

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 18, 2020

**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, New York 10017

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (917) 289-1117

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(s)	Name of each exchange on which registered
Common Stock, \$0.0001 Par Value	EYEN	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 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

<b>Exhibit No.</b>	<b>Description</b>
<u>99.1</u>	<u>Eyenovia, Inc. corporate update presentation dated December 18, 2020.</u>

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SIGNATURE

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 18, 2020

By: /s/ John Gandolfo  
Name: John Gandolfo  
Title: Chief Financial Officer

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# Forward-Looking Statements

Except for historical information, all of 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 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 SEC.

In addition, such statements could be affected by risks and uncertainties related to, among other things: volatility and uncertainty in the global economy and financial markets in light of the evolving COVID-19 pandemic and uncertainties arising from the recent U.S. elections; fluctuations in our financial results; our estimates regarding the potential market opportunity for our product candidates and platform technology and potential revenue from licensing transactions; reliance on third parties to develop and commercialize certain of our product candidates; the ability of us and our partners to timely develop, implement and maintain effective manufacturing, commercialization and marketing capabilities and strategies for certain of our product candidates; 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 and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; the potential impacts of COVID-19 on our supply chain; 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 ability to raise additional capital; intellectual property risks; our ability to attract and retain key personnel; 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, we do not undertake any obligation to update any forward-looking statements.

# Investment Highlights

## Late-stage therapeutics pipeline

MicroStat (Mydcombi™) for mydriasis (pupil dilation) - Phase 3 studies completed, planned NDA submission in 2020  
MicroLine for presbyopia (improved near vision) - Phase 3 VISION-1 study commenced in 2020

## Clinically validated

in multiple Phase 2 and Phase 3 studies

## Development and commercialization partnerships

with leading global eyecare companies validate technology and provide significant non-dilutive capital. **Arctic Vision** – Announced August 2020 for Greater China and South Korea  
**Bausch Health** – Announced October 2020 for the US and Canada

## Platform technology

allows for potential pipeline expansion into further high-value ophthalmic indications

**A leading ophthalmic company**  
developing next-generation therapeutics delivered using its proprietary Optejet® microdose array print (MAP™) dispensing technology

# Leadership Team



**Dr. Sean Ianchulev,  
MD, MPH  
CEO, CMO and Co-Founder**

- Head of ophthalmology research and directed development and FDA approval of Lucentis, most successful ophthalmic drug for Genentech
- IanTech founder for cataract device approved by FDA in 2016 and inventor of Intra-operative Aberrometry at Wavetec-Alcon/Novartis
- CMO of Transcend Medical (acquired by Alcon/Novartis)



**John Gandolfo  
CFO**



**Michael Rowe  
VP Commercial**



**Jennifer Clasby  
VP Clinical Operations**



**Dr. Lee Kramm  
Regulatory Affairs  
Consultant**



**Luke Clauson  
VP R&D,  
Manufacturing**



# Late-Stage Ophthalmic Pipeline for US Registration

Product Candidate	Therapeutic Area	Pre-Clinical/ Formulation	Phase 1	Phase 2	Phase 3	NDA
MydCombi™ ( <i>trop+phen</i> )	Pharmacologic Mydriasis	\$250M+ US market opportunity*			MIST-1 MIST-2	
MicroLine <sup>1</sup> ( <i>pilocarpine</i> )	Improvement in near vision in patients with presbyopia	~\$7.7B US market opportunity <sup>2</sup>			VISION-1 VISION-2	
MicroPine <sup>3</sup> ( <i>atropine</i> )	Reduction of pediatric myopia progression	\$5B+ US market opportunity*				CHAPERONE <sup>4</sup>

\* Estimate only

<sup>1</sup> Out-licensed to Arctic Vision in Greater China and South Korea

<sup>2</sup> Estimate from DelveInsight Presbyopia report; December 2020

<sup>3</sup> Out-licensed to Bausch Health in the US and Canada, and Arctic Vision in Greater China and South Korea

<sup>4</sup> CHAPERONE oversight and costs assumed by Bausch Health

Potential pipeline expansion activities leveraging Optejet technology are ongoing

# Standard Eyedroppers Have Limited Therapeutic Approaches

## ➤ Potential overexposure to drug and preservatives

- Conventional droppers can overdose the eye by as much as 300%+<sup>1</sup>
- Known to cause ocular and systemic side effects<sup>1</sup>



## ➤ Protruding tip may create cross-contamination risk

- More than 50% of administrations touch ocular surface<sup>2</sup>

## ➤ 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

# Optejet Microdose Array Print (MAP) Technology

## Designed for Optimal Drug Delivery

### Precise, Physiological Dosing:

Directly coats the cornea with ~80% less exposure to drug and preservative toxicity (based on 8 $\mu$ L dose).<sup>1</sup>  
Designed to eliminate drug overflow for a more comfortable patient experience.

### Efficacy:

Demonstrated statistical and clinically significant efficacy in both IOP reduction and pharmacological mydriasis.<sup>2,3</sup>

### Safety:

Low systemic drug absorption and good ocular tolerability.<sup>3,4</sup>  
Non-protruding nozzle for no-touch spray application, potentially minimizing minimize risk of cross contamination seen with traditional eyedroppers.



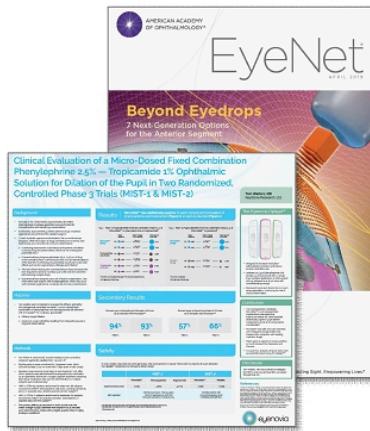
### Ease of Use:

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

### Compliance and Adherence:

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

# Optejet: Significant Clinical Experience and Validation



**Future Science**

**Therapeutic Delivery**

**Microdose Leans Hard**

**Latanoprost with high precision, pico-dose microdose delivery for IOP lowering efficacy results of the PG21 study of 0.4 µg daily**

**Introduction**

**Conclusion**

**References**

**Author Information**

**Keywords:** microdose; eye drops; microdose; ocular drug delivery; ocular medication; pico-dose; precision eye drops

**High-precision pico-injection ocular microdosing Phase II study on focal and systemic effects of topical phenylephrine**

**Author Information**

**Abstract**

**Conclusion**

**References**

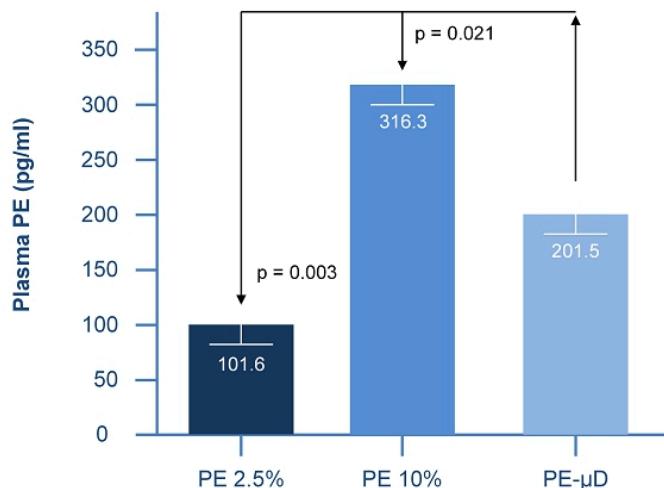
**Author Information**

**Keywords:** microdose; eye drops; microdose; ocular drug delivery; ocular medication; pico-dose; precision eye drops

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



## Reduced Systemic Levels



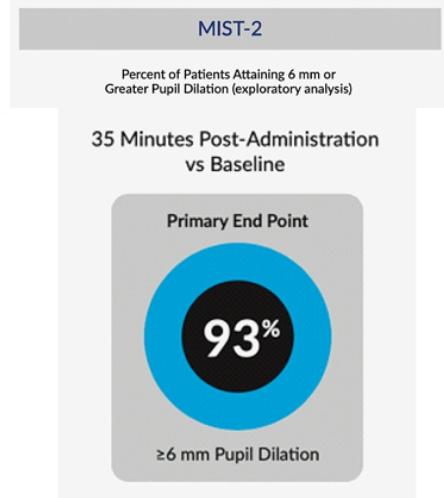
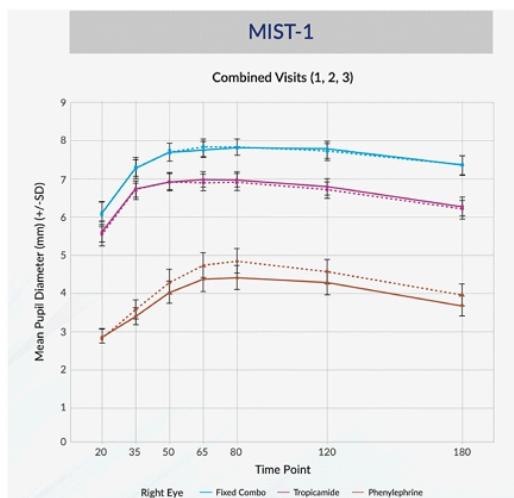
Drugs in traditional eyedroppers can **enter systemic blood circulation** and may cause **significant side effects**.<sup>1</sup>

**Microdose delivery** of phenylephrine 10% (PE-μD) **was associated with significantly less systemic exposure** than traditional eye drops (PE 10%).<sup>2</sup>

# Optejet: Demonstrated Effectiveness in Multiple Phase 3 Studies

**Microdosing** a fixed combination of tropicamide-phenylephrine had a superior mydriatic effect compared to either component formulation<sup>1</sup>

## Microdose Efficacy



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

**82% - 94%**

## **Next-Generation Ophthalmic Therapeutics**

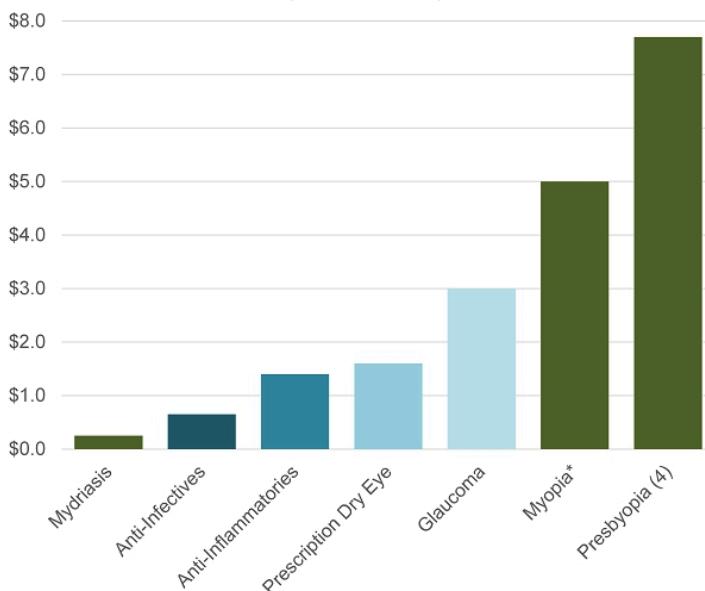
- Eyenovia's microdose therapeutics follow the 505(b)(2) registration pathway and are not currently regulated as medical devices or drug-device combinations
- The FDA categorizes the Optejet as a container closure system

## **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

# Potential Topical US Ophthalmic Market For Platform Technology\*

Market Size Estimates for the United States  
(in US\$ Billions)



**Current Portfolio: ~\$12.9 Billion\***

Existing Eyenovia portfolio in mydriasis, presbyopia, and myopia, with late-stage, first-in-class therapeutics.

**Anti-Infectives: ~\$650 Million<sup>1</sup>**

Eliminate contamination from poor usage of eyedropper bottles.

**Anti-Inflammatories: ~\$1.4 Billion<sup>1</sup>**

Reduce IOP spikes due to high doses of steroids.

**Prescription Dry Eye: ~\$1.6 Billion<sup>2</sup>**

Improve clinical probability of success. Enable patients, especially the elderly, to better instill medication for improved results. Multi-dose preservative free options.

**Glaucoma: ~\$3 Billion<sup>3</sup>**

Improve systemic safety profile and allow for development of PGA + BB fixed combinations. Improvement in topical (e.g., hyperemia) and systemic AE profile. Multi-dose preservative free options.

# MicroLine for Presbyopia



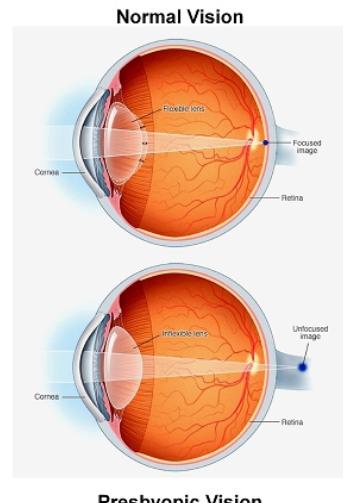
## Etiology

- 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



## 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, anti-histamines and diuretics



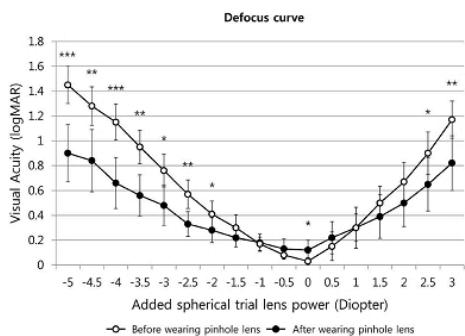
## Diagnosis

- Basic eye exam, with refraction assessment

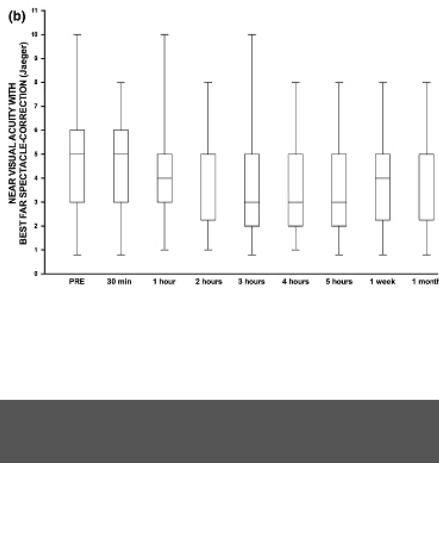
# Pilocarpine: Dual Action Mechanism Improves Near Vision

- Pilocarpine is a Miotic (cholinergic) and has a clinically established a dual action mechanism
- Accommodation and extended-depth of focus
- Optimized profile through microdose

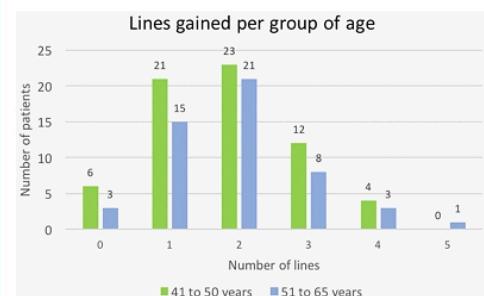
## Pin-Hole Effect Improves Near Vision<sup>1</sup>



## Pilocarpine Topical Near Vision Effect<sup>2</sup>



## Pilocarpine Topical Near Vision Effect<sup>3</sup>



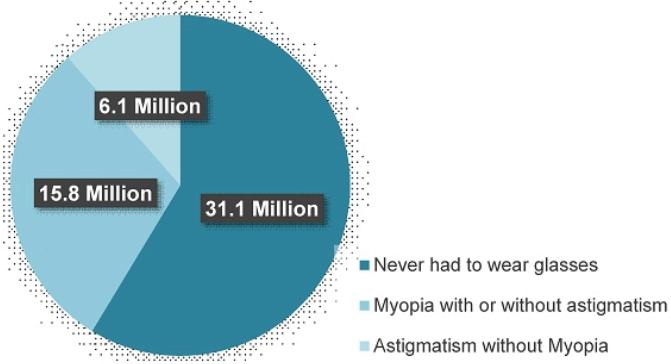
Number of lines gained in near vision 2h after instillation of one eye drop to each eye according to age group

## Pharmacologic Treatment of Presbyopia: Targeting Millions of Patients Who “Never Wore Glasses”



~113 million people in the US are presbyopic

Of the ~53 million adults between 45 and 60 years of age, ~31 million previously never had to wear glasses

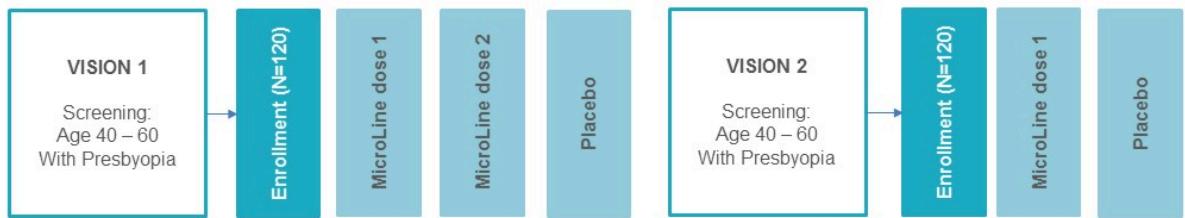


- Majority of presbyopia patients have never had to wear glasses prior to having difficulty with near vision
- Having to wear glasses can be an inconvenience and an outward signal of aging
- A “no glasses” option may be valuable and more convenient to patients
- Eyenovia’s MicroLine is intended to be a companion product to spectacles, not a replacement
  - “On Demand”

# MicroLine: Phase 3 Program

- Two double-masked, placebo-controlled, cross-over superiority trials
  - Phase 3 (microdosed pilocarpine 1.0%, 2.0% and placebo)
- Primary endpoint: binocular distance corrected near visual acuity

VISION



## Optejet MAP Technology



## Traditional Eye Drops



**Eyenovia is differentiated from competitors through unique combination of factors including:**

- *Optejet MAP Technology for ease of administration<sup>1</sup>*
- *80% less corneal exposure to drug and preservatives<sup>2</sup>*
  - *Low systemic drug absorption<sup>3</sup>*
- *Smart device compatibility designed for customized applications*

# MicroPine for Progressive Myopia



Progressive of Myopic Maculopathy

Affects ~25M children in the US alone, with ~3M considered to be at high risk<sup>4</sup>

- Back-of-the-eye disease
- Mostly begins in early childhood, with a genetic link to myopic parents<sup>1</sup>
- Pathologic elongation of sclera/retina which can lead to significant morbidity and visual sequelae<sup>2</sup>
  - 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 more<sup>3</sup>

# Strategic Partnerships to Potentially Extend Commercial Reach



## Arctic Vision

Validating partnership for the development and commercialization of **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 US<sup>1</sup>*

## BAUSCH Health

## 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)

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

Territory: US and Canada

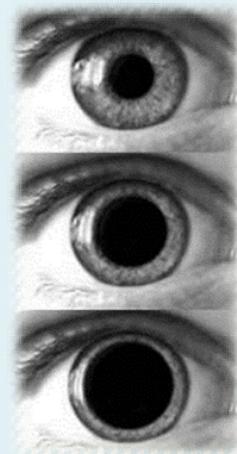
US impacted population with high myopia estimated at approx. 3M<sup>2,3</sup>

# Future Licensing Opportunities



# MydCombi for Mydriasis

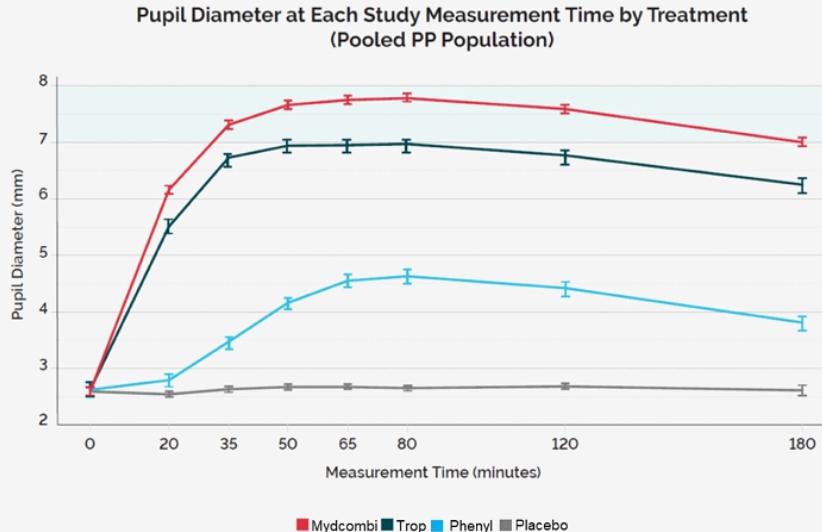
- Pharmacologic mydriasis (pupil dilation) is part of the comprehensive eye exam
  - **Estimated 80 million office-based comprehensive and diabetic eye exams and 4 million ophthalmic surgical dilations performed annually in the United States**
  - Essential for diabetic retinopathy, glaucoma and retina disease screening
  - An estimated \$250 million US market opportunity<sup>1</sup>
- 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
- **NDA** filing expected by end of Q4 2020





- 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 time<sup>1</sup>
- Touch-free, comfortable application with less than 2% of patients experiencing stinging discomfort<sup>2</sup>
- Lower drug and preservative exposure, including systemic absorption of phenylephrine, which can be problematic in hypertensive patients<sup>2,3</sup>
- Reliable in numerous patient practices. More than 9 out of 10 patients achieved clinically significant mydriasis at 35 minutes post-dosage<sup>2</sup>

# MydCombi has a Superior Mydriatic Effect vs. Single Agents



## Prompt Mydriasis

Significant, prompt mydriasis achieved with microdose fixed-combination Phen-Trop

## 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

# MydCombi Commercialization Strategy



## Single Distribution Partner

**Single specialty pharmacy distribution partner to maximize efficiencies and control costs**

- Ecommerce site, all purchases by credit card
- No third-party billing, reimbursement, etc.



## Targeted Account Management

**Targeted Account Management team focused on the highest population centers**

- 10 account managers to cover the equivalent of 80 million lives
- Model can be scaled up as demand grows



## Streamlined Sales Process

**Streamlined sales process designed to increase cost efficiency and improve productivity**

- One evaluation sample per office
- Offices may be able to recover any additional cost through reduced “chair time”
- Real-time sales data to help inform account team of customer status

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

**Worldwide patents are granted** on the dispenser, the drop size, velocity of delivery and data capture from the base unit are in effect **until late 2031**

**Provisional patents have been filed** on the Gen 2 dispenser and if approved will bring protection **through 2040**

An **additional barrier** is the clinical and regulatory hurdles a competitor would have to meet to gain approval for an 8 $\mu$  dose

## Financial Snapshot

### Nasdaq:

**EYEN**

**Common Shares Outstanding** 24.9M

**Equity Grants Outstanding Under Stock Plans** 3.5M

**Warrants** 2.3M

**Fully Diluted Shares** 30.7M

**Cash** \$22.9M

**Pro-forma cash as of Nov. 10, 2020** \$31.0M

**Debt** None

## Appendix

## Board of Directors



**Dr. Fred Eshelman**  
Chairman

Founder and former CEO of PPDI,  
founding chairman of Furlex  
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 Eynovia



**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



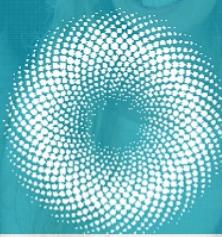
**Dr. Anthony Sun**  
Board Member

CEO, Zentalis  
Pharmaceuticals, Inc.



**Dr. Sean Ianchulev**  
Board Member

CEO, CMO and Co-  
Founder of Eynovia



eyenovia

## Making it Possible

December 18, 2020