

**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): **January 18, 2016**

**EYEGATE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**000-55362**

(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))
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**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 Noble Financial Capital Markets’ 12<sup>th</sup> Annual Conference, being held January 17-20, 2016 in Sandpiper Bay, Florida, at which Stephen From, President and Chief Executive Officer of the Company, will be presenting on January 18, 2016.

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 January 18, 2016.

## **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: January 18, 2016

## **Exhibit Index**

99.1      Presentation of the Company, dated as of January 18, 2016.



# Eyegate Pharmaceuticals, Inc.

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

*Corporate Presentation  
January 2016*

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## 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 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.

- **Ophthalmology company (NASDAQ: EYEG)**
- **EyeGate® II Delivery System: non-invasive delivery of therapeutics to front or back of eye**
- **Lead program: EGP-437 (corticosteroid) delivered by system**
  - **Licensed to Valeant Pharmaceuticals (Bausch + Lomb)**
  - **License Agreement for first indication (Uveitis) only**
  - **Developing for other indications**
    - **Macular Edema**
    - **Post Cataract Surgery Inflammation**
- **Next Generation Delivery System: at home version**

### 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® 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
  - Delivers small and large molecules to anterior or posterior of eye
  - Significant patient and clinician advantages over drops or ocular injections



## Unique Ophthalmic Delivery Platform



## Anterior Segment : Eye Drops



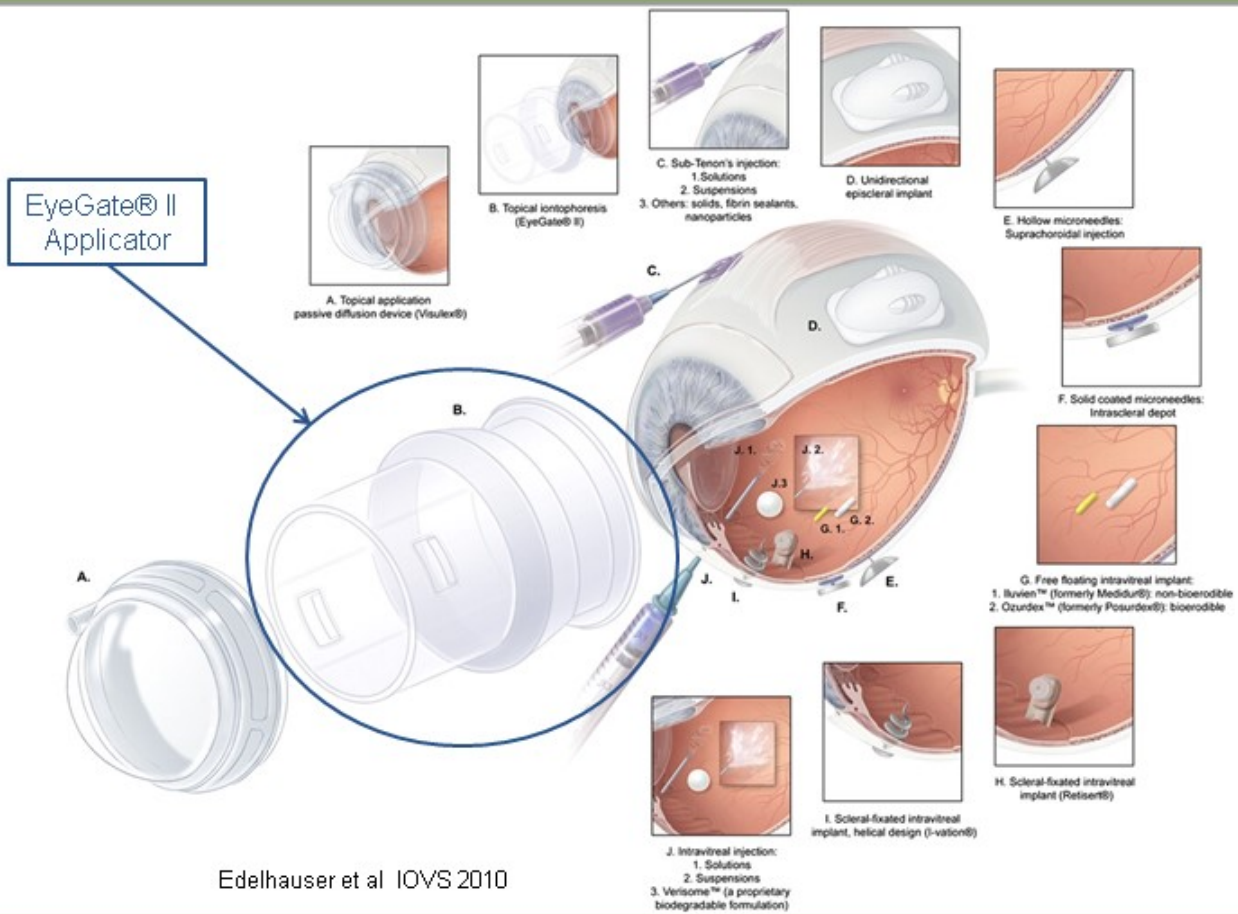
- Protective layer and biological functions limit penetration of drug into tissues
- Frequent instillations required
- Extreme burden on patient: non-compliance
- Sight-threatening complications

## 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

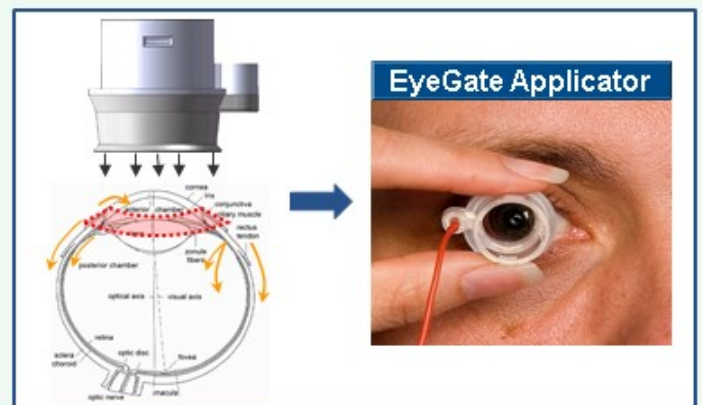
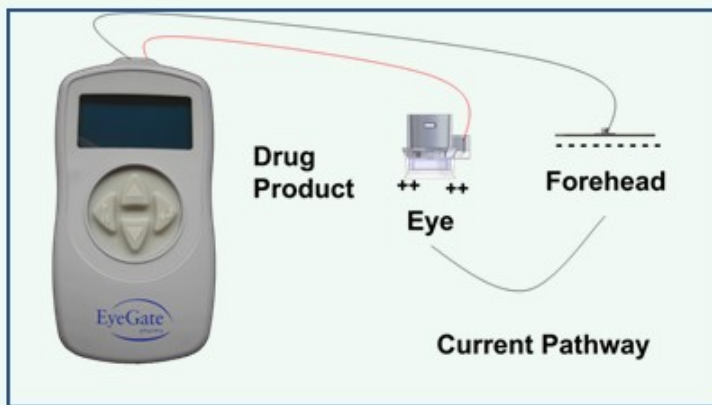
# EyeGate has the only Non-Invasive Solution



Edelhauser et al IOVS 2010

## Iontophoresis

- 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



Program	Indication	Current Status	Planned Trials
EGP-437	<b>Anterior Uveitis</b>	<ul style="list-style-type: none"> <li>Phase 1-2 dose ranging trial completed</li> <li>First Phase 3 pivotal trial completed</li> </ul>	<ul style="list-style-type: none"> <li>Confirmatory Phase 3 pivotal trial initiated</li> <li>Top-line data: Q1 2017</li> </ul>
	<b>Macular Edema</b>	<ul style="list-style-type: none"> <li>First leg of Phase 1b/2a POC trial completed</li> </ul>	<ul style="list-style-type: none"> <li>Initiate and complete second leg of Phase 1b/2a proof-of-concept trial</li> <li>Top-line data: end of Q1 2016</li> </ul>
	<b>Cataract Surgery</b>		<ul style="list-style-type: none"> <li>Initiate and complete second leg of Phase 1b/2a proof-of-concept trial</li> <li>Top-line data: end of Q1 2016</li> </ul>

## EGP-437

- Confirmatory Phase 3 anterior uveitis trial
  - Initiated and top-line data expected Q1 2017
- Macular Edema proof-of-concept trial
  - First leg completed, second leg top-line data expected by end of Q1 2016
- Cataract Surgery Pilot trial
  - Top-line data expected by end of Q1 2016

## Alternative Platform (at-home use)

- Animal data: H1 2016

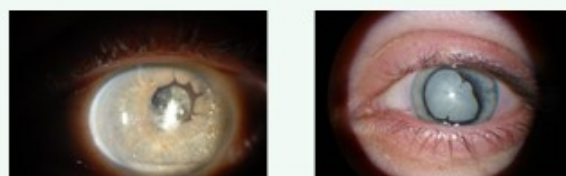
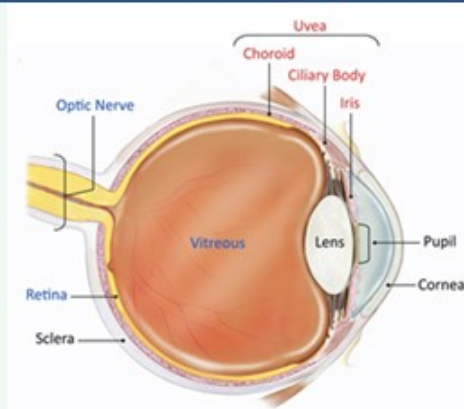
## **EGP-437**

### **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



Non-compliance leads to sight-threatening complications

### 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
2.0	16 to 25
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



## EGP-437: A Highly Differentiated Product

*Dramatically Reduces Patient Burden from 154 to 2 or 3 Treatments*



### Standard of care: corticosteroid eye drops

- First pivotal Phase 3 trial: 2 EyeGate treatments vs 154 eye drop treatments



vs.

2 to 3  
treatments



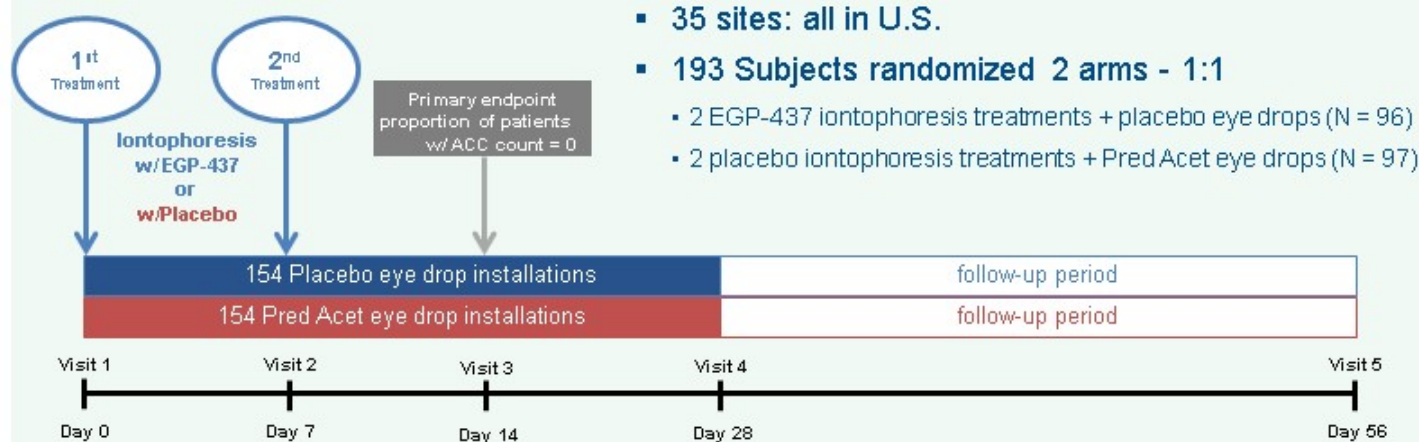
154 treatments

# Initial Phase 3 Non-Inferiority Anterior Uveitis Trial

## Trial Design and High-Level Results



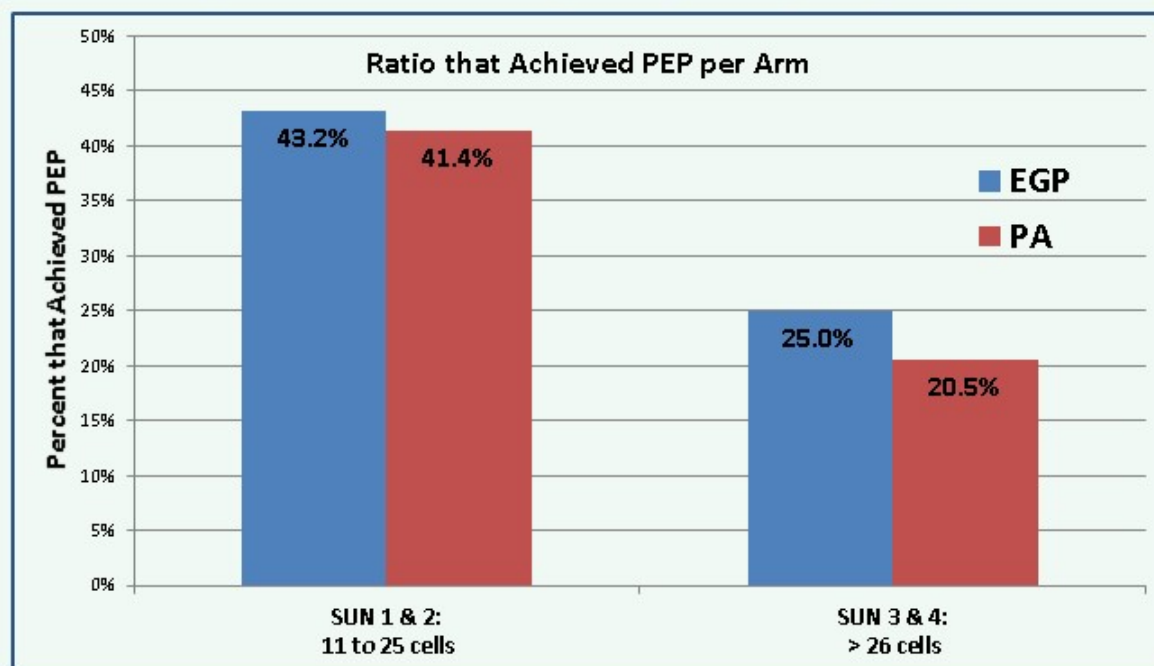
### Trial Design



### High-Level Results

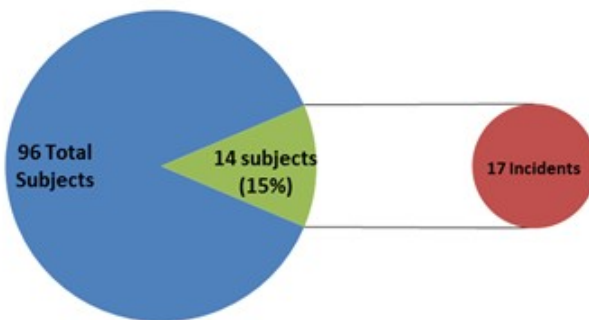
- Successfully demonstrated same response rate when comparing EGP-437 to standard of care (prednisolone acetate 1%)
- Lower incidence of increased intraocular pressure (IOP) with EGP-437 treatment

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

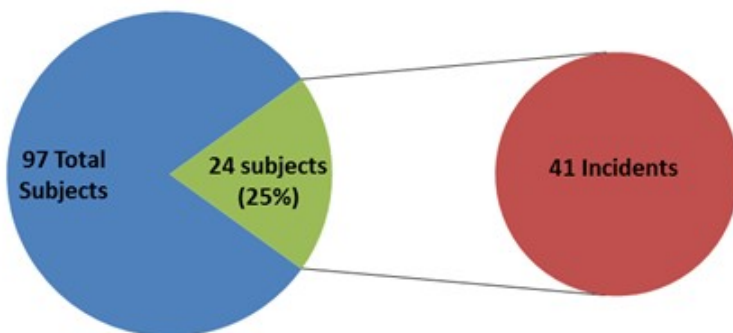


\*ITT = Intent to Treat

EGP-437: Subjects with IOP Increase

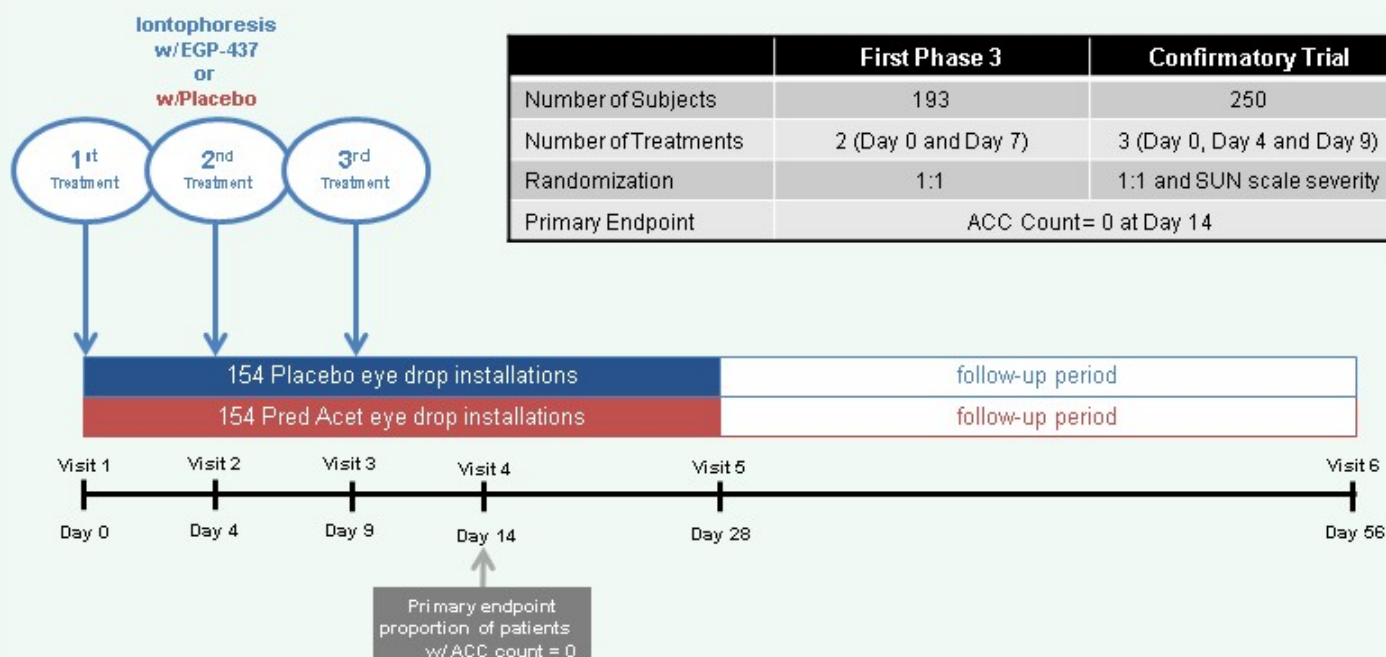


Pred Acetate: Subjects with IOP Increase



- 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

# Anterior Uveitis: Confirmatory Pivotal Phase 3 Trial Design



- **Control arm:** Same dose and frequency
- **Active arm:** additional iontophoretic treatment prior to Primary Endpoint visit
  - Same iontophoretic dosage: 1.5mA by 2.7 minutes



- 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

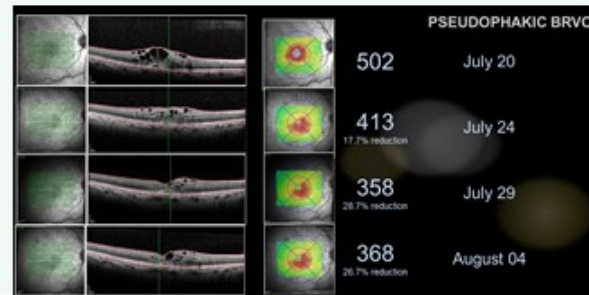
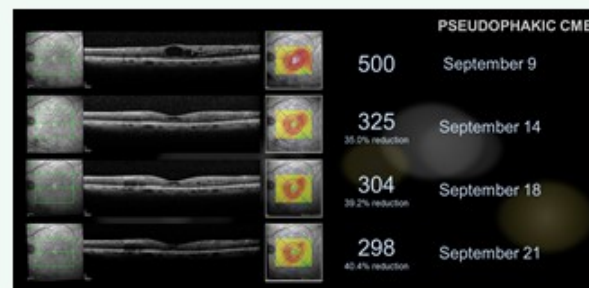
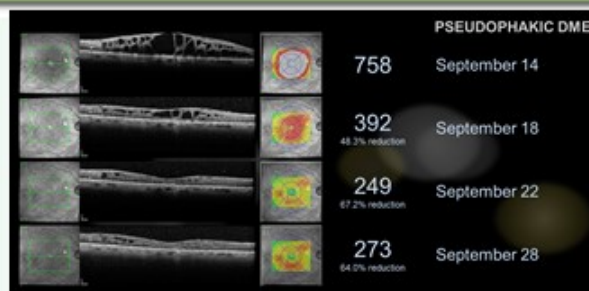
### Trial Design

- Phase 1b / 2a clinical trial: First Leg
- 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
- **First Leg Completed**

- **Proof of concept trial confirms that iontophoresis can non-invasively deliver efficacious quantities of drug to back of eye**

	Number	DME	RVO	CME
Phakic	9	6	3	
Pseudophakic	9	4	3	2

- **Efficacy: one-third of subjects responded**
  - Pseudophakic eyes responded better than phakic eyes
  - Positive response from all subtypes (DME, RVO and CME)
- **Excellent Safety: no increase in IOP**
- **Second leg: additional 15 subjects**
  - Test hypothesis of phakic vs pseudophakic eyes
  - Enroll 5 phakic and 10 pseudophakic eyes
  - Modify dosing regimen
- **Medical Need: steroid interrogation, reduce anti-VEGF injections**

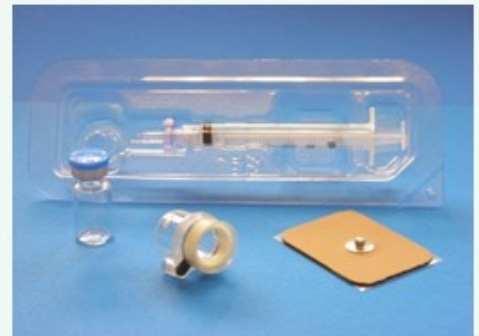


- **Valeant Pharmaceuticals – Bausch + Lomb (NYSE/TSX: VRX)**
  - Exclusive license to manufacture, sell, distribute and commercialize throughout the world for use in field of uveitis
    - Upfront cash payment and milestone payments
    - Royalties based on net sales: high single digits
  - EyeGate responsible for completion of the development of anterior uveitis indication in U.S.
  - Valeant responsible for development outside U.S.
  - Valeant has right of last refusal for product outside field of uveitis
    - Must negotiate for access to additional indications
- **EyeGate is developing EGP-437 for additional indications**
  - Macular Edema
  - Post Cataract Surgery Inflammation



### 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)

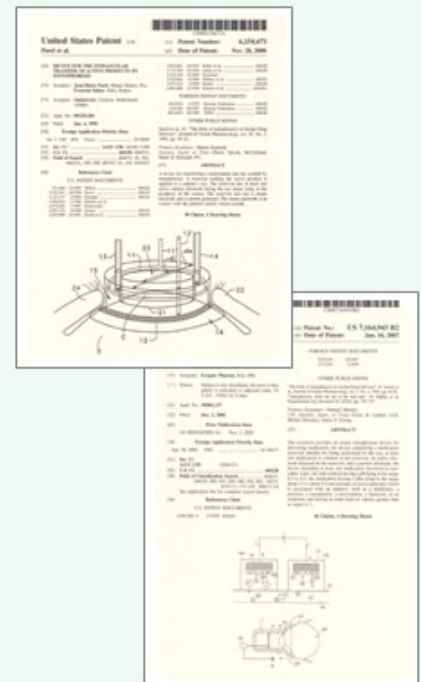


### Reimbursement: In-office treatment involves multiple code sets.

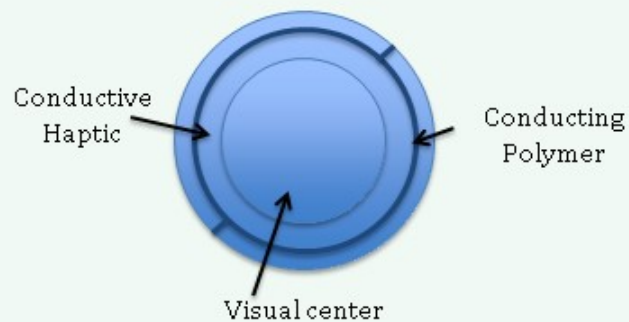
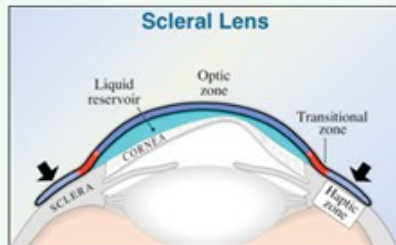
- **CPT Code:** In addition to office reimbursement, reimbursement for performing treatment
- **J-code:** The kit (drug + disposables) will be billed under a J-code Payment that would be based on ASP (price we establish) + x% for the kit

## 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



- **Objective:** *In Vivo* (rabbits) proof-of-concept by end of Q1 2016
- **Stage 1: Screening**
  - The effect of specific parameters determined
    - polymer charge and composition
    - polymer drug loading and drug release
- **Stage 2: Testing *In Vivo* - on the Eye**
  - Demonstrate results of a loaded lens design vs the current applicator
  - Will include data on the response of the animals as well as tissue concentration data



- **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**
  - Confirmatory pivotal Phase 3 trial initiated
  - Potent drug with proven safety profile when delivered by our system
  - Mitigates corticosteroid side-effect, elevated IOP
  
- **Macular Edema Trial Ongoing**
  - 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