
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): December 6, 2021

EYENOVIA, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38365
(Commission
File Number)

47-1178401
(IRS Employer
Identification No.)

295 Madison Avenue, Suite 2400, New York, NY 10017
(Address of Principal Executive Offices, and Zip Code)

(917) 289-1117
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:

(Title of each class)	(Trading Symbol)	(Name of each exchange on which registered)
Common stock, \$0.0001 par value	EYEN	The Nasdaq Stock Market (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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 8.01. Other Events.

Attached hereto as Exhibit 99.1 and incorporated herein by reference is a corporate update presentation Eyenovia, Inc. intends to use with various investors and analysts.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Eyenovia, Inc. corporate update presentation dated December 2021</u>
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 hereunto duly authorized.

EYENOVIA, INC.

Date: December 6, 2021

/s/ John Gandolfo

John Gandolfo
Chief Financial Officer



Except for historical information, all the statements, expectations and assumptions contained in this presentation are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our product candidates and platform technology. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission.

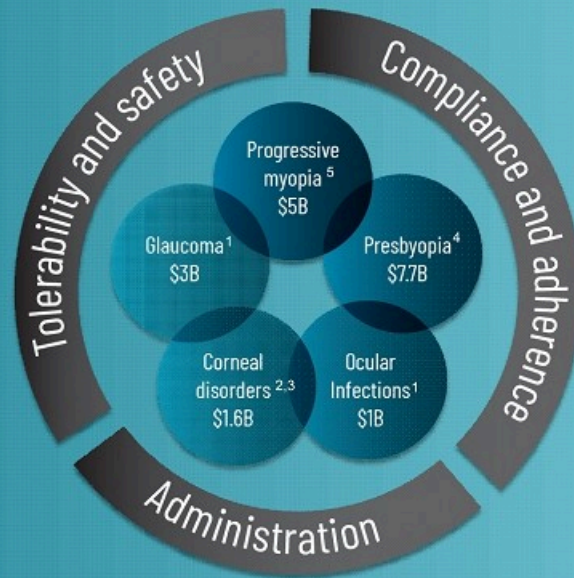
In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could still be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the

timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential impacts of COVID-19 and related economic disruptions on our supply chain, including the availability of sufficient components and materials used in our product candidates; the potential advantages of our product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; intellectual property risks; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and our competitive position.

Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.

We have designed our microdose array print (MAP™) technology to improve the lives of patients with ophthalmic diseases and disorders

- Advanced options for diseases and disorders with no or few existing therapies
- Therapies that reduce patient burden due to tolerability, safety or administration issues
- Therapies that improve compliance and adherence





Transforming ophthalmology through the development and commercialization of high-value therapeutics based upon our proprietary Optejet® Microdose Array Print (MAP™) technology



CLINICALLY TESTED

in multiple Phase 2 and Phase 3 studies

LATE-STAGE THERAPEUTICS PIPELINE

Mydcombi™ for mydriasis / pupil dilation:

- Under FDA review

MicroPine for pediatric progressive myopia:

- Phase 3 CHAPERONE study full enrollment expected 2022

MicroLine for presbyopia / improved near vision:

- Phase 3 VISION-1 study successfully completed 2Q 2021
- Second Phase 3 VISION-2 study completion targeted 1H 2022

DEVELOPMENT AND COMMERCIALIZATION PARTNERSHIPS

with leading eyecare companies validate technology and provide significant non-dilutive capital.

Arctic Vision – MicroPine, MicroLine and MydCombi for Greater China and South Korea

Bausch Health – MicroPine in the US and Canada

PLATFORM TECHNOLOGY

for potential pipeline expansion into further high-value ophthalmic indications



Sean Ianchulev, MD, MPH
CEO, CMO and Co-Founder



John Gandolfo
CFO



Michael Rowe
COO



Jennifer Clasby
CVP Regulatory, Clinical and Quality



Malini Batheja
VP, Pharmaceutical R&D



Beth Scott
VP, Medical Affairs



Norbert Lowe
VP Sales & Marketing



Product Candidate	Therapeutic Area	Phase 3	NDA
MydCombi™ ¹ (trop+phen)	Pharmacologic Mydriasis	\$250M+ US market opportunity* MIST-1 MIST-2	
MicroLine¹ (pilocarpine)	Presbyopia	~\$7.7B US market opportunity ² VISION-1 VISION-2	
MicroPine³ (atropine)	Progressive Myopia	\$5B+ US market opportunity* CHAPERONE ⁴	

Potential pipeline expansion activities leveraging Optejet® technology are ongoing



Potential overexposure to drug and preservatives

- Conventional droppers can overdose the eye by as much as 300%+¹
- Known to cause ocular and systemic side effects¹



Protruding tip may create cross-contamination risk

- More than 50% of administrations touch ocular surface²



More difficult to use with poor compliance

- Requires head tilting and aiming which may be compromised in pediatric and elderly populations
- No dosage reminders or tracking which may lead to missed doses

Precise, Physiological Dosing

Directly coats the cornea with ~80% less exposure to drug and preservative toxicity (based on 8µL dose).¹
Designed to eliminate drug overflow for a more comfortable patient experience.

Efficacy

Demonstrated statistical and clinical benefit in IOP reduction, pharmacological mydriasis and presbyopia (improvement in near vision)^{1,2,5}

Safety

Low systemic drug absorption and good ocular tolerability.^{3,4}
Non-protruding nozzle for no-touch spray application, potentially minimizing risk of cross contamination seen with traditional eyedroppers.



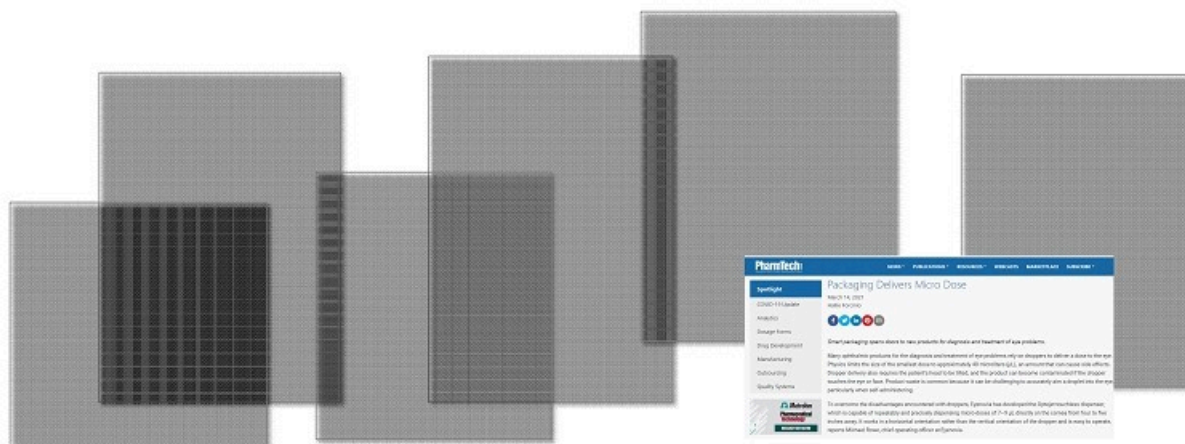
Ease of Use

Horizontal drug delivery means no need to tilt the head back. Demonstrated first-time success with both medical professionals and patients.²

Compliance and Adherence

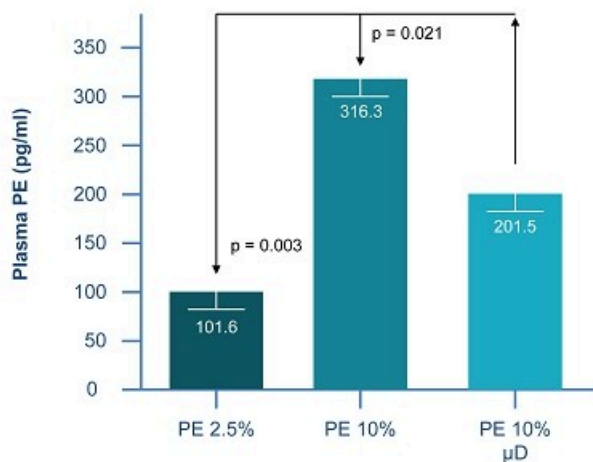
Can be paired with smart devices to enable dosage reminders and tracking.





Seven Phase 2 or Phase 3 clinical trials to date featured in dozens of publications and major meetings including ASCRS, AAO, AAOpt, OIS and EYEcelerator.

REDUCED SYSTEMIC LEVELS

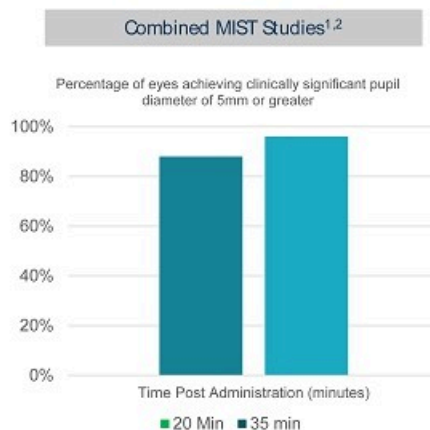
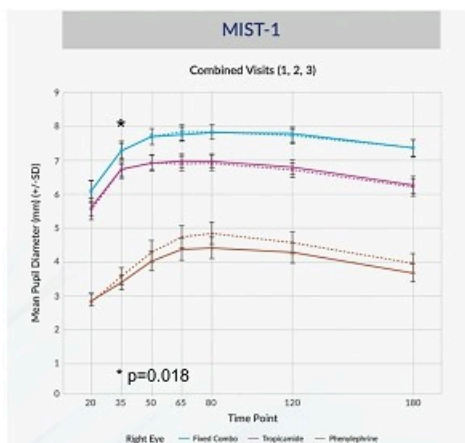


Drugs in traditional eyedroppers can **enter systemic blood circulation** and may cause **significant side effects**.¹

Microdose delivery of phenylephrine 10% (PE- μ D) **was associated with significantly less systemic exposure** than traditional eye drops (PE 10%).²

Microdosing a fixed combination of tropicamide-phenylephrine
had a **superior mydriatic effect** compared to either component formulation¹

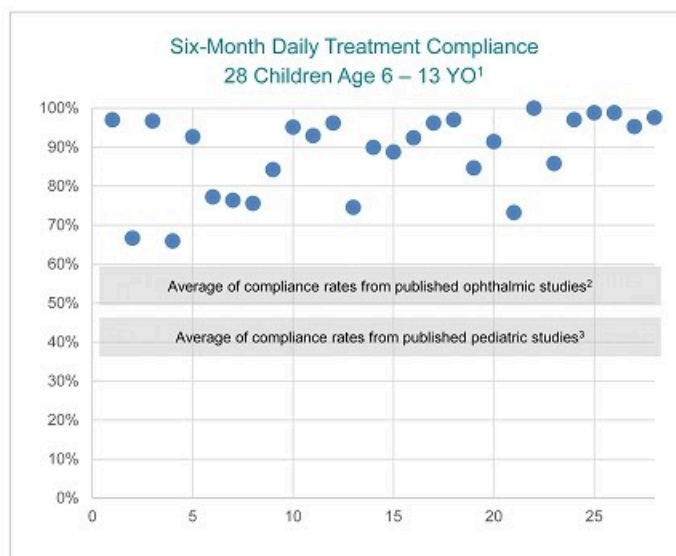
MICRODOSE EFFICACY



Real Improvement in Real World Use

In an ongoing late-stage trial, among the initial group of children using the Optejet once-daily, average compliance was nearly 90% during 6 consecutive months of Optejet use

This compares favorably to the approximately 50% compliance rate for pediatric medications as a whole, or the 59 – 69% range published for adult topical ophthalmic drug users^{2,3}



**Estimated Gross Margins
Based on \$100/Month Price¹**

82% - 94%

Next-Generation Ophthalmic Therapeutics

- Eyenovia's microdose therapeutics are regulated as drug-device combination products, with primary mode of action being the drug. Primary oversight is by CDER, with additional input from FDA device reviewers

Eyenovia Products Aim to Provide Competitive Pharmaceutical Margins:

- All pipeline products are Eyenovia's own proprietary micro-formulations
- Eyenovia currently owns the pharma-economics of the entire prescription value chain
- MicroLine has strong potential as a cash-pay cosmeceutical

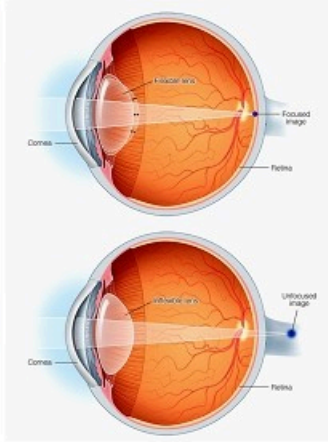
Etiology

- The progressive loss of ability to focus on nearby objects
- Non-preventable, age-related hardening of the lens

Symptoms

- Tendency to hold reading material farther away to make the letters clearer
- Blurred vision at normal reading distance
- Eye strain, headaches after reading or doing close-up work

Normal Vision



Presbyopic Vision

Risk Factors

- Age
- Medical conditions and co-morbidities such as cardiovascular conditions, multiple sclerosis, and type 2 diabetes
- Drugs associated with premature symptoms include antidepressants, antihistamines and diuretics

Diagnosis

- Basic eye exam, with refraction assessment

- Majority of presbyopia patients have never had to wear glasses prior to having difficulty with near vision
- Having to wear glasses can be an inconvenience and an outward signal of aging
- An alternative to glasses may be valuable and more convenient to patients
- Eyenovia's **MicroLine** is intended to be a companion product to spectacles, not a replacement
- **MicroLine** provides freedom to use the product *as needed*








18 million people 40-55 years of age who never previously needed glasses suffer from presbyopia in the US alone

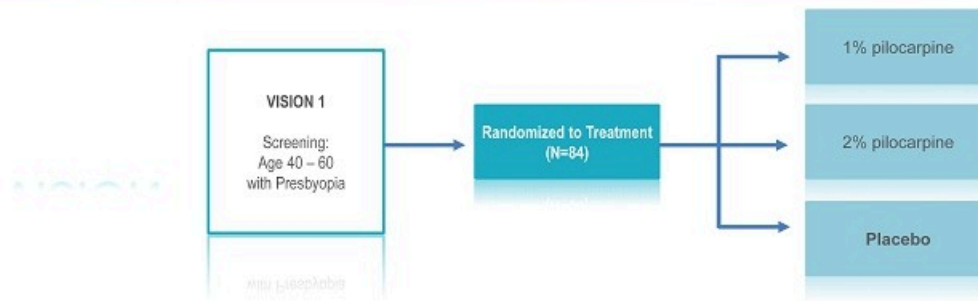
A 7.7 billion dollar¹ addressable market

- A well-known and established drug
- **Pilocarpine has been demonstrated to constrict the pupil of the eye and create a “pinhole” effect that increases the depth of field.**
- Onset 10-30 minutes, with duration of action 4-8 hours
 - *The most frequently reported adverse reactions occurring in $\geq 5\%$ of patients in the pilocarpine 2% populations were: **headache/brow ache***, accommodative change, blurred vision, eye irritation, visual impairment (dim, dark, or “jumping” vision), and eye pain.*

*Microdosing is hypothesized to reduce/eliminate headache

-  Effective at restoring functional vision, such as the ability to read a menu or cell phone
-  Ability to use “as needed” without chronic dosing
-  Rapid onset of action
-  Easy to administer
-  Comfortable instillation with low incidence of brow or headache to drive patient satisfaction and re-use

- Phase 3, double-masked, placebo-controlled, cross-over superiority trial
 - Microdosed pilocarpine 1%, 2% and placebo ophthalmic sprays
- Primary endpoint: mesopic high-contrast binocular DCNVA gain at 120 minutes post-treatment
 - Analyzed separately for 2 cohorts: baseline DCNVA < 0.6 logMAR and ≥ 0.6 logMAR
- Study time period: December 2020 – March 2021



1° Outcome
≥3-line gain

OR7.7²
p-value<0.05

Patients Report
seeing improvement

71%

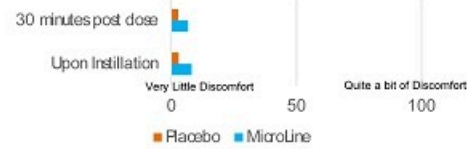
Exit survey: Percent reporting
significant improvement in near
vision

Key Safety Outcomes

All AEs were Transient in Nature

	MicroLine	Placebo
Moderate Hyperemia ¹	2%	0%
Instillation Discomfort	2%	0%
Brow ache	2%	0%

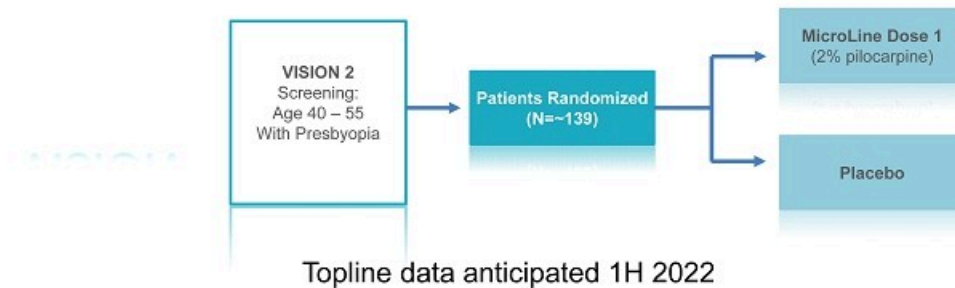
Patient Comfort Assessment



In a separate study among 100 presbyopic patients and 100 optometrists . . .

- ✓ Most likely users were between 40 and 55 years old in the top half of household incomes
- ✓ A price of approximately \$30 - \$35 a month is not an issue for the vast majority of potential users
- ✓ Four hour duration of action is appropriate
- ✓ Lack of side effects, especially headache, was deemed "very important"

- Phase 3 double-masked, placebo-controlled, cross-over superiority trial
 - microdosed pilocarpine 2% and placebo ophthalmic sprays
- Primary endpoint: improvement in mesopic distance corrected near visual acuity 2 hours post-treatment
- First patient enrolled November 4, 2021





Progressive of Myopic Maculopathy

Affects ~25M children in the US alone, with ~5M considered to be at high risk⁴

- Back-of-the-eye disease
- Mostly begins in early childhood, with a genetic link to myopic parents¹
- Pathologic elongation of sclera/retina which can lead to significant morbidity and visual sequelae²
 - Retinal detachment
 - Myopic retinopathy
 - Vision loss
 - Quality of life
- Currently, no FDA-approved drug therapies to slow myopia progression
- Atropine may slow myopia progression by 60% or more³

Current treatment options for myopia include:

- Eyeglasses
- Contact Lenses
- Orthokeratology
- Atropine

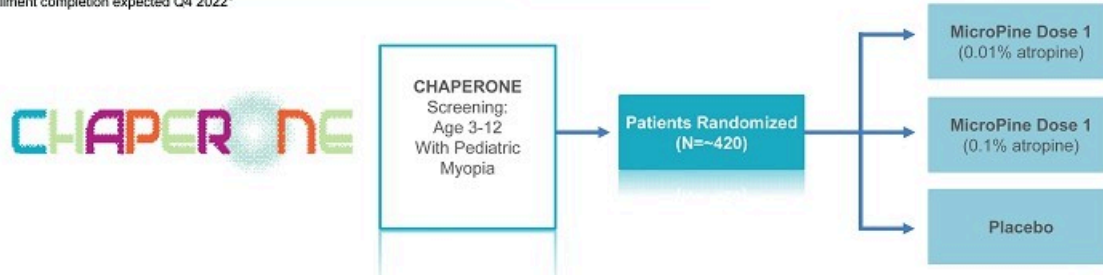
Atropine 0.01% must be compounded by a specialty pharmacy and is not approved by the FDA for myopia control. It is not covered by insurance and can cost \$100 per bottle for a 3-month supply.

Significant variability in the efficacy and side effect profile of the same concentration of atropine across different studies.

Patient medical insurance does not typically cover myopia clinic visits or treatment.

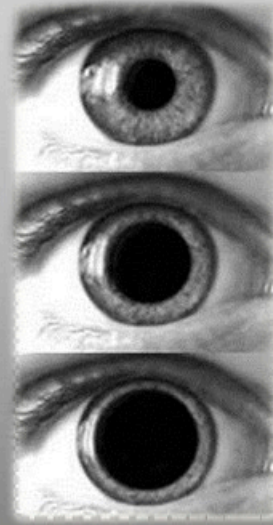


Enrollment completion expected Q4 2022*



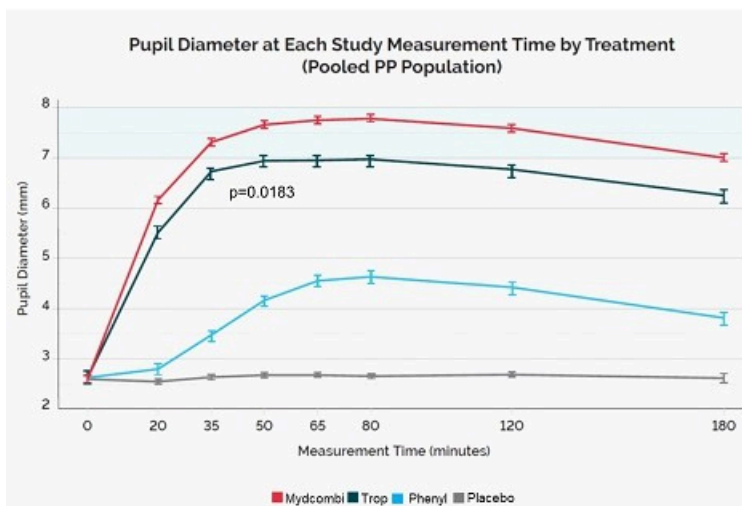
*Strategic partnership with Bausch Health for the development and commercialization of MicroPine

- Pharmacologic mydriasis (pupil dilation) is part of the comprehensive eye exam
 - Estimated 100 million office-based comprehensive and diabetic eye exams and 4 million ophthalmic surgical dilations performed annually in the United States
 - Essential for diabetic retinopathy, glaucoma and retina disease screening
 - An estimated \$250 million US market opportunity¹
- Places technology at the initial point-of-care with prescribers (ophthalmologists and optometrists)
- No direct contact increases patient safety by reducing potential cross contamination associated with the use of shared dilating drops in OD/OPH offices
- No anticipated reimbursement hurdles; expect to sell directly to ophthalmology and optometry practices
- Able to commercialize efficiently with a small, targeted sales force
- Now being reviewed as as drug-device combination product





- If approved, the only fixed combination of the two leading mydriatic medications in the US
- Administered with the push of a button, saving up to ten minutes of technician time¹
- Touch-free, comfortable application with fewer than 1% of patients experiencing stinging discomfort²
- Lower drug and preservative exposure, including systemic absorption of phenylephrine, which can be problematic in hypertensive patients^{2,3}
- Reliable in numerous patient practices. More than 9 out of 10 patients achieved clinically significant mydriasis at 35 minutes post-dosage²



Prompt Mydriasis

Mydriasis >5mm achieved in 88% of patients at 20 minutes, without the delay of instilling multiple drops

Superior Efficacy

MydCombi achieved superior efficacy over single-agent components

Office & Surgical Use

Mydriasis >6 mm achieved in >93% of patients at 35 minutes post-dosage which is clinically meaningful for both office retinal exam and surgical dilation

In the MIST-1 and MIST-2 studies, adverse events were infrequent and generally mild with none over 5% in incidence.



Big Eye Pharma

11 FTE for \$2.2 million Calling on large group practices in largest population centers for 50% reach at launch	Sales Team 	100 FTE for \$20.0 million Calling on 18,000 doctors across the US for 80% reach at launch
Not needed. Product is a diagnostic bought by the practice.	Managed Care Group 	8 FTE for \$1.6 million Often delay of up to 1 year to obtain formulary access.
\$2.0 million Glossy pieces and interactive programs are not needed. Key Account People will train and leave a sample for evaluation.	Promotion 	\$10.0 million Dinner meetings, large convention booths, investigational grants, advertising, lunch and learns.
Total: ~\$4.2 million		Total: ~\$31.6 million



Validating partnership for the development and commercialization of **MydCombi™**, **MicroPine** and **MicroLine**



Upfront payment: \$4M



Potential milestone payments and reimbursed development costs: \$41.75M

Commercial supply terms or royalties: mid-single digits

Territory: **Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea**

Impacted population estimated at approx. more than 8x the US³

BAUSCH+Health

Strategic partnership for the development and commercialization of **MicroPine**



Upfront payment: \$10M



Potential milestone payments and
reimbursed development costs: \$50M

*Reimbursed development costs associated with
Phase 3 CHAPERONE trial to begin immediately*

US impacted population with high myopia estimated at approx. 3M^{2,3}

Royalties on gross profit: mid-single digit to mid-teen percentages

Territory: **US and Canada**



Technology that has Multiple Layers of IP,
Clinical and Regulatory Protection

13 U.S. Patents Issued

84 O.U.S. Patents Issued

Volume delivered, method of delivery, speed of delivery, data capture

Various patent coverage in effect until late 2031

Provisional patents filed to bring protection through 2040



Nasdaq: EYEN

Common Shares Outstanding	26.0M
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Equity Grants Outstanding Under Stock Plans	4.3M
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Warrants	1.2M
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Fully Diluted Shares	31.5M
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Cash	\$21.4M
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Debt	\$7.3M
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Dr. Fred Eshelman
Chairman

Founder and former CEO of PPDI, founding chairman of Furiex Pharmaceuticals, and founder of Eshelman Ventures



Dr. Ernest Mario
Board Member

Former Chairman and CEO of Reliant Pharmaceuticals, ALZA, and Glaxo Holdings



Dr. Curt LaBelle
Board Member

Managing Director of GHIF venture fund and Co-Founder of Eyenovia



Kenneth Lee Jr.
Board Member

General partner of Hatteras Venture Partners



Charles Mather IV
Board Member

Managing Director, Equity Capital Markets at Suntrust Robinson Humphrey



Dr. Anthony Sun
Board Member

CEO, Zentalis Pharmaceuticals, Inc.



Dr. Sean Ianchulev
Board Member

CEO, CMO and Co-Founder of Eyenovia



Dr. Julia Haller
Board Member

Ophthalmologist-in-Chief
Wills Eye Hospital