#### 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): September 5, 2018

#### 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))
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 7.01 Regulation FD Disclosure.

EyeGate Pharmaceuticals, Inc. (the "Company") hereby furnishes the updated investor presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company may use in presentations to investors from time to time, including at the H.C. Wainwright 20<sup>th</sup> Annual Global Investment Conference, being held September 4-6, 2018, at the St. Regis Hotel in New York City, at which Stephen From, President and Chief Executive Officer of the Company, will be presenting at approximately 2:10 p.m. Eastern Time on September 6, 2018.

The information furnished pursuant to Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

The information furnished in this report, including Exhibit 99.1, shall not be deemed to constitute an admission that such information or exhibit is required to be furnished pursuant to Regulation FD or that such information or exhibit contains material information that is not otherwise publicly available. In addition, the Company does not assume any obligation to update such information or exhibit in the future.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The Company hereby furnishes the following exhibit:

99.1 Presentation of the Company, dated as of September 5, 2018.

#### 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: September 5, 2018



#### Forward Looking Statements

Some of the matters discussed in this presentation contain forward-looking statements that involve significant risks and uncertainties, including statements relating to the prospects for the Company's OBG and EGP-437 product candidates, for the timing and outcome of the Company's clinical trials, the potential approval to market OBG and EGP-437, and the Company's capital needs. Actual events could differ materially from those projected in this presentation and the Company cautions investors not to rely on the forward-looking statements contained in, or made in connection with, the presentation.

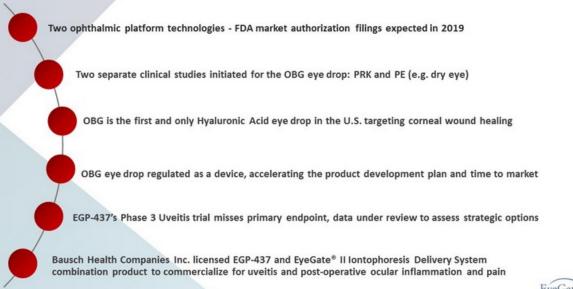
Among other things, the Company's clinical trials may be delayed or may eventually be unsuccessful. The Company may consume more cash than it currently anticipates and faster than projected. Competitive products may reduce or eliminate the commercial opportunities of the Company's product candidates. If the U.S. Food and Drug Administration or foreign regulatory agencies determine that the Company's product candidates do not meet safety or efficacy endpoints in clinical evaluations, they will not receive regulatory approval and the Company will not be able to market them. Operating expense and cash flow projections involve a high degree of uncertainty, including variances in future spending rate due to changes in corporate priorities, the timing and outcomes of clinical trials, regulatory and developments and the impact on expenditures and available capital from licensing and strategic collaboration opportunities. If the Company is unable to raise additional capital when required or on acceptable terms, it may have to significantly alter, delay, scale back or discontinue operations.

Additional risks and uncertainties relating to the Company and its business can be found in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the SEC on March 02, 2018. The Company undertakes no duty or obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or changes in the Company's expectations, except as required by applicable law.

The Company uses its website (<a href="www.EyeGatePharma.com">www.EyeGatePharma.com</a>), Facebook page (<a href="https://www.facebook.com/">https://www.facebook.com/</a> EyeGatePharma), corporate Twitter account (<a href="https://www.facebook.com/">https://www.facebook.com/</a> EyeGatePharma), and Linkedin page (<a href="https://www.facebook.com/">https://www.facebook.com/</a> EyeGatePharma), and Linkedin page (<a href="https://www.facebook.com/">https://www.facebook.com/</a> EyeGatePharma), and Linkedin page (<a href="https://www.facebook.com/">https://www.facebook.com/</a> EyeGatePharma), corporate Twitter account the Company information, and the Company may use these channels to comply with its disdosure obligations under Regulation FD. Therefore, investors should monitor the Company's website and its social media accounts in addition to following its press releases, SEC fillings, public conference calls, and webcasts. The social media channels that the Company intends to use as a means of disclosing the information described above may be updated from time to time as listed on the Company's investor relations website.



# Company Highlights (NASDAQ: EYEG)



EyeGate

#### Two Proprietary Technology Platforms

#### Cross-Linked Hyaluronic Acid (CMHA-S) Platform

- Platform based on uniquely modified hyaluronic acid that is well known for its healing properties
- EyeGate Ocular Bandage Gel (OBG), a topically applied eye drop, is first product developed from this platform
- Separate trials underway to assess treatments to:

   a) Heal the cornea in patients who have undergone PRK surgery; and
  - b) reduce corneal staining in patients with punctate epitheliopathies (e.g. dry eye)
- Versatility of cross-linking enables the incorporation of therapeutic agents into a gel or film

#### Iontophoresis Drug Delivery Platform

- EyeGate® II Delivery System, utilizes a small electrical current to propel optimal therapeutic levels of drug into the eye
- Device can overcome key limitations of conventional ocular drug delivery methods while maintaining a non-invasive approach
- First drug delivered is EGP-437, a reformulation of an established corticosteroid (dexamethasone phosphate)
- Initially being assessed as a treatment for anterior uveitis and cataract surgery



# Anticipated Inflection Points

#### Assessing Strategic Options for Both Platforms and Company

Program	Disease Area	Q3 2018	Q4 2018	
OBG Eye Drop	Large Corneal Wounds:	2nd Pilot Study	2nd Pilot Study	
	Photorefractive Keratectomy (PRK)	Initiated	Top-Line Data	
Cross-linked Hyaluronic Acid	Punctate Epitheliopathies (PE):	Pilot Study	Pilot Study	
	e.g. Dry Eye	Initiated	Top-Line Data	
EGP-437 (Corticosteroid) Iontophoresis Delivery System	Anterior Uveitis	Phase 3 Trial Top-Line Data		





#### OBG: A Differentiated Product on a Rapid Path to Approval

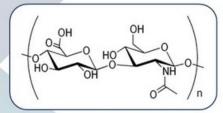
# Proprietary Formulation of a Known and Trusted Substance Creates a Unique and Differentiated Product

- Unique crosslinked HA produces a preservative-free, high concentration eye drop that resists degradation and adheres to the ocular surface without blurring vision
- > Hydrating, protectant and lubricant that facilitates management of corneal re-epithelialization
- > Addresses continued unmet medical need and research supports favorable economics
- > Positive results in human trial with two ongoing clinical studies for PRK and PE (dry eye)
- > Following a medical device pathway, filing expected in 2019



# Hyaluronic Acid (HA)

#### HA is a Naturally Occurring Molecule that Possesses Beneficial Properties



Hyaluronic Acid

- > Non-immunogenic: does not illicit an immune response
- Binds up to 1,000 times its volume in water weight providing hydration and lubrication ideal for the ocular surface
- Contributes to cellular proliferation and migration during the wound healing process
- Approved in the U.S. for wound and burn management as well as osteoarthritis
- ➤ A low concentration formulation (0.1% to 0.4%) is the Standard of Care in Europe and Asia for dry eye
- > Well known and trusted substance in US ophthalmic care



# Ocular Bandage Gel (OBG) Eye Drop

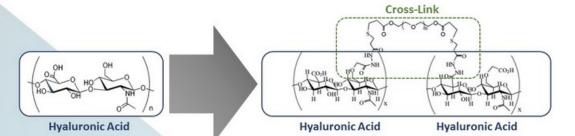
#### OBG is Differentiated by its Unique Cross-Linked, High Concentration Formulation of HA

#### The unique cross-linked HA creates a 3D structure that stabilizes the molecule providing:

- > A safe, well tolerated product
- Resistance to degradation and prolonged retention on the ocular surface
- > A scaffolding matrix which protects the ocular surface

EyeGate

Higher viscosity and shear rate that thins during blinking for clear vision



# Ocular Bandage Gel (OBG) Eye Drop

- > A clear, viscous, preservative-free eyedrop containing a high concentration (0.75%) of crosslinked hyaluronic acid (CMHA-S)
- ➤ A long-acting lubricant that protects the corneal surface to promote healing and reduce staining associated with Punctate Epitheliopathies in dry eye patients
- > Demonstrated ability to accelerate re-epithelialization in PRK patients

#### Efficacy of CMHA-S has Been Demonstrated in Various Animal Pathologic Conditions

- Post traumatic corneal stromal ulcers (real world dogs and cats)
- > Dry eye (veterinary dogs who failed topical cyclosporine)
- > Corneal abrasion and alkali burn injuries (rabbit models)

#### Molly: 12 year old cat with a non-healing corneal defect



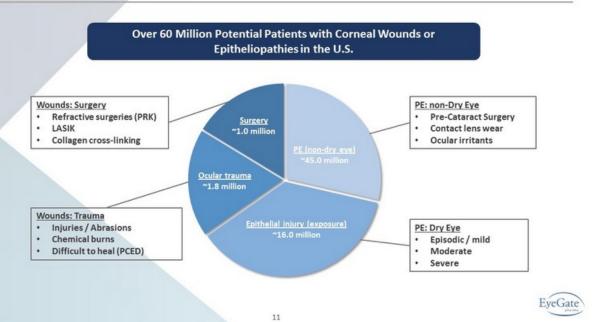


A. Non-healing at 42 days

B. Ulcer healing after 12 days of using 0.75% CMHA-S



# **Broad Market Opportunity**



#### Increasing Prevalence of Dry Eye Disease with Favorable Economics

#### Dry Eye Disease is One of the Most Common Chronic Ophthalmologic Diseases<sup>1,23</sup>

Nearly half of all U.S. adults (48%) experience one or more dry eye symptoms regularly

Half of all women (52%) experience one or more dry eye symptoms regularly

2 in 5 women age 45-54 who suffer from dry eye symptoms (42%) experience blurred vision 30% of men 55 and older have experienced dry eye symptoms for more than 10 years

#### Payer Research, which Anticipates Generic Restasis, Supports Pricing in the Range of \$125-\$225

#### Primary focus is on the punctate epitheliopathy (dry eye) market

- > Patients are currently not adequately managed on artificial tears and/or adjunctive to Restasis and Xiidra
- > Physician research supports the need for additional treatment options and strong support for OBG profile in dry eye and wound management

Gayton JL. Clin Ophthalmol. 2009;3:405-12.;
 Report of the international dry eye workshop (DEWS). Ocul Surf. 2007;5(2):65-204.;
 Allergan Dry Eye Survey, American Optometric Association, November 6, 2011.



# Positive Clinical Trial Results

#### Completed First Human Clinical Trial in PRK Patients

#### $Re-epithelialization\ Wound\ Healing\ Study^{I}:\ OBG\ vs.\ Standard\ of\ Care\ (Bandage\ Contact\ Lens\ +\ Artificial\ Tears)$

- Approximately 55% more patients treated with OBG healed by Day 3
- As early as Day 1 (24 hr. post-op) average wound size was around 36% smaller and 83.3% smaller by Day 3 with OBG alone

	Number of Subjects Per Arm	Healed Wound on Day 3		Day 1		Day 3	
		Number	Percent	Horizontal*	Vertical*	Horizontal	Vertical
Arm 1 Ocular Bandage Gel	12	10	83.3%	4.1	4.5	0.1	0.2
Arm 2 Ocular Bandage Gel + Bandage Contact Lens	14	9	64.3%	6.3	6.5	0.3	0.3
Arm 3 (Standard of Care) Bandage Contact Lens + Artificial Tears	13	7	53.8%	6.4	6.2	0.6	0.6
, % Be	Ocular Bandage		54.8%	35.9%	27.4%	83.3%	*Length in m



#### Ongoing Clinical Trials

#### Currently Enrolling for Two Studies for Management of Corneal Injury

#### New study for patients with Punctate Epitheliopathies (PE)

- · Objective is to demonstrate a decrease in Fluorescein staining of the cornea: targeting dry eye patients
- · 30 subjects (2 arms): OBG vs saline
- · 2 week screening period with wash-out / run-in: all patients stop taking Rx eye drops and receive saline only
- · Randomized after 2 week screening period if patient meets criteria
- Study lasts 4 weeks post randomization: staining completed at Day 7, 14, 21 and 28
- Primary performance is change in corneal staining from baseline to each visit between both arms
- Top-line data expected in Q4 2018

#### Additional study for patients that have undergone bilateral Photorefractive Keratectomy (PRK)

- · Objective is to demonstrate re-epithelialization of large corneal epithelial defects
- · 45 subjects (3 arms): OBG (2 dosing regimens) vs standard of care (bandage contact lens + artificial tears)
- · Evaluated by a masked reading center (Tufts) using digital photography of fluorescein stained slit lamp photos
- Top-line data expected in Q4 2018





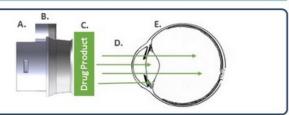
# Iontophoresis Platform EyeGate® II Delivery System and EGP-437

# EyeGate® II Delivery System and EGP-437

#### A Non-Invasive Method of Propelling Charged Active Compounds into Ocular Tissues

- A. Applicator
- B. Small electrical current at electrode
- C. Charged drug product (in applicator)
- D. Active product propelled into the eye
- E. Eye receiving drug product noninvasively

Dose is controlled by current strength and application time





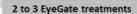
EGP-437, a reformulated corticosteroid, Dexamethasone Sodium Phosphate is delivered into the ocular tissues through EyeGate's proprietary innovative drug delivery system, the EyeGate® II Delivery System



# A Highly Differentiated Product

The EyeGate®II Delivery System Combined with EGP-437 Significantly Decreases the Patient Burden by Reducing Treatment Applications by up to 98%

VS





The EyeGate® II Delivery System takes less than 5 minutes to administer and over 2,400 treatments performed to date

# Up to 154 eye drop treatments Week 1 Week 2 Week 3 Week 4

The current Standard of Care for both Anterior Uveitis and Cataract Surgery are corticosteroid eye drops



#### Exclusive Licensing Agreement with Bausch Health (Formerly Valeant Pharmaceuticals)

Worldwide License to Manufacture, Sell, Distribute, and Commercialize EGP-437 with the EyeGate® II Delivery System for Uveitis and Post-Operative Ocular Inflammation and Pain

# BAUSCH-Health BAUSCH+LOMB

\$136.5 million in potential payments, including up-front, development and commercial milestones

#### **Anterior Uveitis**

- \$1 million up-front payment
   Up to \$32.5 million development and commercials milestones
- High Single Digit Royalties based on net sales with upward adjustment to double-digit for cataract surgery

#### Cataract Surgery

\$4 million up-front payment Up to \$99 million development and commercials milestones

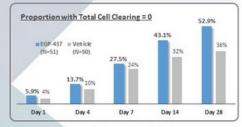
 $\label{prop:continuous} Eye Gate is responsible for the completion of clinical development and FDA filing for both indications. \\ Bausch holds no rights to "use of system" with other drugs.$ 



#### EGP-437 Clinical Data Results

#### Inflammation Post Cataract Surgery Phase 2 Clinical Trial

Double-masked, placebo-controlled, two-arms, 101 subjects



- ✓ EGP-437 demonstrated better clinical performance than the vehicle control trending towards statistical significance (p = 0.08)
- Secondary endpoints: change in mean cell count and change in mean pain score
  - Total Cell Clearing count = 0 on Day 7 (p=0.0096)
  - Pain Score = 0 on Day 1 (p=0.0149)
- ✓ EGP-437 arm demonstrated a favorable safety profile with no serious adverse events reported

#### Anterior Uveitis Phase 3 Non-Inferiority Trial

Missed Primary Endpoint on Day 15

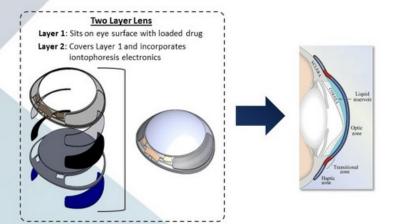
- Non-inferiority was not demonstrated between EGP-437 and Control (the lower limit of the two-sided 95% confidence interval (CI) for the difference is less than -10%)
- Control group had higher rate of success (ACC count=zero) than the EGP-437
  - The Chi-square test shows significant difference between Control and EGP-437, preferring the Control group

N	Test	EGP-437 Zero	Control Zero	EGP-Control, Two- Sided 95% CI	p-value <sup>1</sup> / p-value <sup>2</sup>
251 patients	ACC Count	53 (42.4%)	75 (60.3%)	(-30.25%, -5.55%)	0.8951/ 0.0052



# The Future of Ocular Drug Delivery: Drug-Embedded Contact Lens

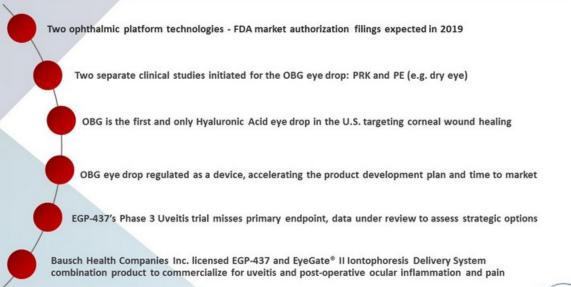
Potential to Revolutionize the Treatment of Chronic Retinal Conditions at Home by Significantly Reducing or Eliminating Intravitreal Injections and Frequent Office Visits



<u>First Indication</u> Dexamethasone for macular edema



# Company Highlights (NASDAQ: EYEG)









# **Thank You**

#### Contact Us

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