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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

September 25, 2020

Date of Report (Date of earliest event reported)

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**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 60010-7208  
(Address of principal executive offices) (Zip code)

(847) 787-7361  
(Registrant's telephone number, including area code)

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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

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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.

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**Item 8.01 Other Events.**

On September 25, 2020, Eton Pharmaceuticals, Inc. issued a press release announcing that the U.S. Food and Drug Administration had approved EM-100 (preservative-free ketotifen ophthalmic solution) for the treatment of allergic conjunctivitis. 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 99.1** [Press Release dated September 25, 2020](#)

**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 25, 2020

By: */s/ W. Wilson Troutman*

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W. Wilson Troutman  
Chief Financial Officer and Secretary  
(Principal Financial Officer)



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**FDA APPROVES BAUSCH + LOMB ALAWAY<sup>®</sup> PRESERVATIVE FREE (KETOTIFEN FUMARATE) OPHTHALMIC SOLUTION, 0.035%**

**First OTC Preservative-Free Eye Drop Approved for the Treatment of Itchy Eyes  
Associated with Allergies**

**Provides Up to 12 Hours of Eye Itch Relief**

LAVAL, Quebec and DEER PARK, Ill., Sept. 25, 2020 – Bausch Health Companies Inc. (NYSE/TSX: BHC) (“Bausch Health”), Bausch + Lomb, a leading global eye health business, and Eton Pharmaceuticals, Inc. (NASDAQ: ETON) today announced that the U.S. Food and Drug Administration (FDA) has approved Alaway<sup>®</sup> Preservative Free (ketotifen fumarate) ophthalmic solution, 0.035%, antihistamine eye drops (EM-100), as the first over-the-counter (OTC) preservative-free formulation eye drop approved to temporarily relieve itchy eyes due to pollen, ragweed, grass, animal hair and dander, which is one of the eye symptoms that affects approximately 80 percent of people with allergies.<sup>1</sup> Preservatives commonly used in eye drops can cause allergic reactions in some people that can lead to redness, irritation, itching or tearing.<sup>2,3</sup>

“We’re excited to add Alaway Preservative Free – the first and only OTC preservative-free formulation eye drop of its kind – to our existing Bausch + Lomb Consumer Health Care portfolio. Alaway Preservative Free can provide up to 12 hours of relief for people suffering from itchy eyes due to certain eye allergies,” said Joe Gordon, U.S. president, Bausch + Lomb. “We expect Alaway Preservative Free will be available for purchase in the Spring of 2021 at major retailers in time for the start of allergy season.”

Alaway<sup>®</sup> Preservative Free is indicated for the temporary relief of itchy eyes due to pollen, ragweed, grass, animal hair and dander in adults and children 3 years of age and older. It is formulated to relieve eye itch within minutes and can provide up to 12 hours of eye itch relief with one dose.

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<sup>1</sup> The 2018 U.S. Study of Allergies, Multi-sponsor Surveys, Inc. February 2018.

<sup>2</sup> Baudouin C. The Ocular Surface in Glaucoma, Cornea, Volume 28, Number 9, Suppl. 1, October 2009.

<sup>3</sup> Baudouin C. Allergic reaction to topical eye drops. *Curr Opin Allergy Clin Immunol.* 2005;5:459–63.

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“We are pleased the FDA has approved Alaway Preservative Free, and we look forward to collaborating with Bausch + Lomb to bring this unique eye drop to patients suffering from itchy eyes associated with eye allergies,” said Sean Brynjelsen, CEO, Eton Pharmaceuticals.

An affiliate of Bausch Health acquired the U.S. rights to Alaway Preservative Free from Eton in 2019.

### **About Eton Pharmaceuticals**

Eton Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing, acquiring, and commercializing innovative products. Eton is primarily focused on hospital injectable and pediatric rare disease products. The company’s first commercial product, Biorphen, is the only FDA approved ready-to-use formulation of phenylephrine injection and was launched in December 2019. The company’s lead pediatric product is the orphan drug Alkindi® Sprinkle, which is currently under review with the FDA. For more information, visit [www.etonpharma.com](http://www.etonpharma.com).

### **About Bausch + Lomb**

Bausch + Lomb, a leading global eye health business of Bausch Health Companies Inc., is solely focused on helping people see better. Its core businesses include over-the-counter products, dietary supplements, eye care products, ophthalmic pharmaceuticals, contact lenses, lens care products, ophthalmic surgical devices and instruments. Bausch + Lomb develops, manufactures and markets one of the most comprehensive product portfolios in the industry, which is available in approximately 100 countries. For more information, visit [www.bausch.com](http://www.bausch.com).

### **About Bausch Health**

Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people’s lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at [www.bauschhealth.com](http://www.bauschhealth.com).

### **Forward-looking Statements**

This news release may contain forward-looking statements, which may generally be identified by the use of the words “anticipates,” “expects,” “intends,” “plans,” “should,” “could,” “would,” “may,” “believes,” “estimates,” “potential,” “target,” or “continue” and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties discussed in Bausch Health’s most recent annual report on Form 10-K and detailed from time to time in Bausch Health’s other filings with the U.S. Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. They also include, but are not limited to, risks and uncertainties caused by or relating to the evolving COVID-19 pandemic, and the fear of that pandemic and its potential effects, the severity, duration and future impact of which are highly uncertain and cannot be predicted, and which may have a material adverse impact on Bausch Health, including but not limited to its project development timelines, and costs (which may increase). Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Bausch Health undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

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*Alaway is a trademark of Bausch & Lomb Incorporated or its affiliates.*

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