research led by Dr. John W. Swann, Ph.D., Distinguished Emeritus Professor of Pediatrics and Neuroscience at Baylor College of Medicine, and funded by CURE Epilepsy has identified impaired IGF-1 signaling as a potential contributor to the development of epileptic spasms. In an animal model, treatment with recombinant human IGF-1 reduced daily spasm counts by approximately 50% and eliminated spasms in 20% of treated animals. These preclinical findings provide a scientific rationale for evaluating mecasermin in children with refractory epileptic spasms.

"The planned clinical trial is also warranted because studies of spasms patients with structural brain abnormalities indicate that IGF-1 levels are reduced in their brains. Consequently, we hope that mecasermin/IGF-1 will serve as a replacement therapy to restore normal brain activity," added Dr. Swann.

"CURE Epilepsy is thrilled to see this long-standing line of research from Dr. Swann's lab move into human clinical trials. Dr. Swann was part of our Infantile Spasms Initiative, which began in 2012, and he and his collaborators have continued to fight to move their basic science discoveries toward clinical relevance for patients and families. Pediatric refractory epileptic spasms are catastrophic; these children urgently need new and better options, and we are grateful to Eton Pharmaceuticals for sponsoring this important next step towards a potential new treatment," said Beth Dean, CEO of CURE Epilepsy.

A research IND has been submitted for an investigator-sponsored Phase 2 to evaluate mecasermin for efficacy, safety, and tolerability in children with refractory epileptic spasms. The study will be sponsored by the University of Chicago and is expected to enroll up to 20 patients ages 2–18 years across three sites, University of Chicago, Baylor College of Medicine, and UCLA, whose spasms have not responded to, or who have been unable to tolerate, hormonal therapy and vigabatrin. Patients will receive twice-daily subcutaneous injections during an initial three- to five-week treatment period. An additional treatment course may be available to certain patients based on clinical response. The study will assess spasm resolution, changes in daily spasm frequency, and resolution or improvement of associated electroencephalogram ("EEG") abnormalities. Additional assessments will evaluate safety, tolerability, and adaptive functioning. Mecasermin is not FDA-approved for the treatment of infantile or epileptic spasms, and its safety and efficacy for these uses have not been established. Initial enrollment and dosing are targeted for the first quarter of 2027.

About Infantile and Epileptic Spasms

Infantile epileptic spasms syndrome is a rare, severe form of epilepsy that typically begins between the ages of 1 and 24 months. According to the American Academy of Pediatrics, approximately 2,500 children are diagnosed with infantile spasms in the United States each year. When spasms persist beyond the age of 2 they are referred to as epileptic spasms.

These seizures, known as epileptic spasms, frequently occur in clusters and may be accompanied by hypsarhythmia, a highly abnormal pattern of brain activity detected on an EEG. Spasms can persist beyond age two into later childhood. Prompt diagnosis and treatment are critical because persistent spasms may adversely affect neurological development.

Treatment resistance remains a significant challenge. A peer-reviewed study published in Epilepsy & Behavior reports that seizures in approximately half of children with infantile spasms fail to improve with initial treatment attempts. Current therapies are not effective for every patient and can be associated with significant limitations. For children whose spasms persist despite treatment, these challenges underscore an urgent need for new therapeutic options.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has twelve rare disease products: KHINDIVI® (hydrocortisone), INCRELEX® (mecasermin), ALKINDI SPRINKLE® (hydrocortisone), DESMODA™ (desmopressin acetate), GALZIN® (zinc acetate), HEMANGEOL® (propranolol hydrochloride), PKU GOLIKE®, IMPAVIDO® (miltefosine), LIBERVANT® (diazepam), Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has six additional product candidates in late-stage

development: AMGLIDIA® (glyburide oral suspension), ASN-001, ET-700, ET-800, ET-900, and ZENEO® hydrocortisone autoinjector. For more information, please visit our website at www.etonpharma.com.

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