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) May 5, 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, 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  $\boxtimes$ 

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.  $\Box$ 

#### 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 Exhibit No. Description Eyenovia, In 99.1 ate update presentation dated May 2021.

#### 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.

#### By:

<u>/s/ John Gandolfo</u> Name: John Gandolfo Title: Chief Financial Officer

Date: May 5, 2021





May 2021

### Forward-Looking Statements

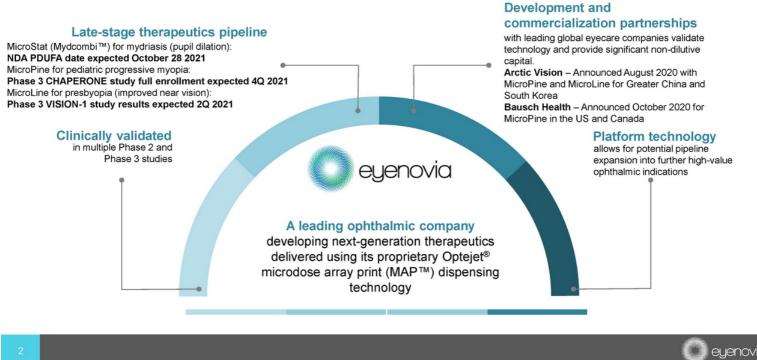
Except for historical information, all of the statements, expectations and assumptions contained in this presentation are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any 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, a ctual 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 U.S. Securities and Exchange Commission.

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 COVID-19 pandemic; fluctuations in our financial results; the timing and our ability or the ability of our licensees to submit applications for, obtain and maintain regulatory approvals for our product candidates; changes in legal, regulatory approval for our products; the potential impacts of COVID-19 on our supply chain; the potential advantages of our product candidates and platform technology and potential revenues from licensing transactions; 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 certain of our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for certain of our product candidates; risks of our ongoing 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; our ability to raise additional money to fund our operations for at least the next twelve months as a going concern; intellectual property risks; and our competitive position.

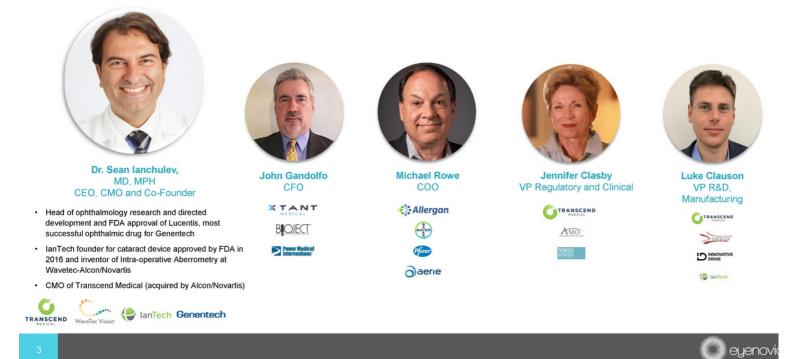
Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.



### **Investment Highlights**



### Leadership Team



### Late-Stage Ophthalmic Pipeline for US Registration in Markets Valued Over \$12.7 Billion

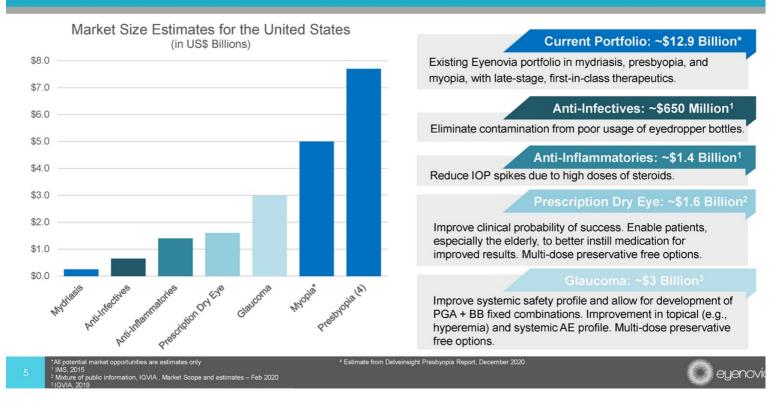
Product Candidate	Therapeutic Area	Pre-Clinical/ Formulation	Phase 1	Phase 2	Phase 3	NDA
MydCombi™ (trop+phen)	Pharmacologic Mydriasis	\$250M+ US mark	et opportunity*		MIST-1 MIST-2	
MicroLine <sup>1</sup> (pilocarpine)	Improvement in near vision in patients with presbyopia	~\$7.7B US marke	t opportunity <sup>2</sup>		VISION-1 VISION-2	
MicroPine <sup>3</sup> (atropine)	Reduction of pediatric myopia progression	\$5B+ US market o	opportunity*		CHAPERON	Ξ4

\* 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 Heelth 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

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### Potential Topical US Ophthalmic Market For Platform Technology\*



### Standard Eyedroppers Have Limited Therapeutic Approaches

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 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 8µL dose).<sup>1</sup> Designed to eliminate drug overflow for a more comfortable patient experience.

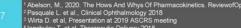
### Efficacy:

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 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.





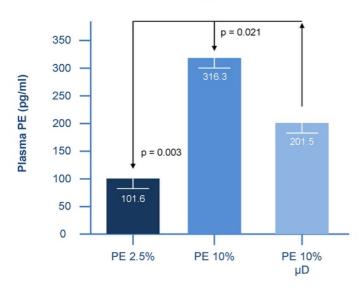
### Optejet: Significant Clinical Experience and Validation

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

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### Optejet: Clinical Experience and Validation



### **Reduced Systemic Levels**

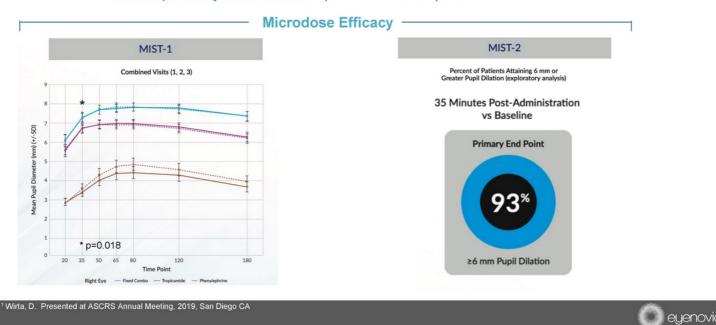
Drugs in traditional eyedroppers can enter systemic blood circulation and may cause significant side effects.<sup>1</sup>

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

<sup>1</sup> Muller, M., van der Velpe, N., Jaap, W., van der Cammen, T.; Syncope and falls due to timolol eye drops. BMJ, 2006 April; 332:960-961 <sup>2</sup> lanchulev, I. High-precision piezo-ejection ocular microdosing: Phase II study on local and systemic effects of topical phenylephrine. Ther Deliv, 2018 Jan;9(1):17-27



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



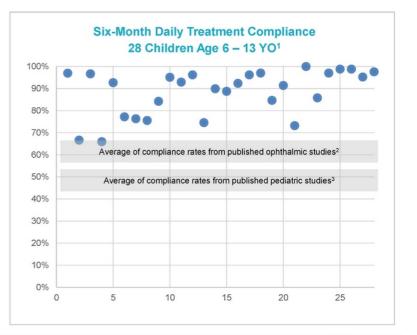
### Optejet: Impressive Treatment Compliance

### **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





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Estimated Gross Margins Based on \$100/Month Price<sup>1</sup>

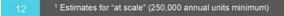
82% - 94%

#### **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

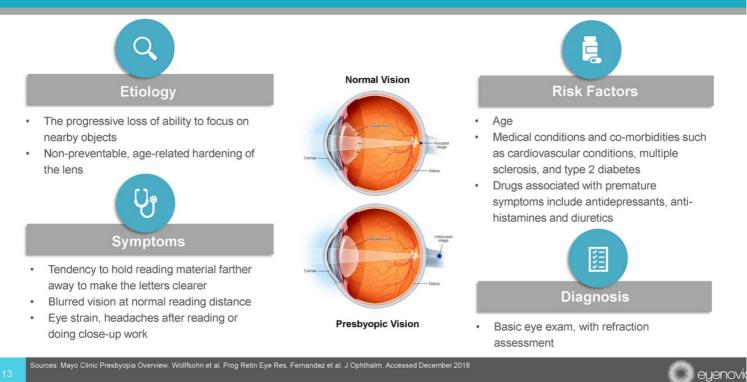
# Eyenovia Products Aim to Provide Competitive Pharmaceutical Margins:

- 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



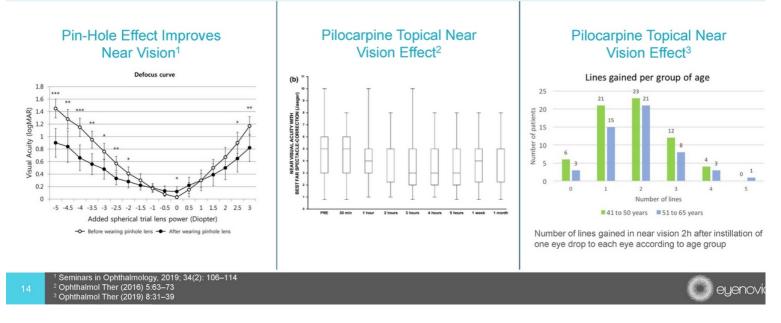


### MicroLine for Presbyopia

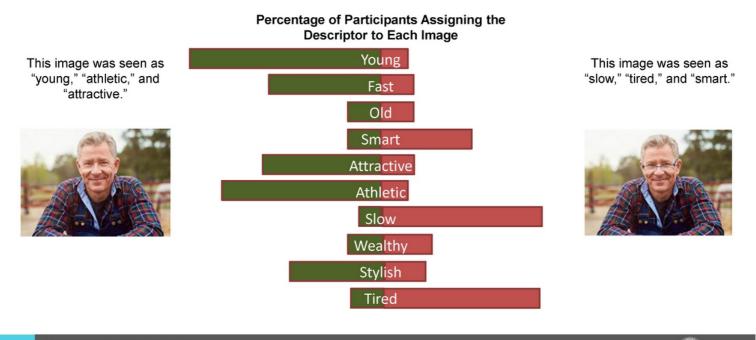


### Pilocarpine: Dual Action Mechanism Improves Near Vision

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



# People Have Preconceptions About People Who Wear Reading Glasses

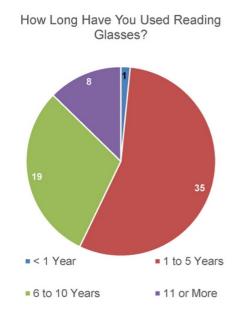


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Source: VISION-1 post-study survey, 2021

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# Attitudes Towards Wearing Reading Glasses



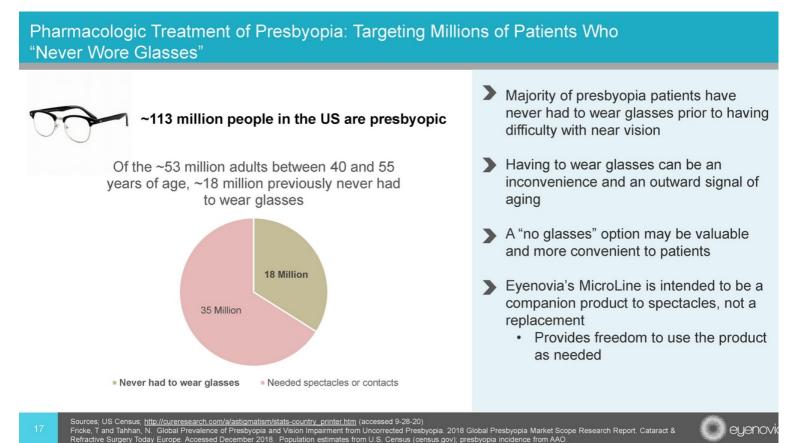
Source: VISION-1 post-study survey, 2021

What One Word Describes How You Feel About Needing to Wear Reading Glasses?					
Old	40%				
Annoyed	16%				
Constrained or Dependent	10%				
Frustrated or Stressed	10%				
Slow	5%				
I'm OK or Fine	8%				
Good or Better	10%				

In What Situations Would You Prefer Not to Wear Your Reading Glasses?

Reading Menus/Books/Labels	56%
At Work	19%
Other Activities	14%
Always	5%
I'm OK Wearing my Glasses	6%

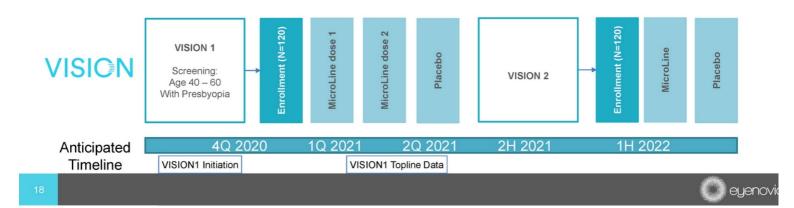
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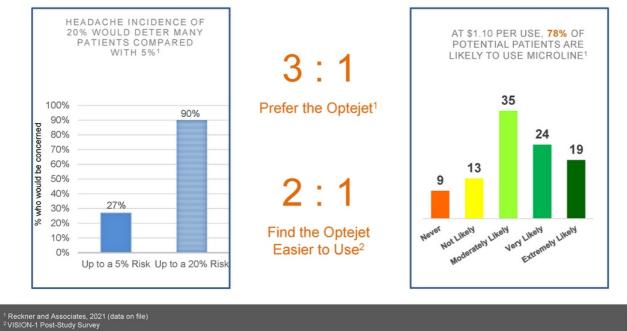
### MicroLine: Phase 3 Program

> Two double-masked, placebo-controlled, cross-over superiority trials

- Phase 3 (microdosed pilocarpine dose 1, dose 2 and placebo)
- > Primary endpoint: binocular distance corrected near visual acuity
- First patient enrolled in VISION 1: December 2020



### MicroLine Compared with the Standard Presbyopia Drop



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# Late Stage Presbyopia Competitive Landscape

Trial	API	Company	Primary EP (3 Line Gain)	Safety	Completion Date
VISION-1 PIII (40-60 YO)	Pilocarpine MAP™ Technology	🔘 eyenovia	Gain of 3 lines or more in mesopic, high contrast, binocular (DCNVA) at Hour 2 versus the vehicle (placebo)	Not yet reported	Fully Enrolled
VISION-2 PIII	Pilocarpine MAP™ Technology	🔘 eyenovia	Gain of 3 lines or more in mesopic, high contrast, binocular (DCNVA) at Hour 2 versus the vehicle (placebo)	Not yet reported	Start Q4 2021
GEMINI-1 PIII (40-55 YO)	Pilocarpine 1.25% formulation	abbvie	Gain of 3 lines or more in mesopic, high contrast, binocular (DCNVA) at Day 30, Hour 3 versus the vehicle (placebo).	~20% Headache No Serious Aes	Completed Q3 2020 PDUFA H2 2021
GEMINI-2 PIII (40-55 YO)	Pilocarpine 1.25% formulation	abbvie	Gain of 3 lines or more in mesopic, high contrast, binocular DCNVA without loss of greater than five letters in (CDVA) with the same refraction at Day 30, Hour 3 versus the vehicle.	~20% Headache No Serious AEs	Completed Q3 2020 PDUFA H2 2021
PRX-100 (48-64 YO)	Aceclidine + Tropicamide	Presbyopia Therapies	Proportion of subjects with at least a 3-line (15 letter) improvement in the study eye [ Time Frame: up to 7 hours post-treatment ]	Not yet reported	Phase IIb Completed May 2018
NEAR-1 PIII (45-64 YO)	Pilocarpine 0.2% + NSAID		$\geq$ 3-line gain in BDCVA at 40cm and no loss in BDCVA $\geq$ 5 letters at 4m. [ Time Frame: Day 8 ]	Not yet reported	Actively Recruiting Q2 2021
NEAR-2 PIII (45-64 YO)	Pilocarpine 0.2% + NSAID		$\geq$ 3-line gain in BDCVA at 40cm and no loss in BDCVA $\geq$ 5 letters at 4m. [ Time Frame: Day 8 ]	Not yet reported	Actively Recruiting Q2 2021
UNR844-CI (45-55 YO)	Lipoic acid choline ester 1.5%	U NOVARTIS	Change in Binocular DNCVA From Baseline [Baseline to Month 3]	Not yet reported	Not Yet Recruiting
NYXOL+PILO (40-64 YO)	Phentolamine 0.75% + Pilocarpine	Ocuphire	Percent of subjects with ≥ 15 letters of improvement in photopic binocular DCNVA [ Time Frame: up to 6 hours ]	Not yet reported	
Not Available	Alpha-crystallin stabilizing molecule			N/A	
BRIMOCHOL (45-80 YO)	Bimochol Carbachol/Brimonodine	VISUS	Change from baseline in near VA [ Time Frame: Baseline ]	Not yet reported	Actively Recruiting

Source: Company press releases and clinicaltrials.gov

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### MicroPine for Progressive Myopia



Progressive of Myopic Maculopathy

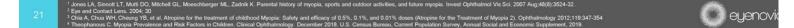
Affects ~25M children in the US alone, with ~5M considered to be at high risk<sup>4</sup> ▶ Back-of-the-eye disease

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

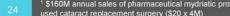
	BAUSCH- Health
Arctic Vision	Bausch Health
Validating partnership for the development and commercialization of <b>MicroPine</b> and <b>MicroLine</b>	Strategic partnership for the development and commercialization of <b>MicroPine</b>
Upfront payment: \$4M	Upfront payment: \$10M
Potential milestone payments and reimbursed development costs: \$41.75M	Potential milestone payments and reimbursed development costs: \$50M (Reimbursed development costs associated with Phase 3 CHAPERONE trial to begin immediately)
Commercial supply terms or royalties: mid-single digits	Royalties on gross profit: mid-single digit to mid-teen percentages
Territory: Greater China (mainland China, Hong Kong,	Territory: US and Canada
Macau and Taiwan) and South Korea Impacted population estimated at approx. more than 8x the US <sup>1</sup>	US impacted population with high myopia estimated at approx. $3M^{2,3}$
<sup>1</sup> Min Chen, 2018 <sup>2</sup> Theophanous C. Myopia Prevalence and Risk Factors in Children. Clinical Ophthalmolog <sup>3</sup> U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement	

# Future Licensing Opportunities

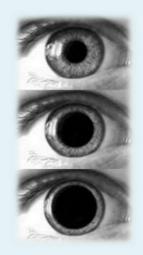


### MydCombi for Mydriasis

- > 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 accepted March 2021



<sup>1</sup> \$160M annual sales of pharmaceutical mydriatic products used during 80M office-based exams (\$2 \* 80M) + \$80M of single bottle mydriatic agents used cataract replacement surgery (\$20 x 4M)



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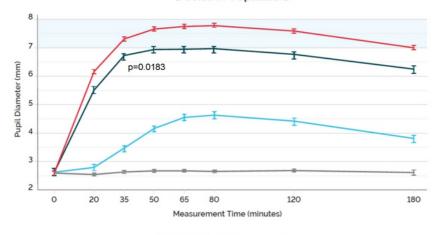
### MydCombi It Will Make Your Eyes Dilate



- 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 fewer than 1% 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 postdosage<sup>2</sup>

	<sup>1</sup> Denion E. et al, A 5-Minute Interval between Two Dilating Eye Drops Increases Their Effect. Optom Vis Sci. 2017 Aug
25	<sup>2</sup> Wirta, D. Presented at ASCRS Annual Meeting, 2019, San Diego CA
	3 Abeleen M. 2020. The Usua And Miles Of Discovered Lingting Devices (On-bible-local and an and 44/2/20
	<sup>3</sup> Abelson M 2020 The Hows And Whys Of Pharmacokinetics, ReviewofOphthalmology.com: accessed 11/3/20





Pupil Diameter at Each Study Measurement Time by Treatment (Pooled PP Population)

#### Mydcombi 🗖 Trop 📃 Phenyl 🔳 Placebo

**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 singleagent components

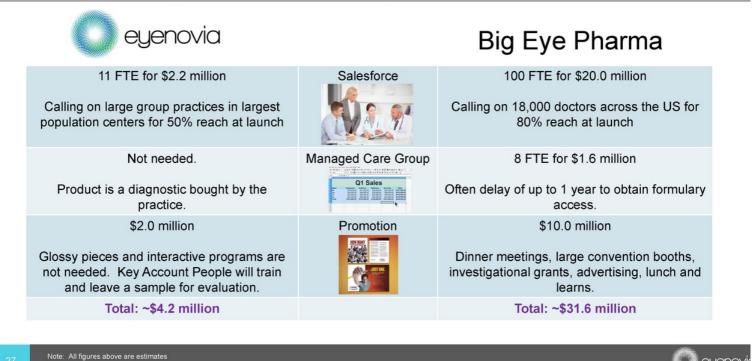
#### Office & Surgical Use

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

26 Presented by S. Rathi et al, American Academy of Optometry Annual Meeting, 2020



### MydCombi Launch Expenses: A Fraction of a Typical Ophthalmic Drug Launch



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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 8µ dose



# Financial Snapshot

Nasdaq: EYEN	
Common Shares Outstanding	25.6M
Equity Grants Outstanding Under Stock Plans	3.5M
Warrants	2.0M
Fully Diluted Shares	31.1M
Cash	\$28.4M
Debt (PPP loan)	\$0.5M

All figures as of December 31, 2020

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### **Board of Directors**



Dr. Fred Eshelman Chairman

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



Charles Mather IV Board Member

Managing Director, Equity Capital Markets at Suntrust Robinson Humphrey



Dr. Ernest Mario Board Member Former Chairman and CEO of Reliant Pharmaceuticals, ALZA, and Glaxo Holdings



Dr. Anthony Sun Board Member

CEO, Zentalis Pharmaceuticals, Inc.



Dr. Curt LaBelle Board Member Managing Director of GHIF

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



Dr. Sean lanchulev Board Member

CEO, CMO and Co-Founder of Eyenovia



Kenneth Lee Jr. Board Member

General partner of Hatteras Venture Partners



Dr. Julia Haller Board Member

Ophthalmologist-in-Chief Wills Eye Hospital

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# Making it Possible

May 2021