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

July 31, 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 60010-7208
(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 July 31, 2026, Eton Pharmaceuticals, Inc. (“Eton” or the “Company”) entered into a license agreement (the "Agreement") for a late-stage rare disease product candidate ASN-001 (timolol topical gel) from Auson Pharmaceuticals Inc. ("Auson") for the treatment of proliferating superficial infantile hemangiomas.

Under the terms of the Agreement, the Company will pay an upfront license fee to Auson of $3.0 million within thirty days of the Agreement. Additionally, the Company will run a bioavailability bridging study for ASN-001 and, if successful, intends to submit the New Drug Application (NDA) upon completion of the study in the second half of 2027.

Upon the successful approval of ASN-001 by the U.S. Food and Drug Administration ("FDA"), the Company would be responsible for the following milestone payments:

- $5,000,000 upon first commercial sale of product after FDA approval.
- $1,000,000 upon first calendar year in which aggregate annual net sales of product meet or exceed $20,000,000.
- $2,500,000 upon first calendar year in which aggregate annual net sales of product meet or exceed $40,000,000.
- $5,000,000 upon first calendar year in which aggregate annual net sales of product meet or exceed $80,000,000.
- $10,000,000 upon first calendar year in which aggregate annual net sales of product meet or exceed $150,000,000.
- $10,000,000 upon first calendar year in which aggregate annual net sales of product meet or exceed $280,000,000.

The Company would pay tiered royalties to Auson as follows: 10% royalty rate for net product sales of less than or equal to $200,000,000; 13% royalty rate for net product sales greater than $200,000,000 but less than or equal to $400,000,000 and 15% royalty rate for net product sales greater than $400,000,000. The royalty tiers are based on cumulative lifetime product sales.

A copy of the press release announcing the transaction dated August 5, 2026 is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 2.01: Completion of Acquisition or Disposition of Assets

As disclosed in Item 1.01, on July 31, 2026, the Company entered into a license agreement for a late-stage rare disease product candidate, ASN-001 (timolol topical gel), from Auson for the treatment of proliferating superficial infantile hemangiomas. The information in Item 1.01 is hereby incorporated by reference into this Item 2.01.

Item 9.01: Financial Statements and Exhibits

Exhibit No.	Description
Exhibit 99.1	Press Release dated August 5, 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: August 5, 2026

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

Eton Pharmaceuticals Expands Infantile Hemangioma Franchise with Acquisition of U.S. Rights to Late-Stage Product Candidate ASN-001

- ASN-001 targets the substantially larger population of moderate infantile hemangiomas currently treated off-label with topical timolol
- Complementary product to HEMANGEOL® (propranolol hydrochloride) oral solution, positioning Eton, if approved, to treat full spectrum of infantile hemangioma patients
- ASN-001 Phase II/III trial results showed week 24 elimination or near-elimination rates of 56% (BID) and 42% (TID) compared with 15% for placebo
- Anticipate NDA submission in 2H 2027 for potential approval and launch in 2028
- Estimated 20,000 to 30,000 patients annually could be candidates for ASN-001, pathway to potentially be the largest revenue generating product in Eton's portfolio
- Leverages Eton's existing pediatric dermatology commercial infrastructure and expands Company's leadership in infantile hemangioma space

DEER PARK, Ill., August 5, 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 that the Company has licensed U.S. rights to rare disease product candidate ASN-001 (timolol topical gel) from Auson Pharmaceuticals Inc. ("Auson"). ASN-001 is under development for the treatment of proliferating superficial infantile hemangiomas.

Auson previously completed a three-arm Phase II/III trial of 168 patients that showed efficacy results for ASN-001. In the study, 56% of patients applying ASN-001 twice daily and 42% of patients taking ASN-001 three times per day showed elimination or near-elimination of their infantile hemangiomas at week 24, compared with 15% in the placebo group. Eton will run a bioavailability bridging study for ASN-001 and intends to submit the New Drug Application (NDA) upon completion of the study in the second half of 2027.

"Our acquisition of HEMANGEOL® (propranolol hydrochloride) oral solution gave us a unique view into the infantile hemangioma treatment landscape. We consistently observed that physicians rely on HEMANGEOL for patients requiring systemic therapy, while a much larger group of moderate patients are treated with ophthalmic timolol products used off-label because no FDA-approved topical option exists. ASN-001 is designed specifically for this population, making it highly complementary to HEMANGEOL and positioning Eton to potentially address the full spectrum of infantile hemangioma treatment. We're highly committed to investing in the development of new therapies and are excited to collaborate with Auson to bring ASN-001 to patients as quickly as possible," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

"This transaction adds yet another high-value, late-stage candidate to our pipeline, and showcases Eton's unique ability to effectively enter new therapeutic areas and leverage its commercial infrastructure and relationships to quickly expand within a specialty," concluded Brynjelsen.

Infantile hemangiomas are non-cancerous vascular tumors that typically appear in the first days or weeks of a newborn's life. In severe cases, infantile hemangiomas can lead to serious complications including loss of vision, trouble breathing, or physical deformities, and require intervention with systemic therapy. They affect more than 100,000 infants annually in the United States and exist across a broad spectrum of severity.

HEMANGEOL is the established standard of care for proliferating infantile hemangiomas requiring systemic therapy, representing an estimated 10,000 to 15,000 patients annually.

For the substantially larger population of moderate infantile hemangiomas, physicians frequently prescribe ophthalmic timolol products to be used off-label. These products were not developed or approved for infantile hemangiomas and present practical limitations, including variable dosing, formulation challenges, and the absence of FDA-approved labeling for this indication. The Company estimates that more than 10,000 patients annually currently use timolol ophthalmic products off-label to treat infantile hemangiomas, and the total market opportunity for an FDA-approved product is estimated to be 20,000 to 30,000 patients.

If approved, ASN-001 would become the first FDA-approved topical therapy for infantile hemangiomas and would complement HEMANGEOL by serving a different segment of the disease spectrum.

ASN-001 is expected to be prescribed by the same healthcare professionals as HEMANGEOL, allowing Eton to leverage its existing pediatric dermatology commercial infrastructure and its strong relationships with infantile hemangioma thought leaders and vascular anomaly centers. ASN-001 has patent protection through 2044 and an additional patent application pending with the United States Patent and Trademark Office.

IMPORTANT SAFETY INFORMATION FOR HEMANGEOL

USE

HEMANGEOL (propranolol hydrochloride) oral solution is a prescription medicine used to treat proliferating infantile hemangioma (a type of birthmark) requiring treatment throughout the body.

Who should NOT take HEMANGEOL?

Do not give HEMANGEOL to your child if they:

• Were born early and are less than 5 weeks corrected age

• Weigh less than 4.5 lbs

• Have asthma or a history of breathing problems (bronchospasm)

• Have certain heart conditions (such as slow heart rate, heart block, or heart failure)

• Have very low blood pressure

• Have high blood pressure caused by a tumor on the adrenal gland, called “pheochromocytoma”

• Are allergic to propranolol or any of the ingredients in HEMANGEOL

IMPORTANT SAFETY INFORMATION

HEMANGEOL may cause serious side effects, including:

Low blood sugar (hypoglycemia), which can be serious and may lead to seizures, loss of consciousness, or even death. This is more likely if your child is not eating well, is vomiting, or is sick. Always give HEMANGEOL during or right after feeding. Do not give a dose if your child is not eating. Signs of low blood sugar may include pale skin, sweating, irritability, unusual sleepiness, or seizures.

Bradycardia and hypotension. HEMANGEOL may slow your child’s heart rate or lower their blood pressure. Call your healthcare provider if your child seems unusually tired, dizzy, faints, or has pale or cold skin.

Bronchospasm. HEMANGEOL can cause breathing problems or make them worse. Get medical help right away if your child has wheezing or trouble breathing.

Cardiac failure. In certain patients with preexisting heart conditions, HEMANGEOL can worsen the heart’s ability to pump blood.

Increased risk of stroke. HEMANGEOL may increase the risk of stroke in children with certain blood vessel conditions (such as PHACE syndrome). Your healthcare provider may check for these conditions, especially in infants with large facial hemangiomas, before starting treatment.

Hypersensitivity. HEMANGEOL may make severe allergic reactions worse and may make it harder to treat these reactions with epinephrine (a medicine used in emergencies).

What are the most common side effects of HEMANGEOL?

The most common side effects include trouble sleeping, respiratory infections (such as colds or bronchitis), diarrhea, and vomiting.

Drug interactions

Tell your healthcare provider about all medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect how HEMANGEOL works or increase the risk of side effects, including medicines that affect how the body processes propranolol or increase the risk of low blood sugar (such as corticosteroids).

You are encouraged to report negative side effects of prescription drugs by contacting Eton Pharmaceuticals, Inc. at 1-855-224-0233 or the U.S. Food and Drug Administration (FDA) at https://www.fda.gov/safety/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information for more information.

About Eton Pharmaceuticals

Eton is an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases. The Company currently has eleven commercial rare disease products: KHINDIVI®, INCRELEX®, ALKINDI SPRINKLE®, DESMODA™, GALZIN®, HEMANGEOL®, PKU GOLIKE®, IMPAVIDO®, Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has four additional product candidates in late-stage development: Amglidia®, ET-700, ET-800 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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