

**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): **June 1, 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:

<b>Title of each class:</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered:</b>
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 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 Jeffries Virtual Healthcare Conference, being held June 2-4, 2020, at which Stephen From, President and Chief Executive Officer of the Company, will be presenting at approximately 2:30 p.m. Eastern Time on June 4, 2020 via webcast at <http://wsw.com/webcast/jeff126/eyeg/>.

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 June 1, 2020](#)

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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: June 1, 2020

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Corporate Presentation



NASDAQ: EYEG

# 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 04, 2020. 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 ([www.EyeGatePharma.com](http://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 the Company and its product candidates. Such information may be deemed material information, and the Company may use these channels to comply with its disclosure 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 filings, 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.

- EyeGate is NASDAQ listed; went public in 2015
- Product under development, OBG, is an eye drop formulation of modified hyaluronic acid (HA)
  - Currently being developed for two indications: wound healing and dry eye
- HA is a natural substance in the body that promotes wound healing and provides hydration and lubrication
- OBG has recently completed clinical development for the first indication, wound healing, by demonstrating **superiority** over standard-of-care in a pivotal study
- OBG has recently completed a follow-on phase 2 dry eye study and continues to demonstrate healing of the corneal surface



- OBG supports corneal health and protects/treats the eye
- OBG is a crosslinked or chemically modified version of the natural polymer hyaluronic acid (“HA”)
  - HA has a high viscosity that promotes wound healing and provides hydration and lubrication
  - Crosslinking stabilizes the HA molecule and prevents degradation while on the ocular surface
- Crosslinking provides a prolonged retention (up to 2 hrs) on the corneal surface without causing blurriness (supporting clinical data)
  - The viscosity of OBG decreases with blinking due to its high shear thinning properties
- Will be the only HA eye drop in the U.S. where HA is the active ingredient
  - HA at 0.75% concentration is preservative free; only other ingredients are water and PBS (pH and osmolarity)

OBG being developed as a class II device (de novo filing)

- Recently, demonstrated statistical significance in a pivotal study against a bandage contact lens for the acceleration of wound healing in patients undergoing PRK surgery (9mm epi defects)
  - Development for this indication complete; preparing *de novo* filing
- OBG has now demonstrated that it effectively treats patients with dry eye
  - A uniquely designed study confirmed the ability of OBG eye drops to improve the ocular surface for several important ophthalmic endpoints
  - Outperforming the positive control, Allergan's Refresh Preservative-Free lubricant
  - Focus is on Moderate Dry Eye patient population (greatest opportunity)
- Next step: pre-submission meeting with FDA's CDRH Division to confirm pivotal study design

**Dry Eye *de novo* filing only requires:**

- **ONE pivotal study and**
- **ONE endpoint**



### ➤ OBG Stand-Alone Device

- **Wound Healing:** Development completed for wound healing (post PRK surgery)
  - Completing manufacturing testing required to file *de novo* application
  - Targeting filing *de novo* application by end of 2020
- **Dry Eye:** FDA meeting scheduled for July 13 to discuss moving into pivotal study
  - Targeting initiation of pivotal study by end of 2020

### ➤ OBG Plus Active

- First combination product is OBG plus an antibiotic - 505(b)(2) filing
  - Pre-IND Meeting scheduled for Aug 10
  - Targeting end of 2020<sup>1</sup> for IND filing
  - Same concentration, dosing regimen, indication as Vigamox (expect only ONE Ph 3 study<sup>1</sup>)

1. Will confirm at pre-IND meeting



## OBG: Dry Eye

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- Follow-on Pilot Study

- Punctates are a sign of epithelial compromise (corneal barrier disruption) and is characterized by a breakdown of the epithelium of the cornea and an increased permeability to fluorescein dye
- Corneal barrier disruption is associated with an increased risk of corneal ulceration, corneal haze and decreased vision
- Corneal permeability to fluorescein dye is used to clinically evaluate severity of corneal barrier disruption
- PE is associated with many pathologic ocular inflammatory conditions, which can include:
  - **dry eye**, conjunctivitis, trauma/corneal abrasions, contact lens wear, and chemical irritation and burns
- Nothing currently approved for the treatment of PE in the U.S.

**Planned “indications for use”:  
improvement of punctate epitheliopathy in patients with dry eye**

- Approximately 18 million **diagnosed** with dry eye in the U.S.<sup>1</sup>

Mild	Moderate	Severe	Total
9.0 Mn	7.6 Mn	1.4 Mn	18 Mn
50%	42%	8%	100%

- Severe Population is well served: 1.4 million patients diagnosed with 62% actively taking Rx anti-inflammatory drops and 94% of these patients are also taking OTC lubricant drops
- **Moderate Population provides a Significant Market Opportunity**
- Only 17% of patients are actively taking Rx anti-inflammatory drops and 80% of these patients are also using OTC lubricant drops
  - Only 17% of patients taking just OTC lubricants

**When OTC lubricants are no longer enough:**

- **OBG is both a treatment and a lubricant**
- **The only dry eye product to beat a bandage contact lens in wound healing<sup>2</sup>**

- 20 patients and 40 eyes as both eyes must qualify for study randomization
- Investigator masked with positive-control
- Patient acted as own control; one eye randomized to OBG and one eye randomized to Refresh®
- 7 day run-in period with all eyes taking Refresh QID, followed by 14 day QID treatment period
- Main Inclusion Criteria:
  - Fluorescein staining of cornea using NEI scale ( $\geq 4$ , max is 15) and
  - Slit lamp Tear Film Break-Up Time ( $\leq 7$  seconds)
- Effectiveness Outcomes:
  - Treatment assessments: at time zero on visit days
  - Post-application assessments: at 30 and 60 minutes after drops applied
    - Drop applied to respective eye after all treatment assessments completed

## ➤ STRONG DESIGN

- **Small N: Only 20 patients – investigator masked with patient as their own control**
  - Both eyes of patient had to qualify; one eye was randomized to OBG and the other eye to a positive control
  - Reduces interpatient variability
- **High Standard: OBG against a positive control; Allergan's Refresh® Preservative Free lubricant**
  - Drugs developed for dry eye go against placebo (vehicle)

## ➤ POSITIVE RESULTS

- **Objectives – corneal health, tear film and vision**
  - All OBG assessments support central cornea healing (Staining, HOA, TFBUT and BCVA)
- **OBG outperforms in central cornea staining with a 25% improvement from baseline vs only 15% for Refresh®**
  - Supports data seen in first study where OBG improvement over vehicle (saline solution) at Day 14 was 19%
  - Xiidra demonstrated a **6.9% difference** over **vehicle** at Day 84 in the Opus 3 study (inferior region)
    - Xiidra (~\$400 million 2018 sales) sold for \$3.4 billion (upfront) in 2019 to Novartis (additional \$1.9 bn milestones)
  - Also, OBG works quickly with a 10% improvement at Day 7 vs NO improvement for Refresh®



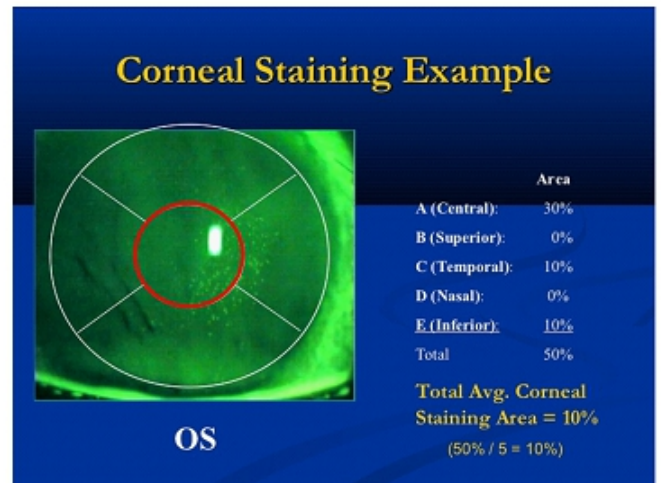
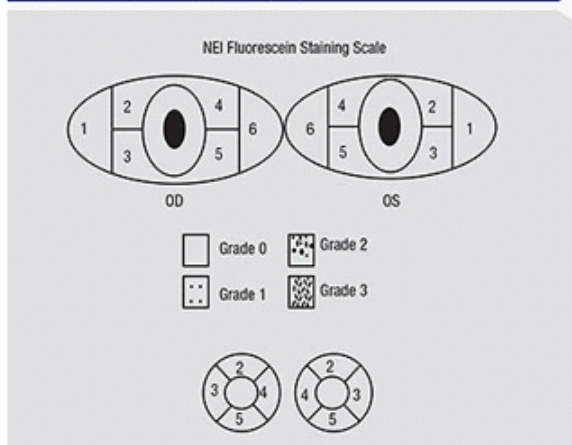
## **OBG: Dry Eye Study Treatment Assessments**

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- Corneal Staining
- High Order Aberrations (HOA)
- Best Corrected Visual Acuity (BCVA)



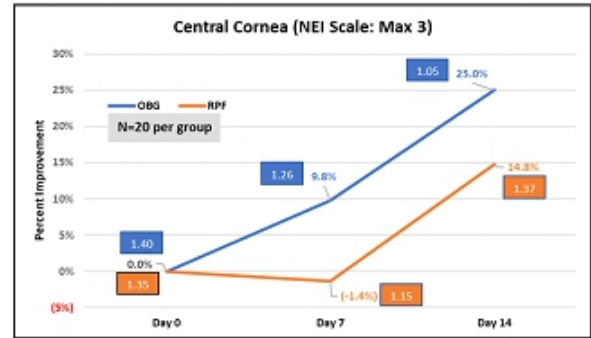
Figure 1. Fluorescein Staining Scale



- NEI Composite Corneal Staining Score: Central Cornea Quadrant Staining Very Important for Vision

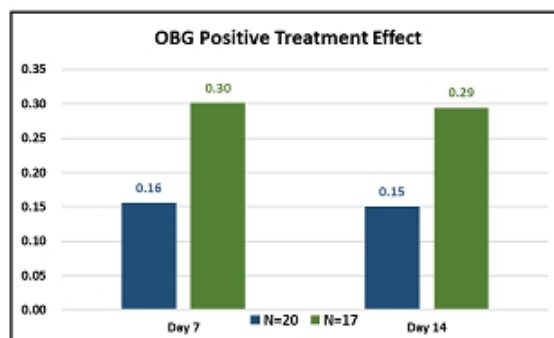


- All 5 corneal regions assessed but central region of cornea is most important as it covers pupil region
  - Responsible for vision quality and corneal sensitivity
- Central corneal staining demonstrated a positive treatment effect at Day 7 and Day 14
- At Day 14, OBG had a strong improvement from baseline of 0.35 (25.0%) versus Refresh Plus PF lubricant at 0.20 (14.8%)
  - Providing an overall positive treatment effect of 0.15 for OBG
- OBG also showed improvement more quickly than Refresh Plus PF with a positive treatment effect of 0.16 at Day 7
  - Restasis and Xiidra take weeks to months



PE-042: Central Cornea:		
NEI Score: Max=3.0	RPF	OBG
Baseline	1.35	1.40
Day 7	1.37	1.26
Change from Baseline	0.02	(0.14)
<b>Treatment Effect</b>		<b>0.16</b>
Day 14	1.15	1.05
Change from Baseline	(0.20)	(0.35)
<b>Treatment Effect</b>		<b>0.15</b>

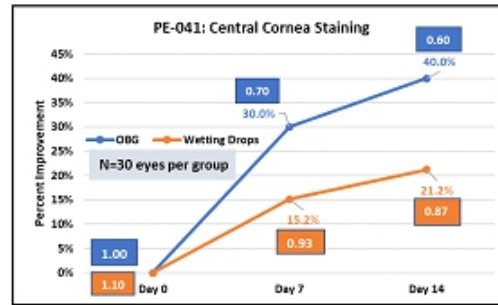
- Enrollment based on Total Corneal Staining
- 3 subjects (of the 20 enrolled) had a zero score in staining of central region of the cornea in at least 1 eye
- Removing these subjects demonstrates a much stronger positive treatment effect for OBG for central region of cornea
- The treatment effect increases by ~100%
- Day 7 is 0.30 versus 0.16 and 0.29 versus 0.15 at Day 14



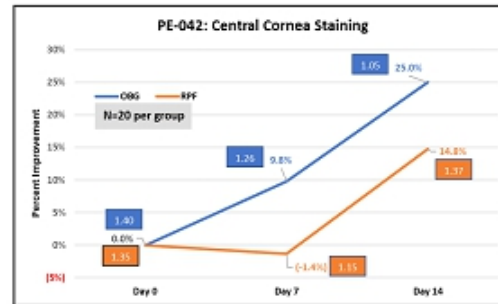
NEI Score: Central Cornea (Max Score = 3)		
N= 20 subjects	RFP	OBG
Baseline	1.35	1.40
Day 7	1.37	1.26
Change from Baseline	0.02	{0.14}
Treatment Effect		0.16
Day 14	1.15	1.05
Change from Baseline	{0.20}	{0.35}
Treatment Effect		0.15

NEI Score: Central Cornea (Max Score = 3)		
N= 17 subjects	RFP	OBG
Baseline	1.41	1.59
Day 7	1.50	1.38
Change from Baseline	0.09	{0.21}
Treatment Effect		0.30
Day 14	1.24	1.12
Change from Baseline	{0.18}	{0.47}
Treatment Effect		0.29

- Staining improvement in central region of cornea was similar to first pilot study against vehicle (wetting drops)
- Both studies demonstrated that OBG works quickly, with a treatment effect of 0.13 and 0.16 at Day 7 against control



PE-041: Central Cornea		
NEI Score: Max=3.0	Wetting Drops	OBG
Baseline	1.10	1.00
Day 7	0.93	0.70
Change from Baseline	(0.17)	(0.30)
Treatment Effect	0.13	
Day 14	0.87	0.60
Change from Baseline	(0.23)	(0.40)
Treatment Effect	0.17	



PE-042: Central Cornea:		
NEI Score: Max=3.0	RPF	OBG
Baseline	1.35	1.40
Day 7	1.37	1.26
Change from Baseline	0.02	(0.14)
Treatment Effect	0.16	
Day 14	1.15	1.05
Change from Baseline	(0.20)	(0.35)
Treatment Effect	0.15	

OBG= Ocular Bandage Gel, RPF= Refresh Plus® Preservative Free (Refresh PF)

## OBG Central Region



Staining of the Central Region  
(over the pupil: affects vision)

## Xiidra Inferior Region



Staining of the Inferior Region  
(below the pupil: does not affect vision)

Scoring for each region is from 0 to 3

### OBG pilot study:

- Against REFRESH Lubricant (positive control)
- Improvement over REFRESH = 0.15

Product	Corneal Region	Control	Treatment Effect
OBG	Central	Refresh Lubricant	0.15
Xiidra	Inferior	Vehicle	0.17

### OPUS 3 Pivotal study:

- Against VEHICLE (negative control)
- Improvement over VEHICLE = 0.17

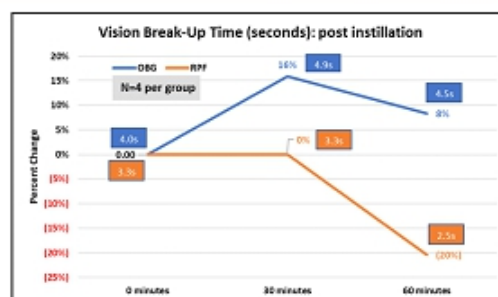


## **OBG: Dry Eye Study Post Application Assessments**

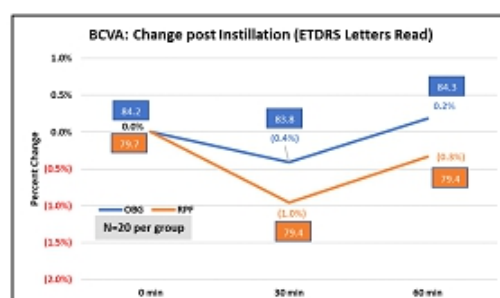
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- Vision Break-Up Time (VBUT)
- Best Corrected Visual Acuity (BCVA)

- First clinical evidence demonstrating that OBG does not cause blurriness while residing on the ocular surface
- Positive VBUT means tear-film more stable. This is expected while OBG resides on the ocular surface. While a very small sample size for VBUT<sup>1</sup>, this validates that OBG is staying on the eye
- OBG's high-viscosity is expected to cause blurriness while on the eye. The BCVA data validates that this is not the case. This is due to the High Shear-Thinning qualities of OBG.



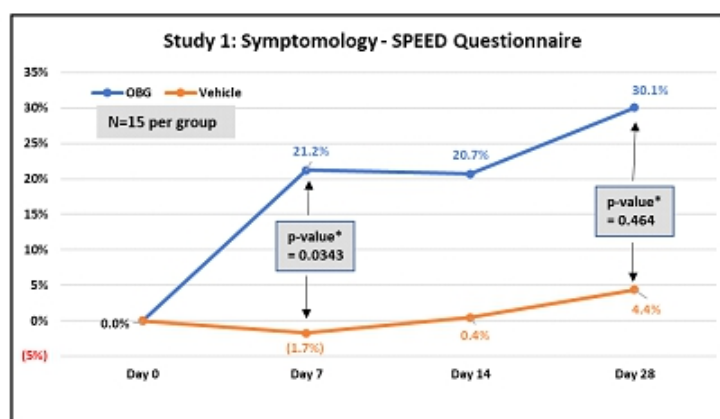
VBUT (seconds)	RFP	OBG
0 minutes	3.33	4.04
30 minutes	3.33	4.92
Change from 0 minutes	0.00	0.88
Treatment Effect		0.88
60 minutes	2.54	4.50
Change from 0 minutes	(0.79)	0.46
Treatment Effect		1.25



BCVA (letters)	RFP	OBG
0 minutes	79.69	84.15
30 minutes	78.93	83.81
Change from 0 minutes	(0.76)	(0.34)
Treatment Effect		0.42
60 minutes	79.43	84.31
Change from 0 minutes	(0.26)	0.16
Treatment Effect		0.42

1. VBUT= Vision Break-up Time: Using a HD Analyzer, it is a non-invasive method to determine Tear-Film Stability or Break-up Time  
 2. BCVA = best corrected visual acuity

- OBG achieved a 30% improvement (decrease) from baseline vs only 4% for control (vehicle)
- OBG demonstrates fast onset with Statistical Superiority at Day 7, which continues through Day 28





## OBG: Wound Healing

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- PRK is a surgical correction of refractive errors for patients who are not suitable candidates for LASIK due to:
  - Inadequate corneal thickness, larger pupil size, dry eye, and anterior basement membrane disease
- PRK involves controlled mechanical removal of corneal epithelium with subsequent lasering of stroma
- Although PRK yields excellent visual results, common complications include:
  - Post-operative pain, risk of infection, corneal haze, decreased contrast sensitivity, and slower visual recovery
- Enabling the epithelium to heal faster may mitigate the immediate peri-operative complications as well as improve the longer visual term outcomes
- PRK population ideal for clinical development:
  - Large population (~700,000 LASIK/PRK surgeries per year in the U.S.)
  - Large wound (9mm), same size for all patients and know time zero
  - Healthy eyes required and time to healing well established
- Standard-of-care is a Bandage Contact Lens (BCL); can result in subsequent erosion of epithelium

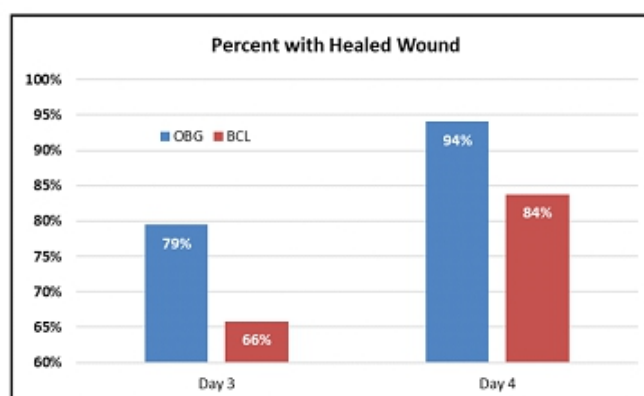
- Two-arm, controlled pivotal study masked via reading center
  - OBG (crosslinked HA eye drop) vs. standard-of-care (bandage contact lens)
  - Endpoint: percentage of eyes in each group with fully closed wound at Day 3 (and remain closed)
    - Wound closure measured by staining of wound; photo of stained wound is sent to reading center
- 250 patients were enrolled (9 sites, all in U.S.) with 234 randomized post surgery (had 16 screen failures)
  - 234 patients qualified for the study with surgery performed and patient randomized to OBG or BCL group
  - Three days post surgery eyes are stained with fluorescein and photos are sent to reading center
  - Patient is followed for 2 weeks post-surgery: all have completed and exited the study

➤ **Clinical development complete**

- **Next step is to file *de novo* application for commercialization**
- **Completing manufacturing testing required to file**

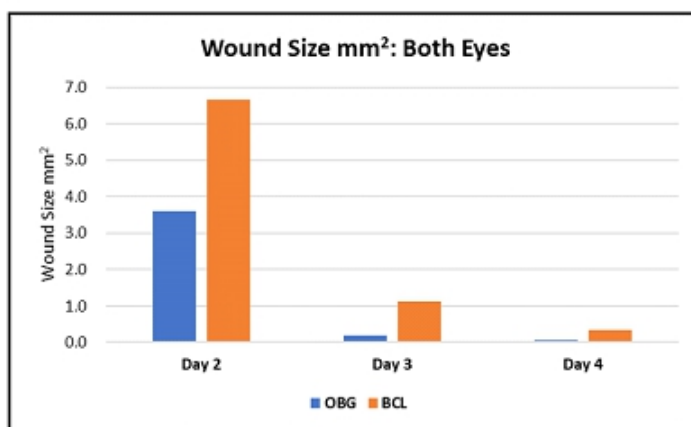
- Comparator is SOC: Bandage contact lens (BCL)
- Primary is percentage healed at Day 3 in each group
- At day 3, 80% of study eyes receiving OBG were completely healed compared with 67% in the BCL group
- Results in a p-value of 0.0203, in favor of OBG: OBG has demonstrated superiority over BCL
- Similar ratio when comparing all eyes at day 3, but stronger p-value of 0.0119

Demonstrated superiority for primary endpoint with a  
**p-value of 0.0203**



- Day 2, the average wound size for all eyes treated with OBG was only 3.61mm<sup>2</sup>, compared to 6.66mm<sup>2</sup> for eyes treated with BCL
- Day 2 is 48 hours post surgery and subjects have only taken 8 drops of OBG
- The maximum wound size was 19.89mm<sup>2</sup> for OBG vs 58.05mm<sup>2</sup> for SOC

**Wound size on average was 46% smaller for OBG subjects on day 2**





## **OBG: Combination Product**

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- OBG plus Moxifloxacin Hydrochloride (Vigamox)
  - A 505(b)(2) filing requiring only one pivotal study for registration (superiority against placebo)
  - Will mirror Vigamox label: same concentration and dosing regimen for the treatment of bacterial conjunctivitis
- Expected IND filing by end of year 2020
  - Preparing for 28 day GLP tox study
  - pre-IND meeting to confirm IND and NDA filing requirements scheduled for Aug 10
- **Antibiotic eye drops are widely prescribed** including conjunctivitis and trauma
  - ALL ocular wounds and surgical procedures (e.g. cataract surgery, PRK and LASIK)

### Large market opportunity:

- 16 million Rx's written annually in the U.S.<sup>1</sup>
- Highly-differentiated product (wound healing device & antibiotic)

### ➤ **Three FDA Meetings Requested**

- June 9: Meeting with CDRH to discuss final packaging (manufacturing)
- July 13: Meeting with CDRH to discuss Dry Eye Pivotal Study
- Aug 10: pre-IND meeting requested with CDER to discuss combination product

### ➤ **PRK *de novo* filing:** Completing manufacturing testing required to file

- Targeting filing of de novo application by end of 2020

### ➤ **Dry Eye:** Targeting initiation of pivotal by end of 2020

### ➤ **Combination Product:** Targeting filing IND by end of 2020

### ➤ **Finance:** Cash into Q1 2021