# 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 8, 2015

## 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

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))

#### 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 Rodman & Renshaw 17th Annual Global Investment Conference in New York, New York, beginning on September 8, 2015, at which Stephen From, President and Chief Executive Officer of the Company, will be presenting.

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 files the following exhibit:

99.1 Presentation of the Company, dated as of September 9, 2015.

#### 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

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Date: September 8, 2015

### Exhibit Index

99.1 Presentation of the Company, dated as of September 9, 2015.



# **Eyegate Pharmaceuticals, Inc.**

Providing innovative products that enhance drug efficacy and patient compliance to improve vision

> Rodman & Renshaw Annual Global Investment Conference 09 September 2015



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 lead product EGP-437, for the timing and outcome of the Company's clinical trials, the potential approval to market 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 FDA 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 31, 2015. 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.

# 2015 Major Milestones Accomplished



### Licensing Agreement with Valeant Pharmaceuticals

- Exclusive, worldwide commercial and manufacturing rights for uveitis
- Upfront cash payment, milestone payments and royalties
- Valeant responsible for 100% of costs outside U.S.

### Positive Guidance from FDA

- We believe positive data from upcoming Phase 3 trial sufficient to support NDA filing
- We believe design of the upcoming Phase 3 trial is acceptable
- Macular Edema Trial Initiated
  - First clinical trial evaluating EyeGate® II delivery system in posterior of eye

### Alternative Platform Collaboration Initiated

At-home non-invasive treatment for chronic diseases like macular degeneration

# **Company Overview**



# **Ophthalmology: Drug Delivery Platform**

- Drug: EGP-437, a corticosteroid (Dexamethasone phosphate)
  - First indication: non-infectious anterior uveitis
  - 505(b)(2) NDA pathway

### Platform: EyeGate II<sup>®</sup> Delivery System

- Proprietary, non-invasive delivery platform; >1,700 treatments performed to-date
- System expected to be approved through a 510(k) filing at time of drug NDA submission
- Easy to use: done by ophthalmologist or optometrist in <5 minutes</p>
- Delivers small and large molecules to anterior or posterior of eye
- Significant patient and clinician advantages over drops or ocular injections

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# **Unique Ophthalmic Delivery Platform**





### Anterior Segment : Eye Drops



- Protective layer and biological functions limit penetration of drug into tissues
- Frequent instillations required
- · Extreme burden on patient: non-compliance
- Sight-threatening complications

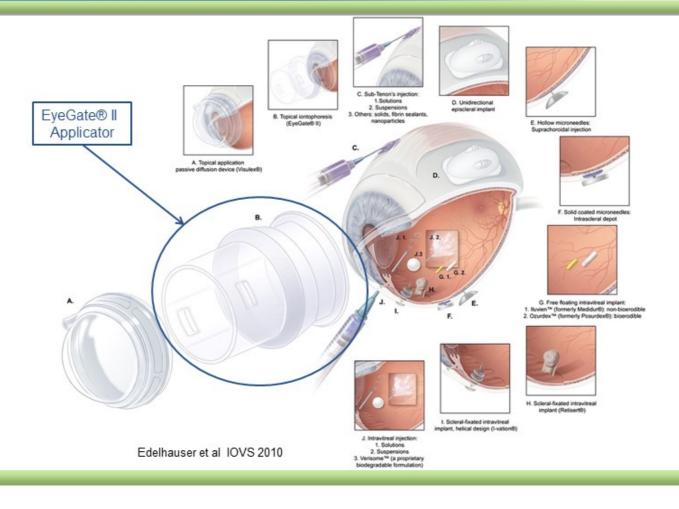
### **Posterior Segment: Intravitreal Injections**



- Potential for collateral damage
- Injections every 4 to 6 weeks
- Must be done by experienced ophthalmologist
- Companion required
- Sight-threatening complications

# EyeGate has the only Non-Invasive Solution





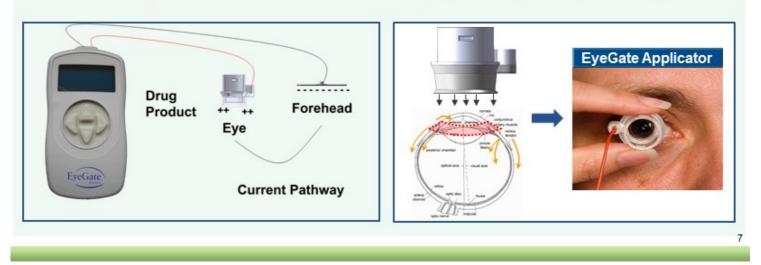
# EyeGate Platform, A Non-Invasive Method

of Propelling Charged Active Compounds Into Ocular Tissues



### lontophoresis

- Small electrical current (constant); current has same charge as active substance (drug)
- Electrode creates repulsive electromotive forces (like charges repel)
- Drug migrates toward return electrode
- Drug mobility is a function of molecular weight and charge
- Drug dose controlled by 2 variables: Current (mA) x Application time (minutes)
- Software-regulated current and duration ensures proper dosing of compatible compounds



# **Clinical Pipeline**



Program	Indication	Current Status	Planned Trials
EGP-437	Anterior Uveitis	<ul> <li>Phase 1-2 dose ranging trial completed</li> <li>First Phase 3 pivotal trial completed</li> </ul>	<ul> <li>Initiate and complete confirmatory Phase 3 pivotal trial</li> <li>Top-line data: Q1 2017</li> </ul>
	Macular Edema	• Initiated	<ul> <li>Complete Phase 1b/2a proof-of-concept trial for macular edema</li> <li>Top-line data: Q4 2015</li> </ul>
	Cataract Surgery	• Exploring opportunity as additional indication for EGP-437	<ul> <li>Phase 2 trial for efficacy and pain following cataract surgery</li> <li>Initiate by year-end2015</li> </ul>

### EGP-437

- · Confirmatory Phase 3 anterior uveitis trial
  - · First patient: year-end 2015 and fully-enrolled: Q4 2016
- Macular Edema proof-of-concept trial
  - Top-line data: Q4 2015
- Cataract Surgery Phase 2 trial
  - Exploring opportunity for cataract surgery as additional indication for EGP-437

### **Alternative Platform**

Animal data: H1 2016

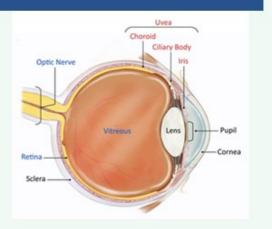


# EGP-437 Anti-Inflammatory



## **Uveitis Overview**

- Inflammation of uvea tract
- Estimated 18% experience transient or permanent loss of vision annually.
- Responsible for more than 2.8% of blindness in the U.S.
- Non-infectious anterior uveitis is most common form
- Incidence in U.S. from approximately 26.6 102 per 100,000 annually
- Chronic and non-compliance of treatment may lead to complications

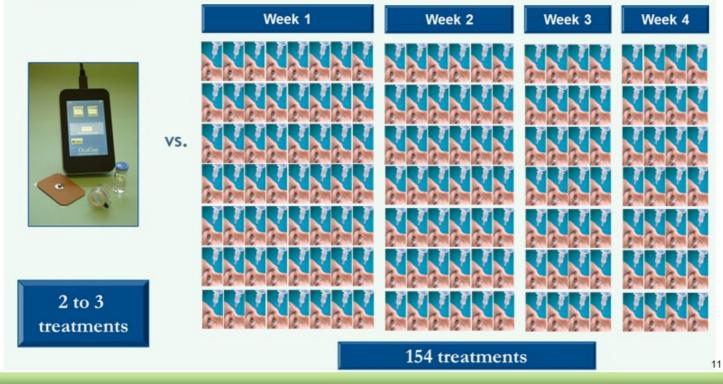






## Standard of care: corticosteroid eye drops

Eye drops suffer from number of drawbacks: low ocular bioavailability and rapid clearance





# Anterior Uveitis Episode 1994 OS OD 20/80 20/20 low grade chronic inflammation Same Patient 10 Years Later (2004): Poor Anti-Inflammatory Therapeutics OS OD No Light Perception 20/400 Blind Legally Blind 12



## Severity of Uveitis: SUN Working Group

- Severity determined by number of white blood cells in the anterior chamber of the eye (Slit-lamp is used)
- Grading scheme for determining degree of inflammation based on number of cells counted
- Inactive disease (cell count of zero) is goal of therapy

Grade	Cells
0	< 1
0.5	1 to 5
1.0	6 to 15 16 to 25
2.0	
3.0	26 to 50
4.0	> 50

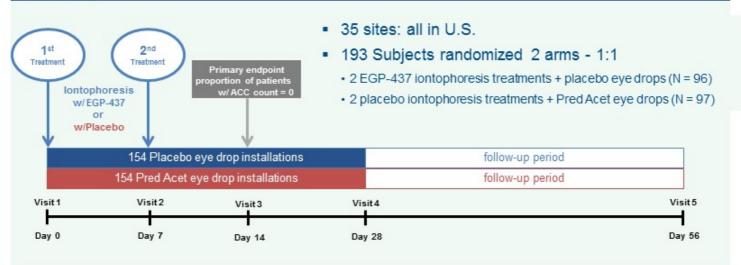
## EGP-437: First Pivotal Phase 3 Trial

- Subjects required minimum 11 cells to be randomized to study
  - Primary End Point (PEP): Total cell clearing at Day 14

# Initial Phase 3 Non-Inferiority Anterior Uveitis Trial

Trial Design and High-Level Results

### **Trial Design**



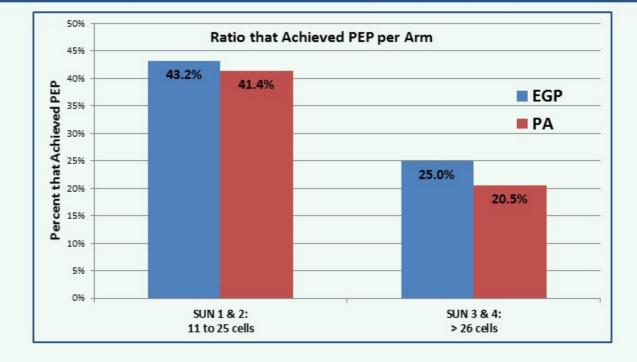
## **High-Level Results**

- Successfully demonstrated same response rate when comparing EGP-437 to standard of care (prednisolone acetate 1%)
- Lower incidence of increased intraocular pressure (IOP) with EGP-437 treatment





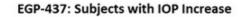
## Percent of subjects\* that achieved primary endpoint (PEP)

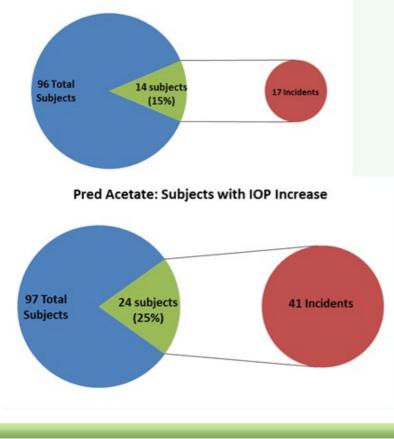


\*ITT = Intent to Treat

# Safety: Intraocular Pressure





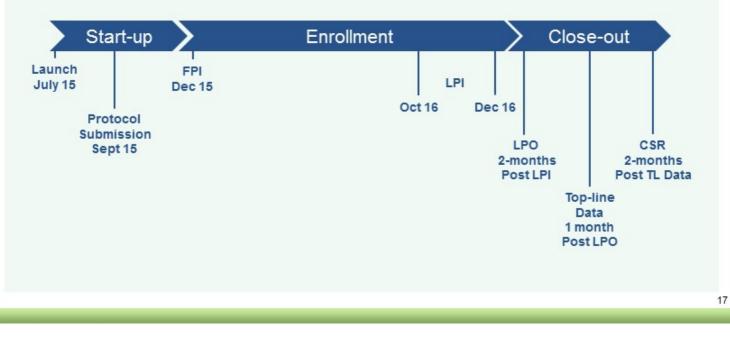


- Each subject had four IOP measurements (Day 7, 14, 28, and 56) compared to baseline (Day 0)
- Significantly less subjects with incidents in the EGP-437 arm
- 2.4X the number of incidents in the standard-of-care control arm



### Three major stages to trial

- 1. Start-up: Clinical supply manufacturing, CRO selection, & site initiations →5 months
- 2. Enrollment: First Patient In (FPI) to Last Patient In (LPI) → 10 to 12 months
- 3. Close-out: Last Patient Out (LPO), Database lock, Top-line data analysis, & clinical study report (CSR) → 5 months



## **Macular Edema**



- Abnormal thickening of macula associated with accumulation of excess fluid in extracellular space of neurosensory retina
- Considered leading cause of central vision loss in developed world.

### **Trial Design**

- Phase 1b / 2a clinical trial
- Up to 20 patients with macular edema associated with Retinal Vein Occlusion, Diabetic Retinopathy or Post-Surgical (Cystoid) macular edema
- 3 treatments at 14.0 mA-min (3.5 mA) on Day 0, Day 4, and Day 9
- Primary outcome: reduction in mean thickness on Day 4, Day 9, Day 14
- Control: Ozurdex® to subjects with no improvement at Day 14 and re-evaluated at Day 21
- Expect data by year-end

# EGP-437: Licensing Agreement



- Valeant Pharmaceuticals (NYSE/TSX: VRX)
  - Exclusive license to manufacture, sell, distribute and commercialize throughout the world for use in field of uveitis
    - Upfront cash payment and milestone payments
    - Royalties based on net sales: high single digits
  - EyeGate responsible for development of anterior uveitis project in U.S.
  - Valeant responsible for development outside U.S.
  - Valeant has right of last refusal for product outside field of uveitis
- EyeGate will continue to develop for indications outside field of uveitis

## Reimbursement



## Single-Use Kit

- Combines drug vial and device disposables:
  - Ensures use of approved drug with applicator
- Shelf-life established at 24 months (drug and applicator)

## Reimbursement: In-office treatment involves multiple code sets.

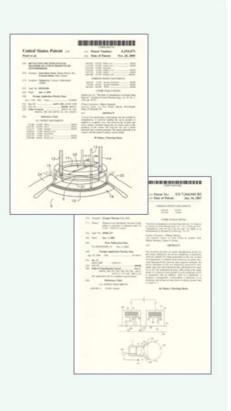
- CPT Code: In addition to office reimbursement, reimbursement for performing treatment
- J-code: The kit (drug + disposables) will be billed under a J-code Payment that would be based on ASP (price we establish) + x% for the kit

# **Strong Patent Portfolio**



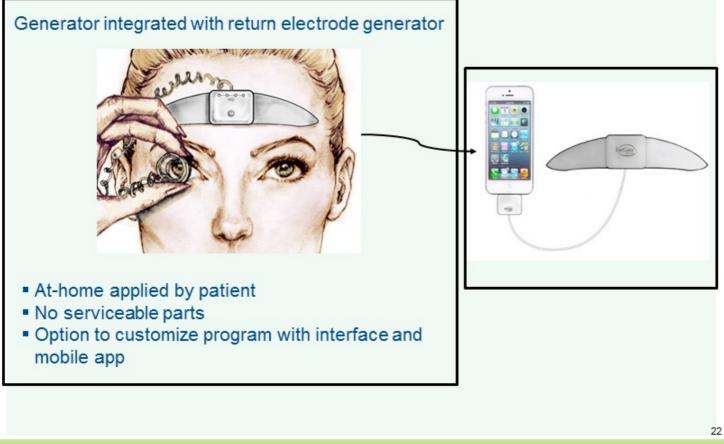
# Ten families (73 patents granted)

- Eight belong to delivery system patent portfolio
  - 13 U.S. and 58 foreign patents granted
  - 3 U.S. and 16 foreign pending applications
- Two relate to drug compositions and treatments utilizing delivery system:
  - 1 U.S. and 1 foreign patent granted
  - · 2 U.S. and 6 foreign applications



\* Granted patent protection until 2024, applications if granted extend this to 2029





## Investment Highlights



### Licensing deal signed with Valeant

- Exclusive, worldwide commercial and manufacturing rights for uveitis
- Upfront cash payment, milestone payments and royalties
- Phase 3 program with clear path to commercialization
  - First Phase 3 trial completed
  - Potent drug with proven safety profile when delivered by our system
  - Mitigates corticosteroid side-effect, elevated IOP
- Macular Edema Trial Initiated
  - First clinical trial evaluating EyeGate® II delivery system in posterior of eye

### Alternative Platform Collaboration Initiated

At-home non-invasive treatment for chronic diseases like macular degeneration