# 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): November 9, 2017

# 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 presentation attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company will use at the Ophthalmology Innovation Summit at AAO, being held November 9, 2017 at The Hyatt Regency in New Orleans, Louisiana, at which Stephen From, President and Chief Executive Officer of the Company, will be presenting at approximately 9:30 a.m. Central Time.

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:

<u>99.1</u> <u>Presentation of the Company, dated as of November 9, 2017.</u>

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#### 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: November 9, 2017

#### Exhibit Index

<u>99.1</u> Presentation of the Company, dated as of November 9, 2017.



Two Versatile Platforms Moving Towards Commercialization



# **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 EGP-437 and OBG product candidates, for the timing and outcome of the Company's clinical trials, the potential approval to market the Company's product candidates, 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.

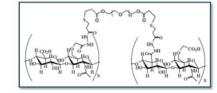
Additional risks and uncertainties relating to the Company and its business can be found in the "Risk Factors" section of the Company's Annual Report on Form 10-K filed with the SEC on February 23, 2017 or described in the Company's other filings. The Company undertakes no duty or obligation to update any forwardlooking 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.

# Two Versatile Technology Platforms Moving Quickly to Commercialization



# **Expected FDA filings Second Half of 2018**

Crosslinked Hyaluronic Acid (CMHA-S) Eye Drop Formulation in the Clinic Iontophoresis Drug Delivery System: EGP-437 (Corticosteroid) in the Clinic



- 510K De Novo pathway with first human clinical trial completed in PRK patients
- From wounds to epitheliopathies: hydrating and accelerating re-epithelization
- Anticipate data from next PRK trial and first SPK trial in H1 2018
- Building infrastructure and preparing for commercialization



- Anticipate data from Ph 3 anterior uveitis trial first half of 2018
- Commercialization rights for EGP-437 licensed to Valeant (Bausch + Lomb) for uveitis and ocular surgery
- Demonstrated in macular edema trial ability to treat retinal diseases
- Platform has ability to deliver biologics (i.e. oligos and proteins)

# What is Hyaluronic Acid?



#### Hyaluronic acid is a naturally occurring compound in the body

- ~15 grams of HA in an adult human body
- Possesses unique properties such as hydration (synovial fluid) and promotion of wound healing (skin): ideal for ocular surface
- Issue: rapidly degrades, one-third is naturally turned-over (degraded and synthesized) every day

# Properties

High-molecular weight HA is non-immunogenic

High-molecular weight HA binds up to 1,000 times its volume in water weight

HA provides: hydration, lubrication, and a meshwork for cell migration

#### U.S. – Dermatology & Osteoarthritis

HA approved in the U.S. as a device for wound and burn management and injections to treat knee pain caused by
osteoarthritis

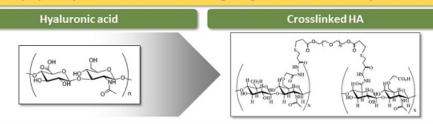
# HA approved in the U.S. as a device osteoarthritis Ex-U.S. – Dry Eye & Wound Healing Low concentration formulations of dry eye and ocular surface damage

 Low concentration formulations of HA eye drops are the standard of care in Europe and Asia for ocular wound healing, dry eye and ocular surface damage

# CMHA-S Platform is a unique crosslinked version of Hyaluronic acid



First and only eye drop candidate in the U.S. targeting acceleration of re-epithelialization



EyeGate crosslinking method prevents degradation and increases residency time on ocular surface

- Crosslinking creates a 3D structure that stabilizes the molecule (resists degradation)
- Prolonged retention time on the ocular surface (90 to 120 minutes)
- Higher viscosity/shear rate thins with blinking and is non blurring
- Scaffolding matrix protects the ocular surface
- Enables potential development of a high concentration eye drop (0.75%) for treating a wide variety of ocular surface pathologies



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

✓ PRK surgery provides several advantages as indication to evaluate the Ocular Bandage Gel (OBG)

A homogenous patient population with same size, large epithelial defects

### ✓ 39 subjects randomized to one of three groups: both eyes received the same treatment

- i) OBG alone (ii) OBG + Bandage Contact Lens (BCL) (iii) Standard of care (BCL + Artificial Tears)
- OBG alone demonstrates accelerated wound healing vs standard of care
  - 30% more patients healed by Day 3
  - Additionally, wound size was as much as ~36% smaller as early as Day 1 (24 hours post surgery) with OBG alone

				Length	in mm	
# Subjects	Closed Wound: Day 3		Day 1		Day 3	
per arm	#	%	Horizontal	Vertical	Horizontal	Vertical
12	10	83.3%	4.1	4.5	0.10	0.20
14	9	64.3%	6.3	6.50	0.30	0.30
13	7	53.8%	6.4	6.20	0.60	0.60
39						
		54.8%	35.9%	27.4%	83.3%	66.7%
	per arm 12 14 13	per arm         #           12         10           14         9           13         7	perarm         #         %           12         10         83.3%           14         9         64.3%           13         7         53.8%           39	per arm         #         %         Horizontal           12         10         83.3%         4.1           14         9         64.3%         6.3           13         7         53.8%         6.4           39	# Subjects         Closed Wound: Day 3         Day 1           per arm         #         %         Horizontal         Vertical           12         10         83.3%         4.1         4.5           14         9         64.3%         6.3         6.50           13         7         53.8%         6.4         6.20           39	per arm         #         %         Horizontal         Vertical         Horizontal           12         10         83.3%         4.1         4.5         0.10           14         9         64.3%         6.3         6.50         0.30           13         7         53.8%         6.4         6.20         0.60           39

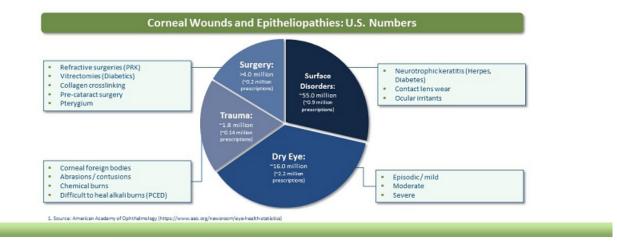
# High-Concentration HA Prescription Eye Drop Well Suited for Treating Various Ocular Surface Defects and Epitheliopathies



#### EyeGate's proprietary crosslinking: Unique differentiation from existing HA eye drops

Low concentration non-crosslinked HA eye drops are standard of care in Europe/Japan for dry eye and ocular surface damage

Targeting data from next PRK trial and SPK trial in first half of 2018, with anticipated filing of de novo 510(k) by year-end 2018

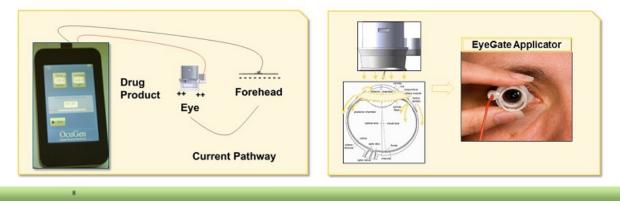


# **Iontophoresis Drug Delivery Platform**



A non-invasive method of propelling charged active compounds into ocular tissues

- ✓ Very low electrical current supplied to electrode that repels drug into ocular tissues
- ✓ Easy to use with more than 2,400 treatments already performed in office setting
- ✓ Demonstrated ability to treat retinal indications with human clinical macular edema trial
- ✓ Versatile platform with potential for other drugs (i.e. small molecules and large)



# Iontophoretic Delivery of EGP-437 (Dexamethasone) Ensures Dosing and Reduces Patient Burden



Licensed to Valeant (Bausch + Lomb) to commercialize for use in the fields of ocular surgery and uveitis

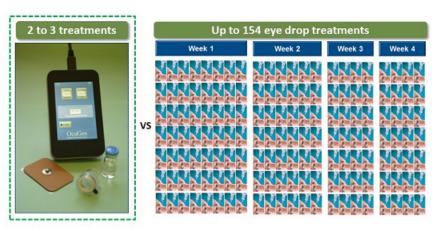
· EGP-437 being developed for 2 inflammatory conditions: cataract surgery and anterior uveitis

#### Cataract Surgery: Ph I/II trial

- Cell count of zero in up to 30% of patients at day 7 and up to 80% at Day 28
- Percentage of patients with zero pain on day 1 was up to 90%

#### Anterior Uveitis: initial Ph 3 trial

- Demonstrated similar response to standard of care (corticosteroid eye drops - prednisolone acetate 1%)
- Lower incidence of increased intraocular pressure (IOP) with EGP-437 treatment

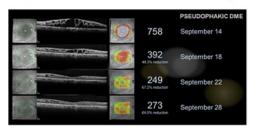


# Welcome to the Future of Ocular Drug Delivery



Iontophoresis and Drug Embedded in a Contact Lens

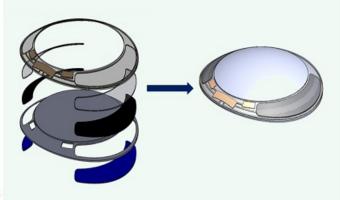
- First indication: dexamethasone for macular edema
- Iontophoresis validated in clinic for retinal drug delivery



In vitro work nearing completion

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- Anticipate proof-of-concept animal data first half of 2018
- Treating chronic retinal conditions at home



Important N	lear-Term	Inflection	Points



Both Platforms Quickly Approaching FDA Filings/Commercialization

	First Half of 2018	Second Half of 2018
OBG: Eye Drop		
PRK	<ul> <li>Pilot Trial: Initiation and top-line data</li> </ul>	<ul> <li>Pivotal Trial: Initiation and top-line data</li> <li>File De Novo 510(k)</li> </ul>
Superficial Punctate Keratitis (SPK)	<ul> <li>Pilot Trial: Initiation and top-line data</li> </ul>	<ul> <li>Pivotal Trial: Initiation and top-line data</li> <li>File De Novo 510(k)</li> </ul>
Iontophoresis: EGP-4	37	
Anterior Uveitis	Phase 3 Trial: Top-line data	File NDA / 510(k): combination product
Cataract Surgery	Phase 2 Trial: Top-line data	Phase 3 Trial: Initiate
Contact Lens	In vivo proof-of-concept data	<ul> <li>IND filed – macular edema trial</li> </ul>
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# **CMHA-S Platform**

- Ocular Bandage Gel (Eye Drop):
  - Anticipate De Novo 510(k) filing second half of 2018 for PRK and SPK
  - Preparing for commercialization launch second half of 2019
- Versatile platform with opportunities for other indications and products

#### **Iontophoresis Platform**

- EGP-437 nearing critical milestones
  - Top-line data for 2<sup>nd</sup> anterior uveitis Phase 3 trial expected first half of 2018
  - Top-line data for Phase 2 cataract surgery trial expected first half of 2018
  - NDA filing for anterior uveitis second half of 2018
  - Both indications licensed to Valeant (Bausch + Lomb) for commercialization
- Versatile platform with opportunities for other drugs and an at-home version of platform

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