

**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

September 28, 2026

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 60010-7278  
(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 September 28, 2026, Eton Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that it has launched IMPAVIDO® (miltefosine) capsules. The Company has integrated full Eton Cares patient support, including \$0 co-pay for eligible commercially insured patients and expanded patient assistance programs.

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<br>104 | <a href="#">Press Release dated September 28, 2026</a><br>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: September 28, 2026

By: /s/ Judith M. Matthews

Judith M. Matthews  
Chief Financial Officer and Secretary  
(Principal Financial Officer)



## Eton Pharmaceuticals Announces U.S. Commercial Availability of IMPAVIDO® (miltefosine) Capsules

- Eton Pharmaceuticals now holds exclusive commercialization rights for IMPAVIDO in the United States
- Eton has integrated full Eton Cares® patient support, including \$0 co-pay for eligible commercially insured patients and expanded patient assistance programs
- Centralized distribution through Anovo Specialty Pharmacy is designed to simplify access and therapy initiation for outpatient prescribing, inpatient consignment, and urgent access coordination

DEER PARK, Ill., Sept. 28, 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 launched IMPAVIDO® (miltefosine) capsules.

"We are excited to be relaunching IMPAVIDO and making Eton Cares available to all patients. By bringing IMPAVIDO into Eton's rare disease commercial infrastructure, we can pair this important therapy with high-touch services designed to help support healthcare providers and expand access for patients. We believe this comprehensive approach will help ensure that patients who need IMPAVIDO can access and initiate treatment without unnecessary delays. We are also working to expand hospital on-site availability across the United States through our consignment inventory stocking program," said Sean Brynjelsen, CEO of Eton Pharmaceuticals.

Clinicians seeking to prescribe IMPAVIDO can e-prescribe by selecting Anovo #5 (Memphis) or fax a patient referral form to 855-813-2039. Patients with questions regarding their prescription or healthcare providers can call Anovo at the dedicated IMPAVIDO line 877-469-4078.

Hospital pharmacies seeking IMPAVIDO for inpatient use may contact Anovo Specialty Pharmacy to establish access through the hospital network.

For urgent or time-sensitive patient needs, Anovo will coordinate an emergency access pathway with treating clinicians, CDC representatives, and hospital pharmacies. The pathway is designed to evaluate the fastest available source of product and delivery option based on the patient's need-by time and the treating institution's location.

Additional product details can be found on the product website, [www.impavidous.com](http://www.impavidous.com).

### Important Safety Information for IMPAVIDO

#### INDICATION

IMPAVIDO® (miltefosine) is an antileishmanial drug indicated in adults and adolescents  $\geq 12$  years of age weighing  $\geq 30$  kg (66 lbs) for treatment of:

- Visceral leishmaniasis due to *Leishmania donovani*.
- Cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*.
- Mucosal leishmaniasis due to *Leishmania braziliensis*.

**Limitations of Use:** *Leishmania* species evaluated in clinical trials were based on epidemiologic data. There may be geographic variation in the response of the same *Leishmania* species to IMPAVIDO. The efficacy of IMPAVIDO in the treatment of other *Leishmania* species has not been evaluated.

#### IMPORTANT SAFETY INFORMATION

##### Contraindications

IMPAVIDO is contraindicated in pregnancy because it may cause fetal harm; in patients with Sjögren-Larsson syndrome; and in patients with hypersensitivity to miltefosine or any component of the formulation.

##### Warnings and Precautions

**Embryo-Fetal Toxicity:** IMPAVIDO may cause fetal harm when administered during pregnancy. Obtain a pregnancy test before initiating therapy in females of reproductive potential. Advise females of reproductive potential to use effective contraception during treatment and for 5 months after completion of therapy. If vomiting or diarrhea occurs during treatment, oral contraceptive effectiveness may be reduced; advise use of an additional non-hormonal contraceptive method.

**Reproductive Effects:** Miltefosine caused impaired fertility in animal studies. The potential effects on human fertility have not been adequately evaluated.

**Renal Effects:** Monitor serum creatinine during treatment and for 4 weeks after completion of therapy.

**Hepatic Effects:** Monitor liver transaminases and bilirubin during treatment.

**Gastrointestinal Effects:** Vomiting and diarrhea are common and may result in dehydration. Encourage adequate fluid intake during treatment.

**Thrombocytopenia:** Monitor platelet counts during therapy in patients treated for visceral leishmaniasis.

**Stevens-Johnson Syndrome:** Stevens-Johnson syndrome has been reported. Discontinue IMPAVIDO if an exfoliative or bullous rash develops.

## **Adverse Reactions**

The most common adverse reactions ( $\geq 2\%$ ) are nausea, vomiting, diarrhea, headache, decreased appetite, dizziness, abdominal pain, pruritus, somnolence, elevated transaminases, and elevated serum creatinine.

To report a suspected adverse event related to IMPAVIDO, contact Eton Pharmaceuticals, Inc. at 1-855-224-0233 or the U.S. Food and Drug Administration (FDA) at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch) or call 1-800-FDA-1088.

**Please see Full Prescribing Information, including Boxed Warning regarding Embryo-Fetal Toxicity.**

## **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® (hydrocortisone), INCRELEX® (mecasermin), ALKINDI SPRINKLE® (hydrocortisone), DESMODA™ (desmopressin acetate), GALZIN® (zinc acetate), HEMANGEOL® (propranolol hydrochloride), PKU GOLIKE®, IMPAVIDO® (miltefosine), Carglumic Acid, Betaine Anhydrous, and Nitisinone. The Company has five additional product candidates in late-stage development: AMGLIDIA® (glyburide), ASN-001, ET-700, ET-800, and ZENEO® hydrocortisone autoinjector. For more information, please visit our website at [www.etonpharma.com](http://www.etonpharma.com).

## **Investor Relations:**

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