
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 8-K

**CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): March 31, 2020

EYEGATE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-36672

(Commission File Number)

98-0443284

(IRS Employer Identification No.)

271 Waverley Oaks Road

Suite 108

Waltham, MA

(Address of principal executive offices)

02452

(Zip Code)

(781) 788-9043

(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, \$0.01 par value	EYEG	The Nasdaq Capital 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 March 31, 2020, EyeGate Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the Company has received positive topline data in the Company’s pilot study using the Ocular Bandage Gel, or OBG, eye drop to treat patients with dry eye.

The press release is filed as Exhibit 99.1 and investors should read the press release in its entirety, including the cautionary statements regarding forward looking statements therein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby files the following exhibit:

[99.1 Press Release of the Company, dated as of March 31, 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 thereunto duly authorized.

EYEGATE PHARMACEUTICALS, INC.

By: /s/ Stephen From

Stephen From

President and Chief Executive Officer

Date: March 31, 2020

EyeGate Pharma Announces Positive Topline Data in Follow-on Dry Eye Pilot Study

WALTHAM, MA, March 31, 2020 (ACCESSWIRE) — EyeGate Pharmaceuticals, Inc. (NASDAQ: EYEG) (“EyeGate” or “the Company”), a clinical-stage company focused on developing products for treating disorders of the eye, announced today that it has received positive topline data in its study using the Ocular Bandage Gel (“OBG”) eye drops in patients with dry eye. OBG is a proprietary crosslinked version of the natural polymer hyaluronic acid (“HA”) that is designed to stay longer on the corneal surface. OBG has recently demonstrated statistical significance in a pivotal study for the acceleration of wound healing in patients that have undergone photorefractive keratectomy surgery. OBG has now demonstrated that it also helps in the treatment of patients with dry eye.

This uniquely designed study confirmed the ability of EyeGate’s OBG eye drops to demonstrate improvement of the ocular surface for several important ophthalmic endpoints. Significantly, OBG eye drops showed an improvement in central corneal region staining, high order ocular aberrations (“HOA”) and best corrected visual acuity (“BCVA”), outperforming the positive control, Allergan’s Refresh Preservative-Free lubricant. This is consistent with the data from EyeGate’s first pilot study where OBG showed positive results in the staining of the central corneal region against a vehicle control.

This investigator masked study enrolled 20 patients, or 40 eyes, at three sites in the United States. The unique study design used the patient as their own control in order to reduce interpatient variability. Accordingly, both eyes of the patient had to qualify where one eye was randomized to receive OBG eye drops and the other eye was randomized to receive Allergan’s Refresh lubricant eye drops.

The positive results demonstrating corneal surface improvement include:

Central Corneal Staining

- OBG demonstrated a 25% improvement from baseline versus 15% for Allergan’s Refresh lubricant. In addition, the study demonstrated that OBG works quickly relative to Allergan’s Refresh lubricant, showing a 10% improvement at Day 7 compared to no improvement in the control group.

HOA and BCVA

- OBG demonstrated an 8.2% improvement in HOA over the two-week period, whereas Allergan’s Refresh lubricant showed short-term worsening in aberrations and no benefit over the two week period. The HOA results represent the irregularities on the corneal surface likely to impact quality of vision and best corrected visual acuity. For the BCVA endpoint, OBG demonstrated a trend of improvement over the two-week period, whereas Allergan’s Refresh lubricant did not.

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- OBG demonstrated a positive trend with a modest benefit over the control, increasing tear film stability by approximately 40% from baseline over a two-week period, compared to approximately 33% using Allergan’s Refresh lubricant.

Additionally, this study confirmed for the first time in the clinic that OBG does not cause blurriness. Vision was assessed at 30 and 60 minutes post application for both OBG and Allergan’s Refresh lubricant and demonstrated that there was no change in vision for OBG versus a small negative change for Allergan’s Refresh lubricant at the 30 minute time point.

“I am excited with the results, demonstrating that EyeGate’s crosslinked HA OBG eye drops improved the ocular surface of dry eye patients in a very uniquely designed study,” said Victor Perez M.D., Scientific Director of the Ocular Immunology Center in Ophthalmology at Duke University School of Medicine. “Also, the correlation between the staining of the central corneal region, high order ocular aberrations and best corrected visual acuity clearly demonstrates improved health of the ocular surface.”

“We are very pleased with the results of this study,” said Stephen From, EyeGate’s CEO. “The fact that we were able to repeat the improvement in staining of the central corneal region in this second study going against Allergan’s Refresh lubricant is very exciting. We plan to meet with the FDA in the near future to confirm that this endpoint is suitable to move forward into the pivotal study with the OBG eye drop.”

About EyeGate

EyeGate is a clinical-stage specialty pharmaceutical company focused on developing and commercializing products for treating diseases and disorders of the eye.

EyeGate’s lead product, Ocular Bandage Gel (“OBG”), is based on a modified form of the natural polymer hyaluronic acid. The product is applied as a clear topical gel, to the damaged ocular surface and possesses unique properties that help hydrate, protect, and heal the ocular surface. EyeGate is in the clinic for two different patient populations: (1) photorefractive keratectomy (“PRK”) surgery to demonstrate corneal wound repair after refractive surgery; and (2) punctate epitheliopathies (“PE”), specifically in patients with dry eye.

The objective of OBG is to re-epithelialize the cornea, reduce the risk of infection, improve symptoms, and improve ocular surface integrity. Often, current treatments fall short because they are ineffective in protecting and enabling corneal re-epithelialization.

If EyeGate receives FDA approval following successful completion of the PRK pivotal study, EyeGate believes OBG will be the only prescription hyaluronic acid (“HA”) eye drop in the U.S. and the only eye drop in the U.S. approved for the healing of corneal epithelial defects. Additionally, if the clinical trials for patients with PE are successful, EyeGate believes OBG will be the only HA eye drop in the U.S. approved for the treatment of Dry Eye.

For more information, please visit www.EyeGatePharma.com.

EyeGate Social Media

EyeGate uses its website (www.EyeGatePharma.com), Facebook page (<https://www.facebook.com/EyeGatePharma/>), corporate Twitter account (<https://twitter.com/EyeGatePharma>), and LinkedIn page (<https://www.linkedin.com/company/135892/>) as channels of distribution of information about EyeGate and its product candidates. Such information may be deemed material information, and EyeGate may use these channels to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor EyeGate’s website and its social media accounts in addition to following its press releases, SEC filings, public conference calls, and webcasts. The social media channels that EyeGate intends to use as a means of disclosing the information described above may be updated from time to time as listed on EyeGate’s investor relations website.

Forward-Looking Statements

Some of the statements in this press release are “forward-looking” and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These “forward-looking” statements include statements relating to, among other things, the commercialization efforts and other regulatory or marketing approval efforts pertaining to EyeGate’s products, including EyeGate’s OBG product, its EGP-437 Combination Product, as well as the success thereof, with such approvals or success may not be obtained or achieved on a timely basis or at all. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this press release, including, among other things, certain risk factors described under the heading “Risk Factors” contained in EyeGate’s Annual Report on Form 10-K filed with the SEC on March 4, 2020 or described in EyeGate’s other public filings. EyeGate’s results may also be affected by factors of which EyeGate is not currently aware. The forward-looking statements in this press release speak only as of the date of this press release. EyeGate expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions or circumstances on which any such statement is based.

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