

**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 14, 2021**

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:

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
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.

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](#)
104 Cover Page Interactive Data File (embedded within the Inline XBRL document).

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/ Brian M. Strem, Ph.D.
Brian M. Strem, Ph.D.
President and Chief Executive Officer

Date: September 14, 2021



EyeGate Pharmaceuticals (NASDAQ: EYEG)

Sept 2021

Forward Looking Statements

Some of the statements are “forward-looking” and are made pursuant to the safe harbor provision of the Private Securities Litigation Reform Act of 1995. These “forward-looking” statements include statements relating to, among other things, the commercialization efforts and other regulatory or marketing approval efforts pertaining to EyeGate’s products, including EyeGate’s PP-001 and OBG products, as well as the success thereof, with such approvals or success may not be obtained or achieved on a timely basis or at all, the ability of EyeGate to complete the acquisition of Bayon Therapeutics in a timely manner or at all, and the results and potential benefits of the acquisition of Bayon Therapeutics, which will be subject to the receipt of all necessary approvals and satisfaction of all closing conditions for the completion of the transaction. These statements involve risks and uncertainties that may cause results to differ materially from the statements set forth in this presentation, including, among other things, certain risk factors described under the heading “Risk Factors” contained in EyeGate’s Annual Report on Form 10-K filed with the SEC on March 25, 2021 or described in EyeGate’s other public filings. EyeGate’s results may also be affected by factors of which EyeGate is not currently aware. The forward-looking statements in this presentation speak only as of the date of this presentation. EyeGate expressly disclaims any obligation or undertaking to release publicly any updates or revisions to such statements to reflect any change in its expectations with regard thereto or any changes in the events, conditions or circumstances on which any such statement is based.

Focus	<ul style="list-style-type: none"> • EyeGate is an ophthalmic specialty pharmaceutical company
Mergers Create Expanded Pipeline	<ul style="list-style-type: none"> • Pipeline in ophthalmology transformed by Panoptes acquisition and Bayon pending acquisition • PP-001 is a best-in-class DHODH inhibitor • B-203 is a small molecule capable of conferring light sensitivity to degenerating retinas*
Clinical Stage	<ul style="list-style-type: none"> • PP-001 Phase 2 PoC trial in Dry Eye Disease ongoing • OBG targeting Phase 3b readiness for accelerating PRK recovery • B-203 first-in-man trial expected to initiate in Q2 2022*
Partnership Opportunities	<ul style="list-style-type: none"> • PP-001 for non-core indications (ie autoimmune diseases) • OBG commercialization



* - Acquisition of Bayon Therapeutics pending, definitive agreement under negotiation

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Corporate Overview

EyeGate Pharmaceuticals is a clinical-stage company with unique platforms

PP-001: 4th gen small-molecule Dihydroorotate Dehydrogenase (DHODH) inhibitor

- Validated immunomodulatory class, approved for RA (Sanofi-Arava) and MS (Sanofi-Aubagio)
- Best-in-class with picomolar potency with no off-target side effects of prior generations

OBG: modified form of Hyaluronic Acid (HA)

- Eye drop that promotes wound healing and provides lubrication
- Ph3 clinical study demonstrated accelerated wound healing in PRK patients

B-203: novel small molecule photoswitch*

- Confers light sensitivity to sections of the retina with upstream degenerated photoreceptors
- Entering Ph1b trials in late-stage RP expected in Q2 2022



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Pipeline - Unique platforms addressing ophthalmic diseases

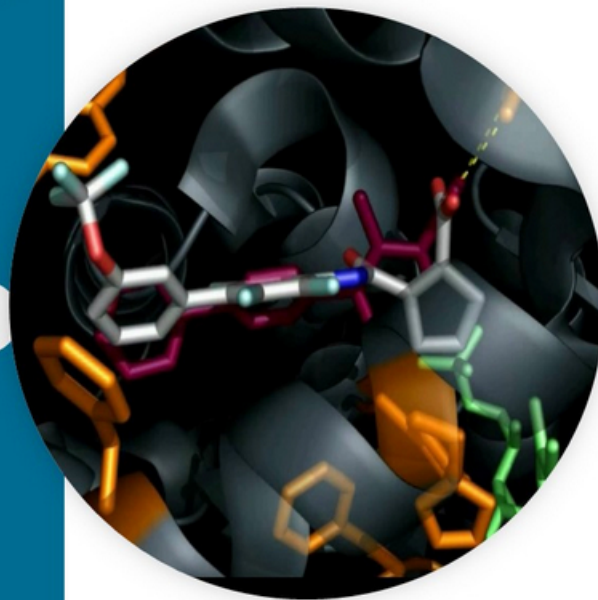
	Category	Product Formulation	Indication	Development Stage				Anticipated Near-Term Milestones
				Pre-clin	Phase 1	Phase 2	Phase 3	
Anterior Segment	Ocular Surface Disease	PP-001 eye drop	Moderate-Severe DED	→				• Data from PoC Ph2 Trial in Q4 2021
	Surgical Recovery	OBG eye drop	PRK Surgical Recovery	→				• PIND in Q4 2021 • Ph3b registration trial in Q3 2022
Posterior Segment	Inherited Retinal Disease	B-203* IVT	Mutation Agnostic Retinitis Pigmentosa	→				• Ph1b POC study in Q2 2022 • PIND in Q2 2022
Systemic	Autoimmune	PP-001 Oral	TBD	→				• IND enabling studies in Q4 2021 • Seeking strategic partnerships



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PP-001
DHODH Inhibitor



Dry Eye: Opportunity

- A **multifactorial disease** of the ocular surface characterized by a **loss of homeostasis of the tear film**
 - Inflammation is the common denominator of pathogenesis
- Significantly affects the quality of life
 - Chronicity, pain and irritation, blindness in severe form
- Tens of millions worldwide
 - 9 million¹ people in U.S. have the moderate/severe form of DED
- No definitive treatment that works in most patients: only ~1.6 out of 9 million patients are being treated
 - Cyclosporine 0.05% (Restasis®, Allergan - 2020 US sales \$1.3 billion²)
 - Lifitegrast 5% (Xiidra®, Shire - 2020 US sales of \$376M³)
 - Steroids
- To date only anti-inflammatories have been approved by FDA
 - Will require multiple mechanisms to satisfy patient population
 - Xiidra's introduction in 2016 helped increase overall prescribing⁴
 - Rx's went from ~3mn to ~4mn per annum (1.4mn unique patients in 2020)



1. Global Data's Dry Eye Syndrome Global Drug Forecast and Market Analysis to 2026: Published June 2018
2. Based on Q4 2020 run rate reported by Abbvie

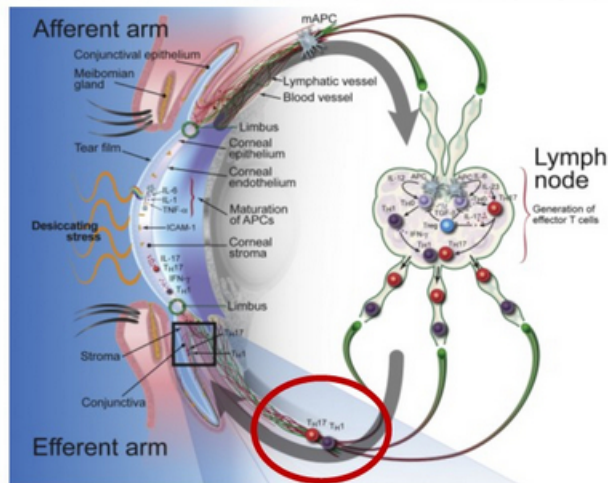
3. 2020 sales reported by Novartis
4. Symphony Health – OIS presentation 2020

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Why Target Dry Eye Disease with PP-001

Dry Eye Disease is T-Cell Mediated

PP-001 acts upstream to inhibit proliferation of T helper cells (Th1 and Th17) in lymph node

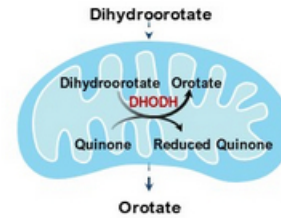
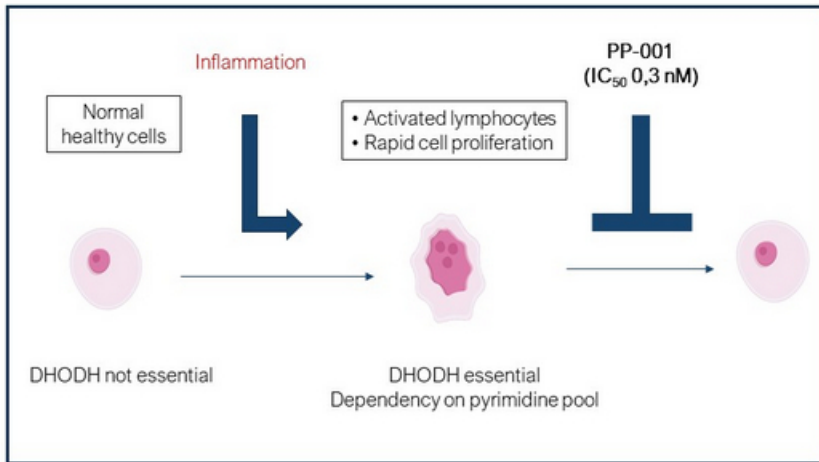


Perez et al., THE OCULAR SURFACE 2016, VOL. 14 NO. 2

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PP-001: an Inhibitor of Dihydroorotate Dehydrogenase (DHODH)

DHODH is an essential mitochondrial enzyme in the pyrimidine pathway for activated / abnormally proliferating cells – targeting DHODH ideal for disease specific therapeutic intervention



- Inhibition of activated lymphocyte proliferation
- Inhibition of tumor cell proliferation
- Blocking of cytokines: IL-17, IFN-g, VEGF, etc.
- Controlling cell differentiation

DHODH Inhibitors – Validated Drug Class for Autoimmune Diseases

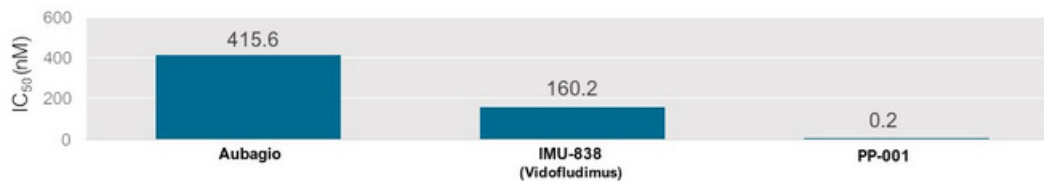
Sanofi: 2 versions of once-daily oral tablet

1. Arava (leflunomide) approved in 1998 for rheumatoid arthritis
2. Aubagio (teriflunomide) approved in 2012 for multiple sclerosis
 - Teriflunomide is the active metabolite of leflunomide

- Low selectivity and potency results in off-target side effects
 - Safety concerns of severe liver injury and other adverse events
 - Black box added regarding the risk of severe liver injury
- Aubagio still achieved revenue ~\$2.5B in 2020

Company	Drug	Status ¹
PTC Therapeutics	PTC299	Ph1b AML Ph2/3 Covid-19
Immunic	IMU-838 (Vidofludimus)	Ph2/3 UC, MS, CD
ASLAN	ASLAN003	Ph2 autoimmune
Clear Creek Bio	Brequinar	Ph2 AML Ph2 Covid-19
EyeGate Pharmaceuticals	PP-001	Ph2 Dry Eye Preclin autoimmune

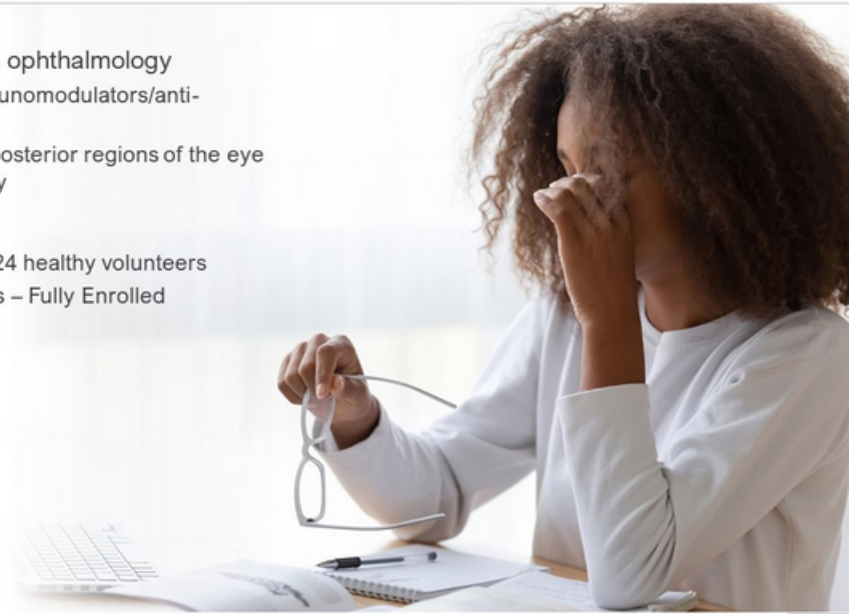
1. Most recent public sources available from April 2021



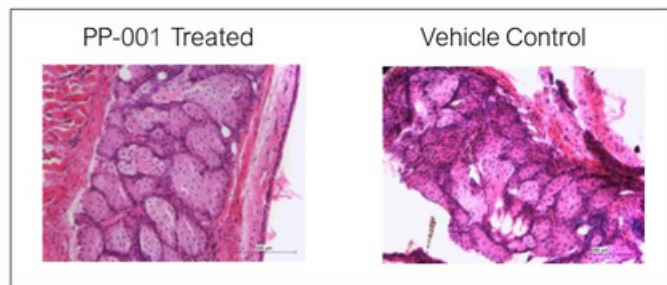
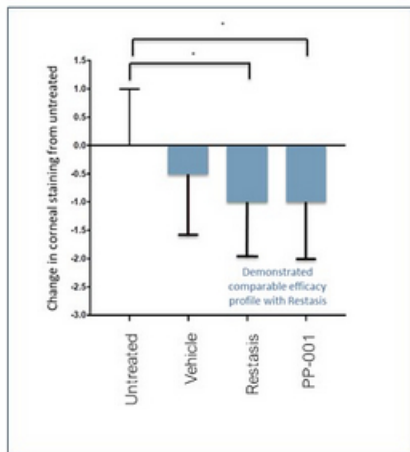
PP-001 overcomes safety concerns with greater specificity and best in class potency

PP-001: A First-in-Class Drug for Ophthalmic Chronic Inflammation

- Clinical development efforts focused in ophthalmology
 - High medical need for novel new immunomodulators/anti-inflammatories
 - Multiple diseases in the anterior and posterior regions of the eye offering substantial market opportunity
- Initial safety and efficacy PoC studies
 1. Dose-ascending study completed in 24 healthy volunteers
 2. PoC efficacy study in 21 DED patients – Fully Enrolled



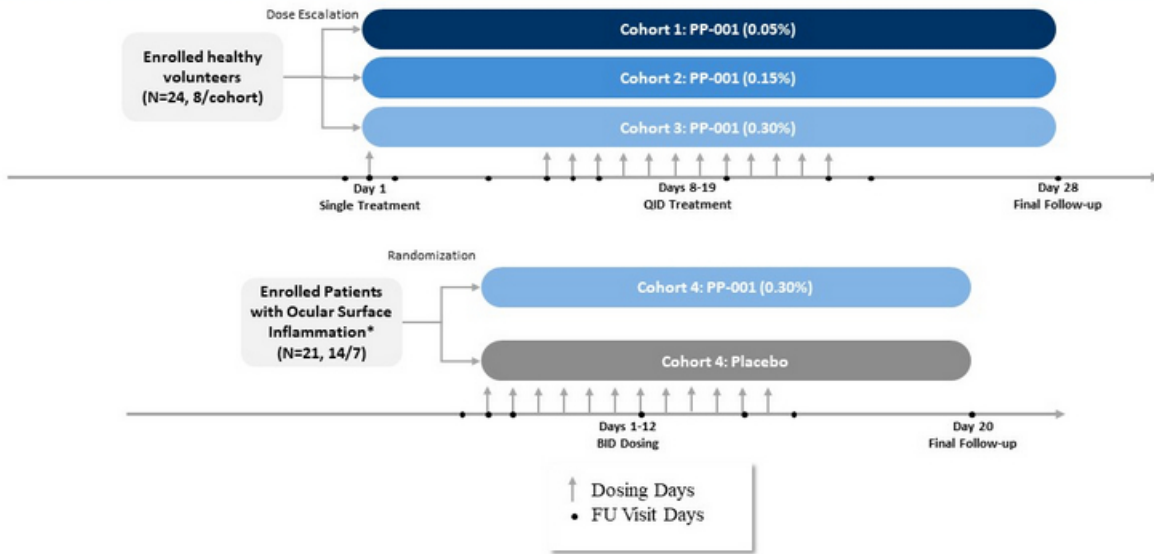
PP-001: Preclinical In Vivo Proof-of-Concept



Scopolamine patch applied for 20 days and placed in a controlled environment chamber

- 16 eyes per group were treated with 10 μ l QID for 20 days

PP-001: Phase 1/2a Dry Eye Trial – Fully Enrolled

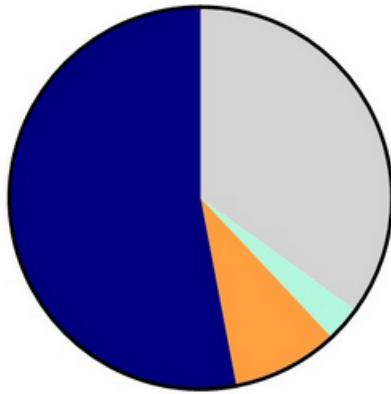


* - Key inclusion criteria: (1) Ocular surface inflammation defined by OSDI of at least 22
(2) Conjunctival hyperemia of Grade 2 on the Efron Scale or more in both eyes

OBG
Crosslinked Hyaluronic Acid



Ocular Surface Diseases



Epitheliopathies: Non-Dry Eye

53% ~28 million US patients
 Contact lens wear
 Ocular irritants
 Glaucoma medications

Epitheliopathies: Dry Eye

35% ~18 million US patients
 Episodic / mild
 Moderate
 Severe

Wounds: Trauma

3% ~2 million US patients
 Injuries / abrasions
 Chemical burns
 Difficult to heal PED/ulcers

Wounds: Surgery

9% ~5 million US patients
 Refractive surgeries (e.g., PRK)
 Cataracts
 Collagen cross-linking



1. American Academy of Ophthalmology (<https://www.aao.org/newsroom/eye-health-statistics>)

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Refractive Market Opportunity for Wound Healing



What Is PRK?

- 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
 - Anterior basement membrane disease
- PRK involves controlled mechanical **removal of corneal epithelium** with subsequent **lasering of stroma**



What Is The Unmet Need?

- While PRK yields superior visual results, **complications** include:
 - Post-operative pain
 - Risk of infection
 - Corneal haze
 - Decreased contrast sensitivity
 - Slower visual recovery
- Standard-of-care is a Bandage Contact Lens (BCL)**, which can result in **subsequent erosion of epithelium**



What Is The Opportunity?

- Enabling the epithelium to heal faster may **mitigate peri-operative complications** and **improve long-term visual outcomes**
- The **PRK population is ideal** for clinical development:
 - Large population (~850,000 LASIK/PRK surgeries per year in the U.S.)¹
 - Large wound (9mm), same size for all patients and known time zero
 - Healthy eyes required and time to healing well-established
- Preferred Laser Vision Correction Procedure of the US Military

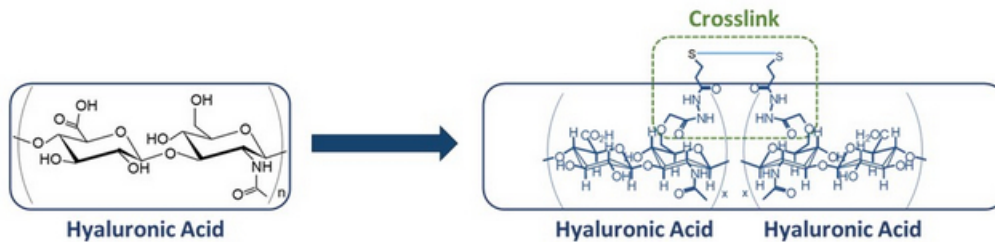


¹ American Academy of Ophthalmology and Ocular Surgery News: April 10, 2019

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OBG, a Natural Substance Promoting Healing

- OBG is based on a modified form of the natural polymer hyaluronic acid (HA)
- HA is a material with a high viscosity that promotes wound healing by enabling enhanced cell migration



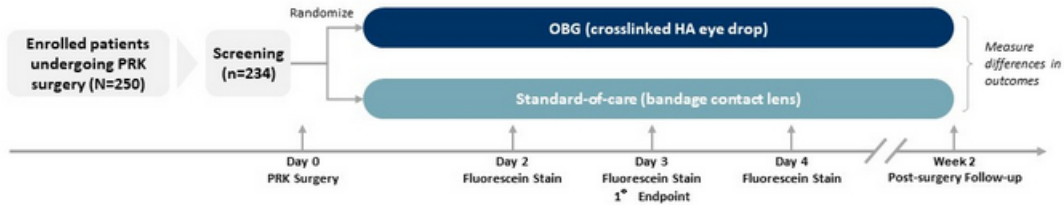
Covalent Crosslinking Creates Unique Attributes Ideal for Ocular Surface

- Improved Product Stability
- Longer retention on the ocular surface over non-crosslinked HA (2 hours vs minutes)
- Higher shear-thinning properties:
 - Able to achieve concentrations up to 7.5x current products (0.75% vs. others at 0.1-0.4%)
 - Decreased viscosity during blinking = no blurred vision
- 5 studies completed (3 PRK surgery and 2 dry eye) and ~400 eyes have been treated with OBG
 - Strong Safety and Efficacy profile

Demonstrated superiority of accelerated wound healing over a bandage contact lens in a late-stage clinical trial

PRK Study Design

Primary Objective: assess the effect of Ocular Bandage Gel (OBG) vs. a Bandage Contact Lens (BCL) in subjects who have undergone bilateral photorefractive keratectomy (PRK)



Study Design	Two-arm, randomized, positive-controlled, masked via reading center
Outcome Measures	<p><u>Primary Endpoint:</u></p> <ul style="list-style-type: none"> Complete corneal re-epithelialization on Day 3 (% of eyes with fully closed wound and remain closed) <p><u>Key Secondary Endpoint:</u></p> <ul style="list-style-type: none"> Mean Wound Size (Days 2, 3, 4)
Enrollment	250 patients enrolled (9 US sites) with 234 qualified patients randomized to OBG or BCL group post-surgery (16 screen failures)

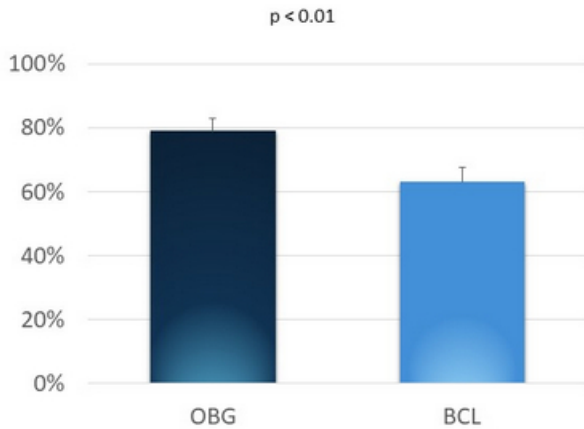


ClinicalTrials.gov Identifier: NCT03938883

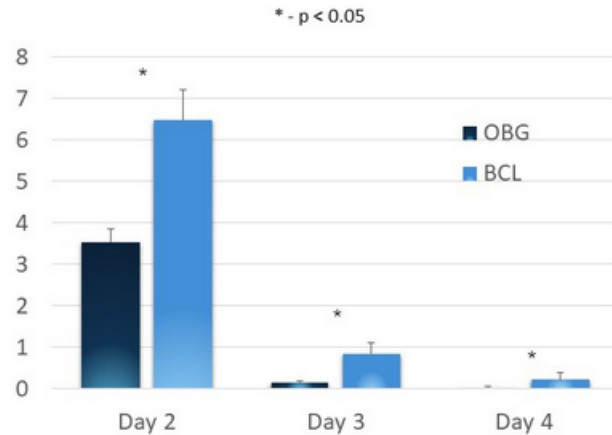
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OBG Demonstrated Superiority versus BCL

Percent of Patients with Complete Re-Epithelialization Day 3 (Mean ± SEM)



Mean Wound Size (mm²) (Mean ± SEM)



RECURRENT EROSION

Only 1 (0.9%) study eye in the OBG group had a recurrent erosion; there were 4 (3.5%) in the BCL group



BCL: bandage contact lens

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B-203 (BENAQ) Molecular Photoswitch*

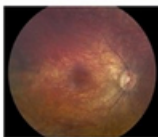


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Retinitis Pigmentosa (RP) – Disease Overview

Normal Eye



RP-affected Eye

Etiology

- 50+ genetically distinct subtypes from 150+ mutations
- Inherited disease

Presentation

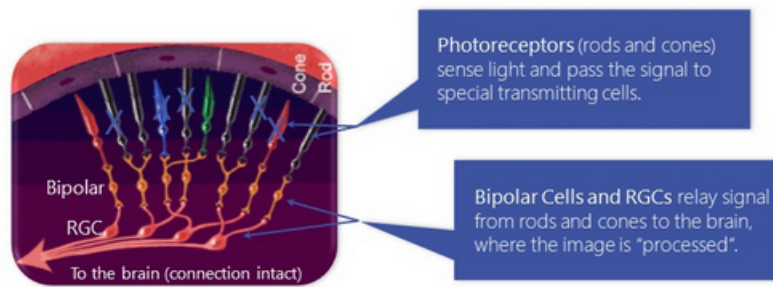
- Night blindness, reduced visual field range and eventual loss of central vision
- Visual acuity declines

Diagnosis

- Retinal exam (Black bone-spicule pigmentation)
- ERG provides definitive diagnosis
- Genetic testing

B-203 can potentially help RP patients with ANY gene mutation

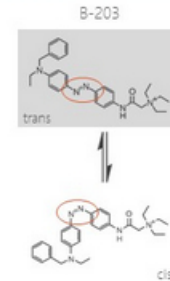
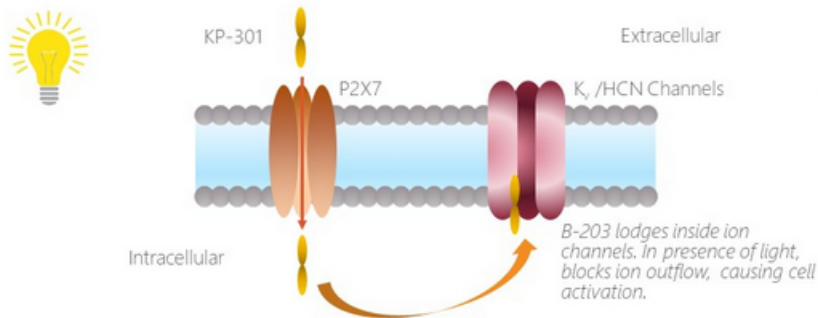
RP – How Retinal Degeneration Occurs



- Normal human retina has about 120 million rods (black & white, night vision, movement) and 6 million cones (color)
- Photoreceptors die (rods first, then cones), unable to activate Bipolar cells and Retinal Ganglion Cells ("RGCs")
- Bipolar cells and RGCs remain intact and retain ability to send signals to the brain

B-203: Turns RGCs "ON" in the Presence of Light

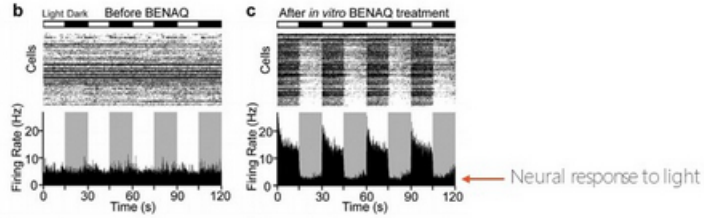
1. In RP, photoreceptors are no longer viable and therefore their companion "signal" cells (RGCs) are not capable of being activated or set to "OFF"
2. B-203 preferentially enters these "OFF" RGCs and turns them "ON" in the presence of light.*



* Visual light causes shape change of B-203 (trans → cis), blocking the movement of positively charged ions out of the cell through the K⁺/HCN channels. This build up of charged ions in the cell triggers activation (phototransduction signaling) to the brain.

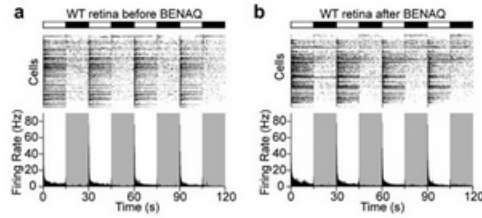
B-203: Flips Light Switch Response “ON” and “OFF”

Diseased Retina



B-203 is selective for RGCs in Degenerating Retinas

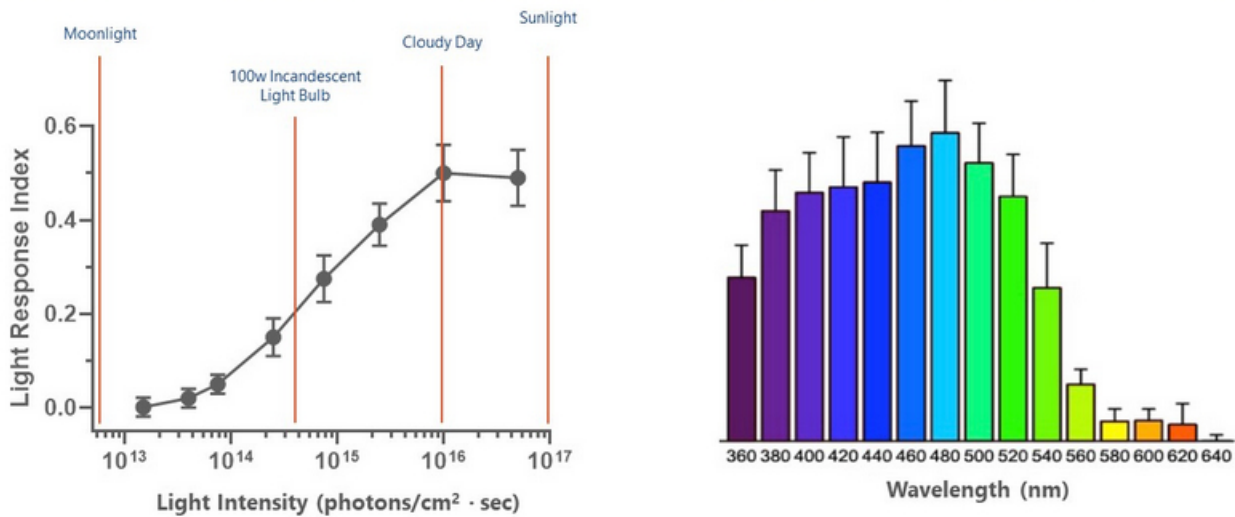
Normal Retina



Sci. Rep. 7, 45487 (2017)
Acquisition of Bayon Therapeutics pending, definitive agreement under negotiation

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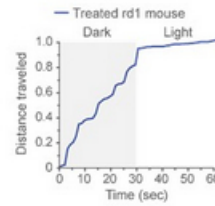
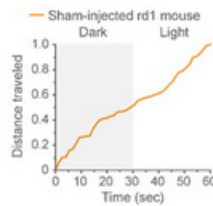
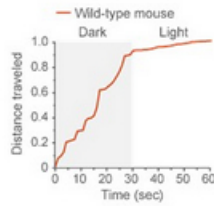
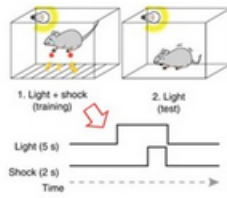
B-203: How Much and Which Wavelengths of Light is Needed?



Sci. Rep. 7, 45487 (2017), Banghart, Trauner et al (2008)
Acquisition of Bayon Therapeutics pending, definitive agreement under negotiation

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B-203 – Behavioural Changes in Diseased Mice



Distance traveled is a relative measure

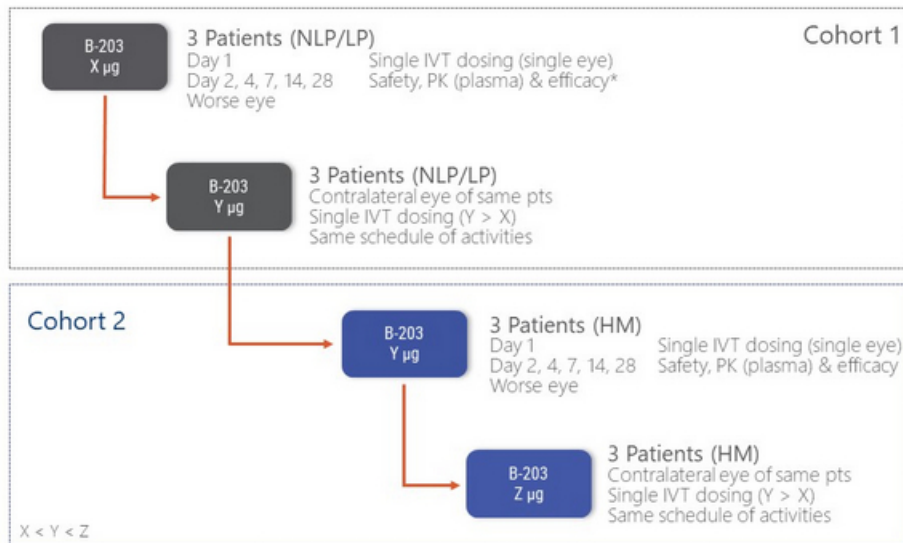
N=10 mice/group

Mice evaluated after IVT inj



Neuron. 81, 809-813 (2014)
This study used a predecessor molecule that behaves similarly to BENAQ, but less potent and shorter in vivo half-life. rd1 mouse has an inherited gene mutation causing similar retinal degeneration as observed in RP patients.
Acquisition of Bayon Therapeutics pending, definitive agreement under negotiation.

B-203: Phase 1b Study Design



Investigator led safety assessment along and between cohorts



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Anticipated Milestones

Q4 2021

- PP-001
 - Topline POC Dry Eye data
 - Oral formulation complete
- OBG
 - PIND for Ph3b readiness (PRK)
- B-203*
 - ODD Filing (RP)

Q1 2022

- PP-001
 - Completion of IND Enabling Studies
- OBG
 - POC study in persistent epithelial defect patients
- B-203*
 - CTN Filing (Australia)

Q2 2022

- PP-001
 - US IND filing Dry Eye
- OBG
 - Topline POC data in persistent epithelial defect patients
- B-203*
 - FPI Ph1b RP Trial
 - PIND for RP



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THANK YOU

