

eyenovia

Making it Possible

August 2020



# 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 in the United States for our product candidates. 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: impacts of and uncertainty related to COVID-19; fluctuations in our financial results, particularly given market conditions and the potential economic impact of COVID-19; our need to raise additional money to fund our operations for at least the next 12 months as a going concern; risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could continue to 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 success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our estimates regarding the potential market opportunity for our product candidates; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; our ability to timely develop and implement anticipated manufacturing, commercialization and marketing capabilities and strategies for existing product candidates; our ability to attract and retain key personnel; 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, we do not undertake any obligation to update any forward-looking statements.

# Eyenovia: Building the Smart Eye Care Company of the Future

- Specialty ophthalmic biopharmaceutical company developing a late stage pipeline of therapeutics in areas of key front and back-of-the-eye indications using proprietary Optejet® microdosing technology
- Validated microdosing approach through multiple Phase II and Phase III studies

## MicroPine



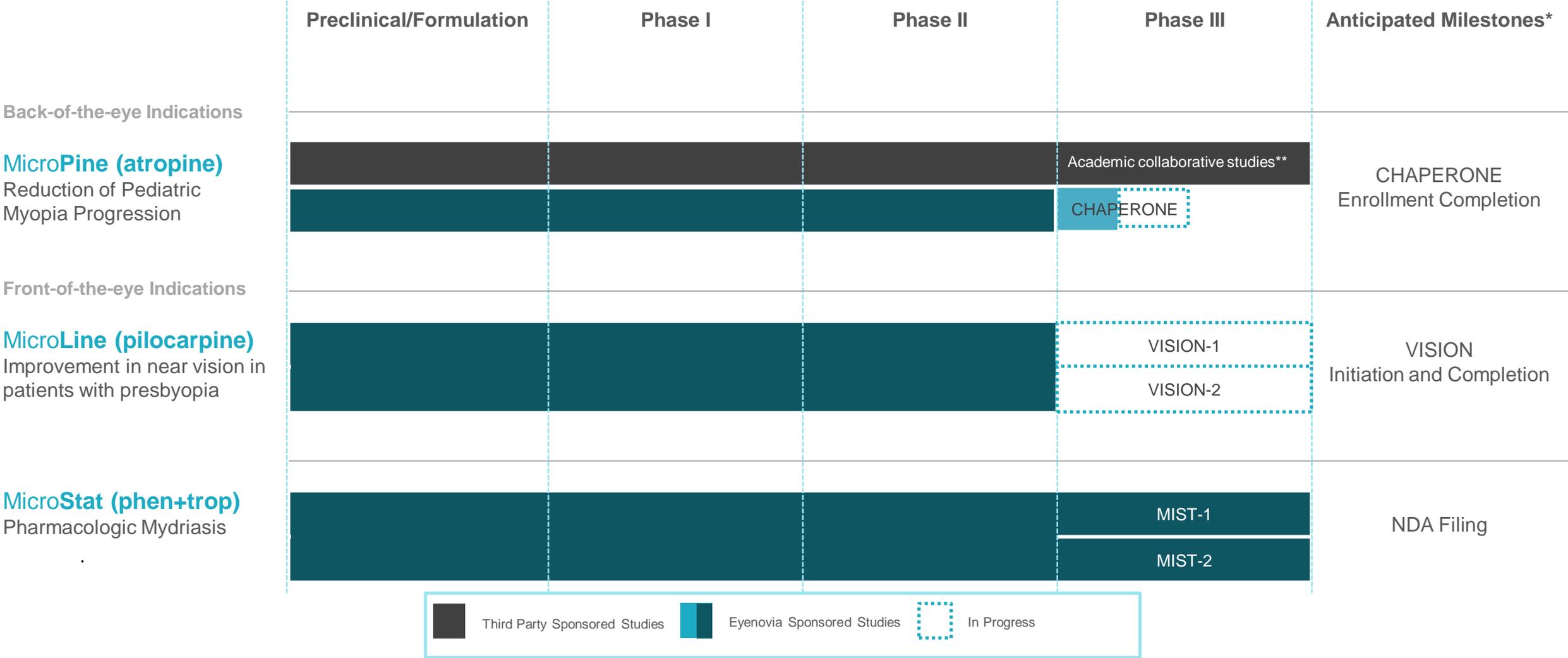
## MicroLine



## MicroStat



# Multiple Late Stage Clinical Assets



\*The company is on track for the MicroStat NDA filing (though it could be delayed due to COVID-19) while the Company previously experienced delays in trial enrollment and initiation as a result of reduced clinical trial activities and operations at investigator sites, it has since been able to resume enrollment in the CHAPERONE study, and in the coming months, subject to any impacts of COVID-19, anticipate initiating its VISION trials for MicroLine.  
 \*\*Completed randomized control trials (RCT's) of low dose topical Atropine from Collaborative Study Groups (ATOM1, ATOM2 and LAMP)



# Significant Clinical Experience and Validation

## Completed Clinical Trials

Ph II

### Mydriasis

Phenylephrine  
Safety

Ph II

### MicroStat

Phen + Trop  
Mydriasis

Ph II

### EYN PG21

IOP Lowering,  
Safety & Usability

Ph III

### MicroStat

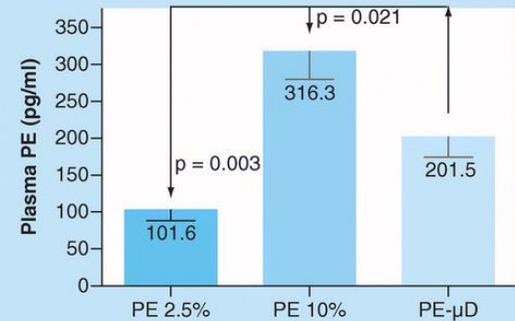
MIST-1  
Mydriasis Program

Ph III

### MicroStat

MIST-2  
Mydriasis Program

## Reduced Systemic Levels



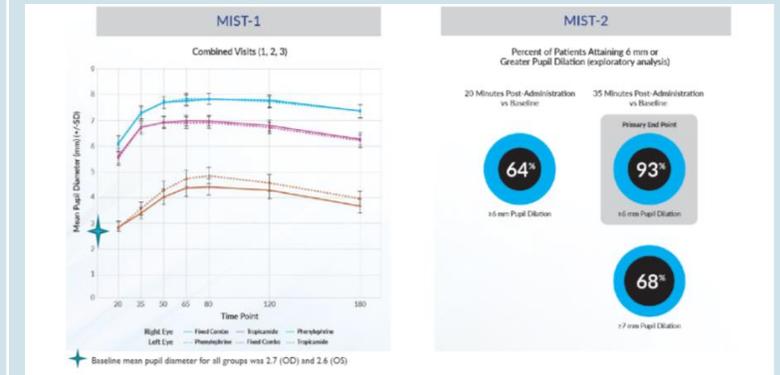
Microdose delivery of phenylephrine was associated with significantly less systemic exposure (Ianchulev, 2017)

## Improved Ocular Tolerability



Microdosing May Reduce Side Effects<sup>1</sup>

## MicroDose Efficacy



Mydriasis with microdose phen-trop fixed combination (Wirta, 2019)

# Progressive Myopia: Back-of-the-eye disease affecting ~5M in the U.S.



Progressive of Myopic Maculopathy

- Pathologic elongation of sclera/retina which can lead to significant morbidity and visual sequelae<sup>1</sup>
  - Retinal detachment
  - Myopic retinopathy
  - Vision loss
  - Quality of life
- Mostly occurs in young adults and children
  - ~9% of children in the United States<sup>2</sup>
  - ~10% of the Worldwide population by 2050<sup>3</sup>
- Currently, no FDA-approved drug therapies to slow myopia progression
- Atropine may slow myopia progression by 60% or more<sup>4</sup>

(1) Eye and Contact Lens. 2004; 30  
(2) Arch Ophthalmol. 2003 Aug;121(8):1141-7).  
(3) Ophthalmology. 2016;123:1036-1042  
(4) Ophthalmology. 2016;123:391-399

# There are No Known FDA-Approved Pharmaceutical Therapies for Myopia

- Significant unmet need as demonstrated by ATOM1, ATOM2 & LAMP studies
- Compounding of atropine in the absence of FDA-approved therapeutic driven by clinical need
- Primarily distributed by compounding pharmacies with limited central quality control



Not Shelf Stable<sup>1</sup>



Often Not Tolerable<sup>2</sup>



Not Currently Covered by  
3<sup>rd</sup> Party Insurance

# MicroPine for Progressive Myopia

- **MicroPine** is Eyenovia's proprietary piezo-compatible microdose formulation of atropine
- One of the first topical therapeutic approaches to prevent a number of back-of-the-eye diseases
- Single Phase III CHAPERONE trial initiated in June 2019
  - Primary EP: Change in refractive error (myopia progression) from baseline through 36 months



# Presbyopia: the Progressive Loss of Ability to Focus on Nearby Objects



## Etiology

- 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



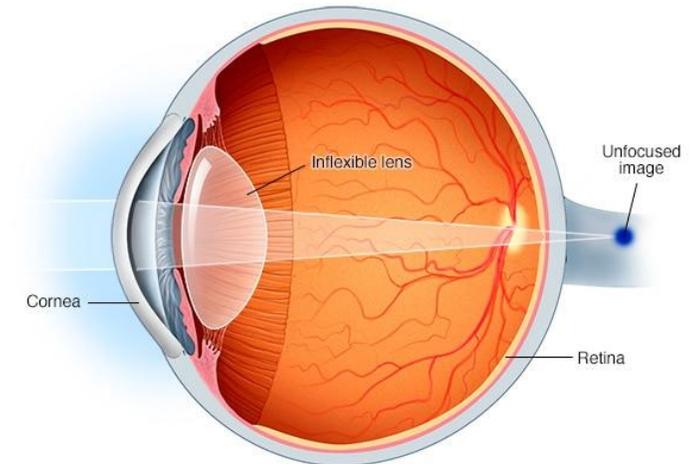
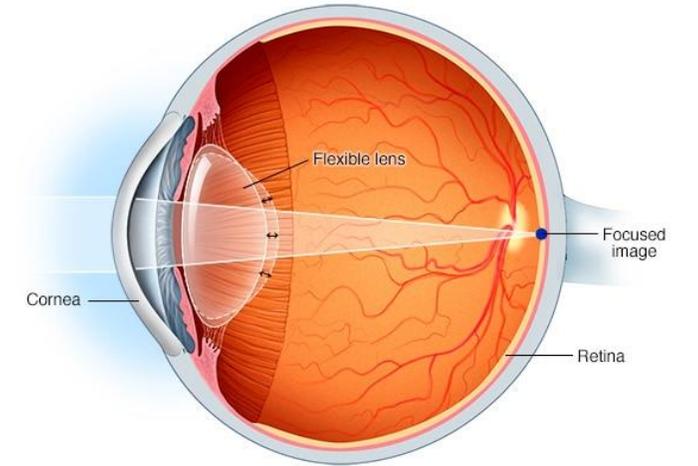
## Risk Factors

- Age
- Medical conditions and co-morbidities such as cardiovascular conditions, multiple sclerosis and type 2 diabetes can increase risk of premature presbyopia
- Drugs associated with premature symptoms include antidepressants, anti-histamines and diuretics



## Diagnosis

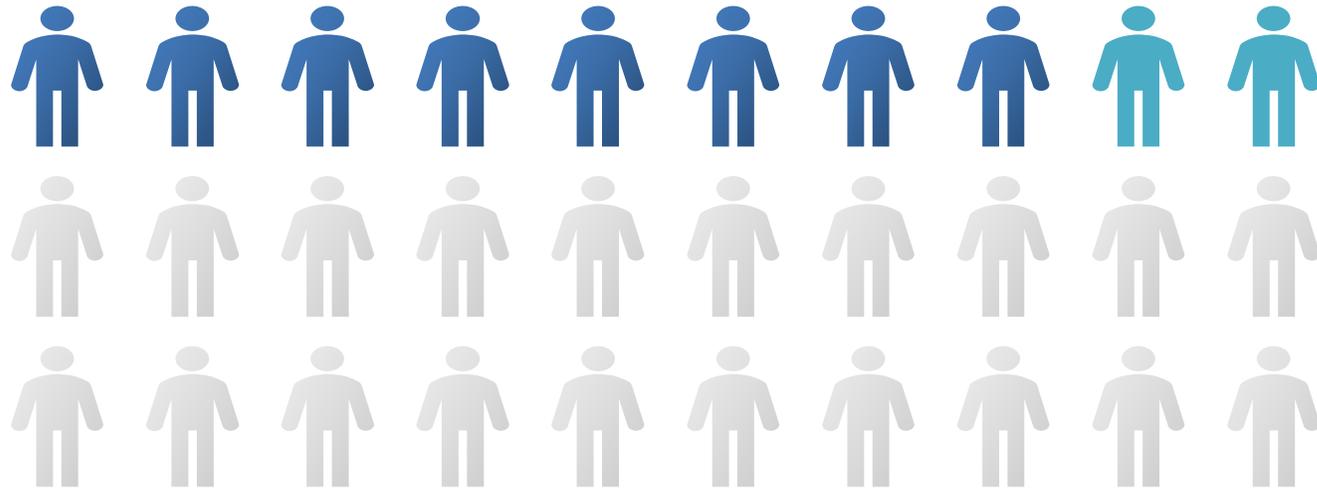
- Basic eye exam, with refraction assessment



# Presbyopia is a Widely Prevalent Vision Correction Issue

**~113 Million** Americans with Presbyopia

**~43 Million** Americans between age 40-65 with Presbyopia and otherwise normal vision and adequate disposable income

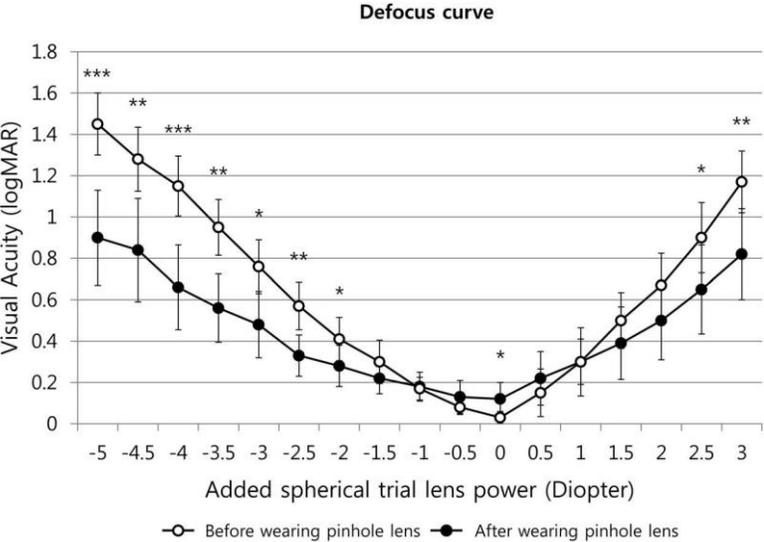


- Prevalence expected to increase and affect ~123 million Americans by 2020, representing >1/3 of United States population; driven by aging population
- Nearly everyone experiences some degree of presbyopia after age 40
- Up to 1/3 of presbyopia sufferers are un-managed
- Presbyopia is a significant and emotional event in an adult's life and often seen as the first sign of aging they cannot hide
- **Psychosocial impact is most important between onset (~40 yo) and retirement age; this subset is also most likely to respond to Rx treatment and willing to pay for it**

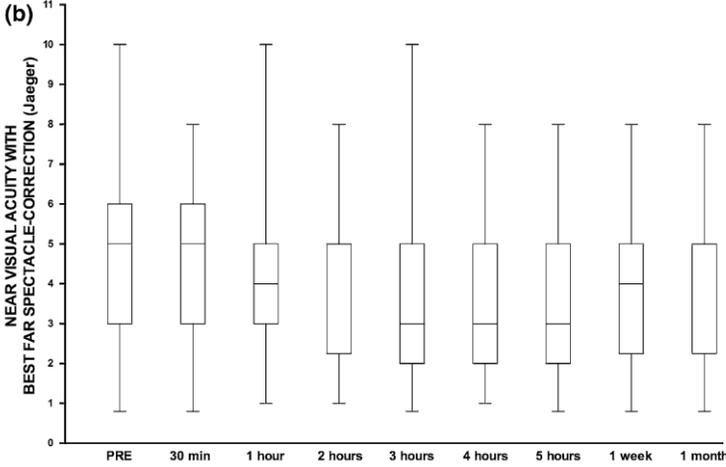
# Pilocarpine: Dual Action Mechanism

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

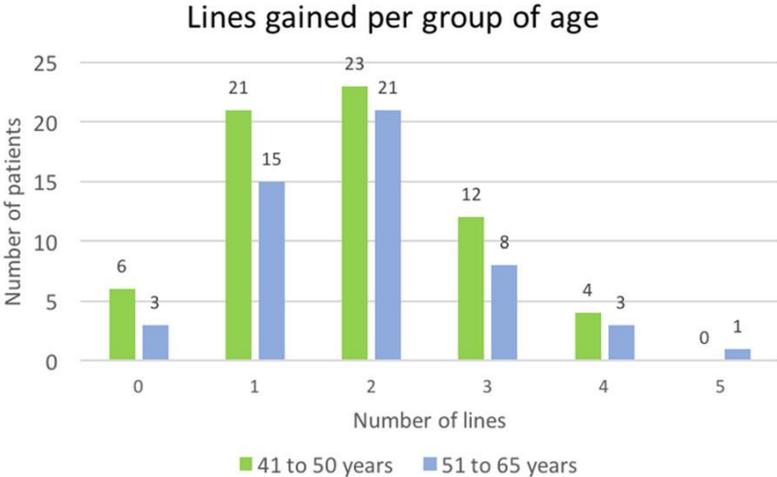
## Pin-Hole Effect Improves Near Vision<sup>1</sup>



## 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

<sup>1</sup> Seminars in Ophthalmology, 2019; 34(2): 106–114  
<sup>2</sup> Ophthalmol Ther (2016) 5:63–73  
<sup>3</sup> Ophthalmol Ther (2019) 8:31–39



# MicroLine: Targeted Corneal Horizontal Delivery with Gentle Microdose

## Indication

- For the improvement in near vision in patients with presbyopia
- Provides ~3-4 hours of near vision with single microRx spray

## Program Overview

- Initiate VISION-1 and VISION-2 Phase III trials

## Commercial

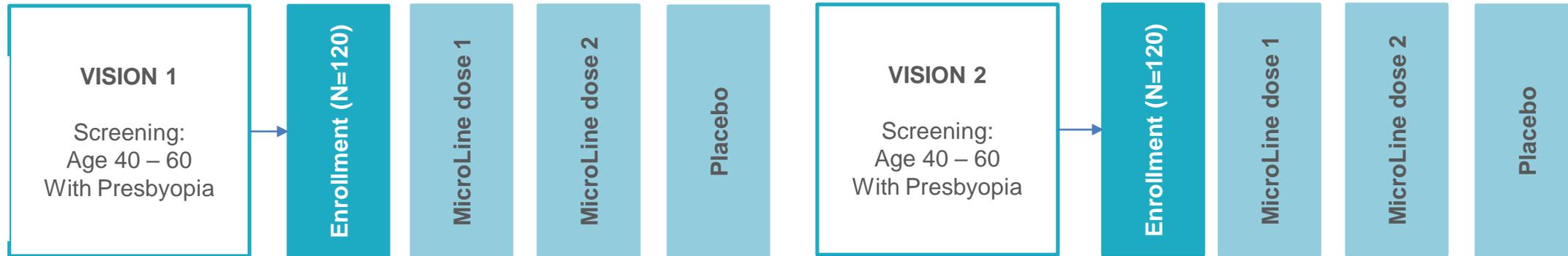
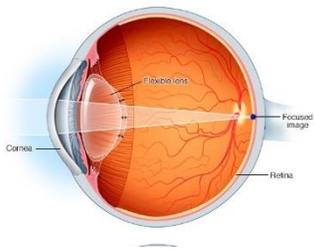
- Estimated addressable population: Adults between 40-65 years old with otherwise normal vision and adequate disposable income
- Estimated addressable United States market: \$2B+
- Anticipated reimbursement: Cash pay

## Competition

- Anticipated among first to market, including Allergan's pilocarpine Phase III eyedrop program
- Eyenovia is the only presbyopia product with piezo-print horizontal delivery and microdosing, designed to address potential pilocarpine side effects and improve user experience

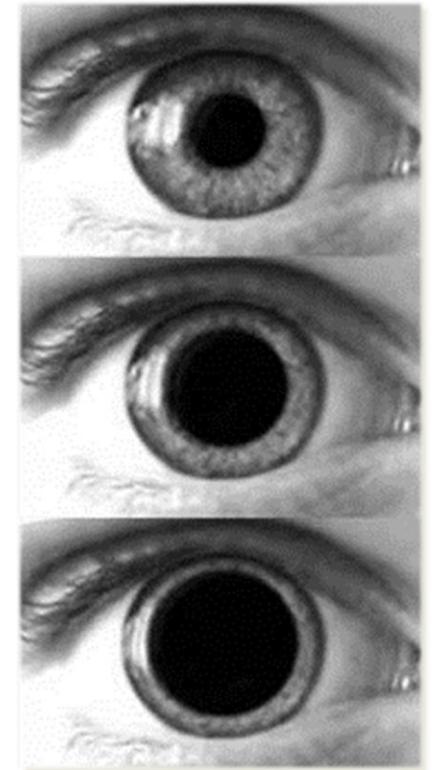
# MicroLine: Phase III Program

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



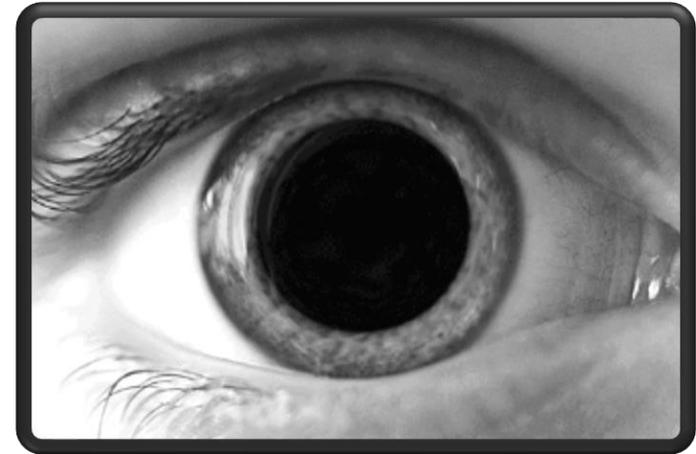
# MicroStat for Mydriasis

- Pharmacologic mydriasis 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
- Reported positive results from pivotal Phase III MIST-1 and MIST-2 trials at the 2019 ASCRS annual meeting
- Places technology at the initial point-of-care with prescribers (ophthalmologists and optometrists)
- Differentiated best-in-class profile with improved simplicity, reliability and tolerability
- 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



# MicroStat Phase III Key Take-Aways

1. Significant, prompt mydriasis achieved with microdose fixed-combination Phen-Trop
2. MicroStat achieved superior efficacy over single-agent components
3. Mydriasis >6 mm achieved in >93% of patients at 35 minutes post-dose which is [Clinically meaningful for both office retinal exam and surgical dilation](#)



# Optejet®: Eyenovia's Unique Technology

- **Novel microdosing technology designed for optimal drug delivery**
  - Piezo-print microdosing to increase precision and reduce waste
  - ~75% less drug and exposure to preservatives (based on 8µL dose)
  - Designed to eliminate drug overflow for a more comfortable patient experience
  - Non-protruding nozzle for no-touch spray application, potentially minimizing risk of cross contamination seen with traditional eye droppers
  - Smart Bluetooth technology to help monitor patient compliance
- **Efficient:** Demonstrated statistical and clinically significant efficacy in both IOP reduction and pharmacological mydriasis<sup>1,2</sup>
- **Safe:** Low systemic drug absorption and good ocular tolerability<sup>2,3</sup>
- **Ease of use:** Both in the hands of medical professionals and patients<sup>1</sup>



<sup>1</sup> Pasquale L. et al., Clinical Ophthalmology 2018

<sup>2</sup> Wirta D. et al, Presentation at 2019 ASCRS meeting

<sup>3</sup> Ianchulev T. et al, Therapeutic Delivery 2018

# EYN PG21: Patients More Likely to Instill Medication with Optejet®

	<b>Optejet® Technician Administration</b>	<b>Optejet® Self Administration</b>	<b>Standard of Care Eyedropper</b>
Total Evaluable Administrations	150	53	
Successful Delivery on First Attempt	95%	88%	39-47%*
Touching Ocular Surface	0%	0%	50+%*

# Microdosing May Reduce Side Effects

- Conventional eye drops may overdose the ocular surface by as much as 300%<sup>1-3</sup>
  - This potentially can cause significant ocular and systemic side effects<sup>4</sup>
- Microdosing has the potential to address these issues by reducing the amount of drug and exposure to preservatives



<sup>1</sup> Washington N, Washington C, Wilson CG. Ocular drug delivery. In: Physiological Pharmaceutics: Barriers to Drug Absorption. 2nd ed. Boca Raton, FL: CRC Press; 2001:249–270.

<sup>2</sup> Mishima S, Gasset A, Klyce SD, Baum JL. Determination of tear volume and tear flow. Invest Ophthalmol. 1966;5(3):264–276.

<sup>3</sup> Scherz W, Doane MG, Dohlman CH. Tear volume in normal eyes and keratoconjunctivitis sicca. Albrecht Von Graefes Arch Klin Exp Ophthalmol. 1974;192(2):141–150.

<sup>4</sup> Wouldn't it be great if eyedrops didn't spill out of your eyes? Science Daily. 2017 Nov

# Eyenovia's Platform Unlocks Pharmaceutical Pipeline Opportunity

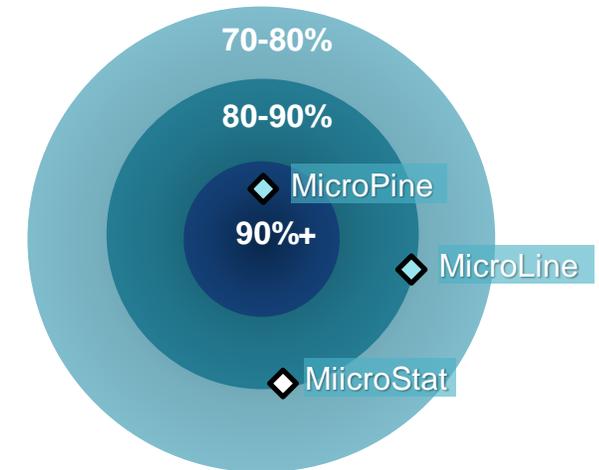
## Next-Generation Ophthalmic Therapeutics

- Eyenovia's microdose therapeutics follow the 505(b)2 registration pathway and are **NOT** currently regulated as medical devices or drug-device combinations
- FDA considers the Optejet<sup>®</sup> to be a container system

## Eyenovia products aim to provide pharmaceutical margins

- All pipeline products are Eyenovia's own proprietary micro-formulations
- Eyenovia currently owns the pharma-economics of the entire prescription value chain
- Micro**Line** has strong potential as a cash-pay cosmeceutical
  - Certain other ophthalmic cosmeceuticals have been well-received into the market with quick penetration

## Estimated Gross Margins



# Strategic Collaboration and Licensing Agreement with Arctic Vision



## Validating partnership for the development and commercialization of MicroPine and MicroLine

- Upfront payment: \$4M
- Potential milestone payments, reimbursed development costs: \$41.75M
  - Potential near-term payments as early as Q4 2020 based on Eyenovia-only development milestone, clinical supplies and other costs
- Commercial supply terms or Royalties: Mid-single digit
- Territory: Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea
  - Impacted population more than eight times greater than the United States (Min Chen, 2018)

# Experienced 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



# Board of Directors



**Dr. Fred Eshelman**  
Chairman

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



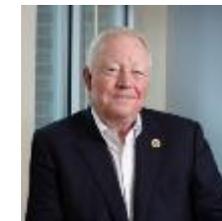
**Dr. Ernest Mario**  
Board Member

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



**Dr. Curt LaBelle**  
Board Member

Managing Director of GHIF venture fund



**Kenneth Lee Jr.**  
Board Member

General partner of Hattteras Venture Partners



**Charles Mather IV**  
Board Member

Managing Director, Equity Capital Markets at Suntrust Robinson Humphrey



**Dr. Anthony Sun**  
Board Member

Former partner at Aisling Capital



**Dr. Sean Ianchulev**  
Board Member

CEO, CMO and Co-Founder of Eyenovia

**Nasdaq:**

**EYEN**

**Common Shares Outstanding<sup>1</sup>**

20.1M

**Equity Grants Outstanding Under Stock Plans<sup>2</sup>**

3.3M

**Warrants**

3.1M

**Fully Diluted Shares**

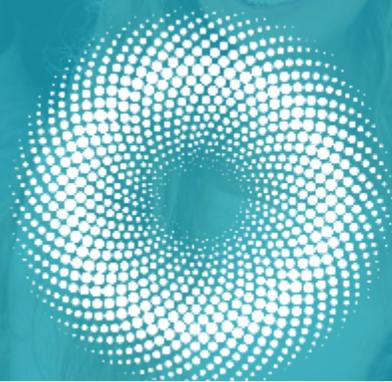
26.5M

**Cash<sup>2</sup>**

\$13.7M

**Debt**

None



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