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): January 30, 2023

EYENOVIA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38365**	**47-1178401**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 an updated corporate presentation Eyenovia, Inc. intends to use with various investors and analysts.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Eyenovia, Inc. Updated Corporate Presentation dated February 2023
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: January 30, 2023

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Forward-Looking Statements

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 the COVID-19 pandemic and resulting decrease in the number of enrolling patients), 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, legislative and geopolitical 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.

Eyenovia at a Glance

Our **Optejet® Microdose Array Print** (MAP™) technology is designed to improve the lives of patients and enhance the practice of optometry and ophthalmic medicine.

Our **commercial model** is designed to maximize the value of our assets while maintaining an efficient cost structure for the benefit of our shareholders.

Eyenovia retains MydCombi™ and MicroLine in the US

+ **Optejet® Available For Licensing** to Increase Therapeutic Coverage

+ **MicroPine Licensed** to Increase Commercial Reach

eyenovia

Investment Highlights

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

LATE-STAGE THERAPEUTICS PIPELINE

MydCombi™ for mydriasis / pupil dilation:
- Potential FDA approval date May 8, 2023

MicroPine for pediatric progressive myopia:
- Phase 3 CHAPERONE IND transferred to Bausch+Lomb

MicroLine for presbyopia / improved near vision:
- Pre-NDA meeting March 28, 2023

DEVELOPMENT AND COMMERCIALIZATION PARTNERSHIPS

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

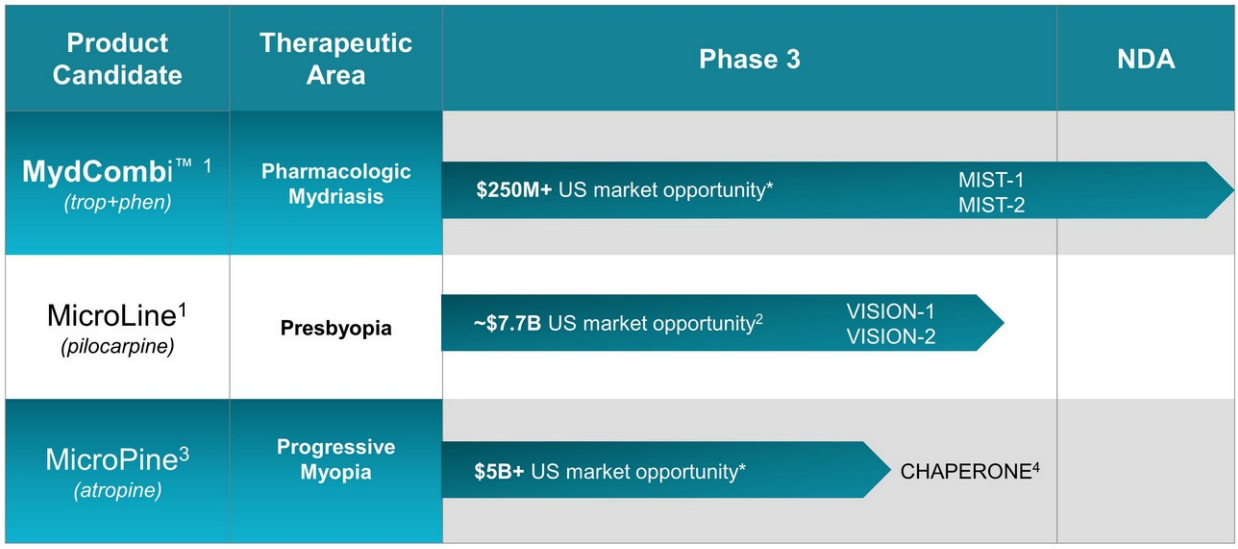
Arctic Vision – MicroPine, MicroLine and MydCombi for Greater China and South Korea; clinical study enrollment underway

Bausch+Lomb – MicroPine in the US and Canada

PLATFORM TECHNOLOGY

for potential pipeline expansion into further high-value ophthalmic indications

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



Potential pipeline expansion activities leveraging Optejet® technology are ongoing

** Estimate only | . [1] Out-licensed to Arctic Vision in Greater China and South Korea | . [2] Estimate from DelveInsight Presbyopia report; December 2020*
[3] Out-licensed to Bausch+Lomb in the US and Canada, and Arctic Vision in Greater China and South Korea | . [4] CHAPERONE oversight and costs assumed by Bausch+Lomb

Eyenovia Leadership Team

Michael Rowe
Chief Executive Officer

John Gandolfo
Chief Financial Officer

Bren Kern
Chief Operating Officer

Malini Batheja
VP, Pharmaceutical R&D
and CMC Regulatory

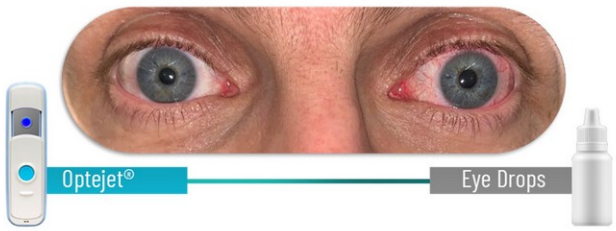
Greg Bennett
VP Clinical Operations
and Medical Affairs

Norbert Lowe
VP, Commercial

Lauren Gidden
AVP, Quality and Regulatory Affairs

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[1]



- **Protruding tip may create cross-contamination risk**
  - More than 50% of administrations unintentionally touch ocular surface[2]
- **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

[1] Abelson, M., 2020. The Hows And Whys Of Pharmacokinetics. ReviewofOphthalmology.com; accessed 11/3/20
[2] Brown MM, Brown GC, Spaeth GL. Improper topical self-administration of ocular medication among patients with glaucoma. Can J Ophthalmol. 1984 Feb;19(1):2-5. PMID: 6608974.

Optejet® - Microdose Array Print (MAP™) Technology Designed for Optimal Drug Delivery

Precise, Physiological Dosing

Directly coats the cornea, reducing overexposure to drug as well as preservative toxicity.[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).[2,5]

Safety

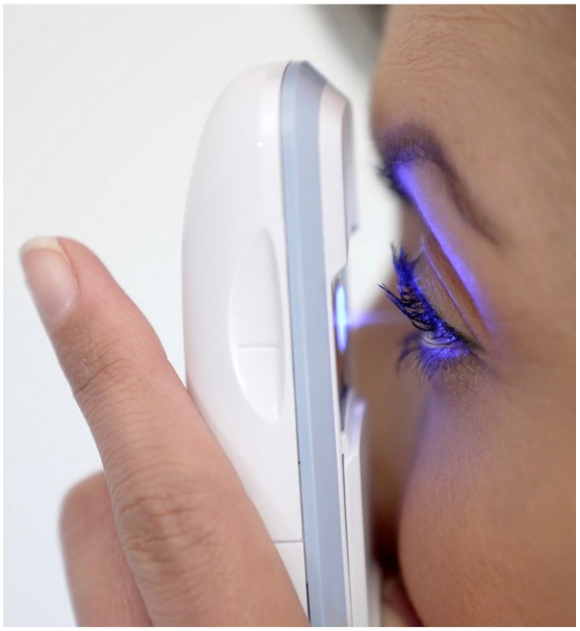
Low systemic drug absorption and good ocular tolerability.[3,4] Non-protruding nozzle for no-touch spray application, potentially minimizing risk of cross contamination seen with traditional eyedroppers.

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 & Adherence

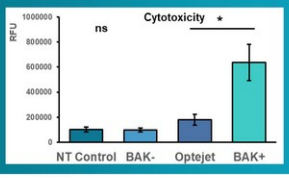
Built-in technology allows pairing with smart devices to enable remote therapeutic monitoring, dosage reminders and therapy tracking.



[1] Study with TUFTS University 2022, Data on File [2] Pasquale L. et al., Clinical Ophthalmology 2018
[3] Wirta D. et al, Presentation at 2019 ASCRS meeting. [4] Ianchulev T. et al, Therapeutic Delivery 2018. [5] Presented at Eyecelerator, July 2021

Minimizes Impact of Preservatives on Ocular Tissues

Results of a human conjunctival cell line assay study with Tufts Medical Center indicate that the impact of preserved medications delivered with the Optejet is similar to non-preserved eye drops[1]



Qualified as a Multidose Preservative-Free Container

Passed 10^6 microbial ingress challenge test demonstrating integrity of the container in normal use[2]

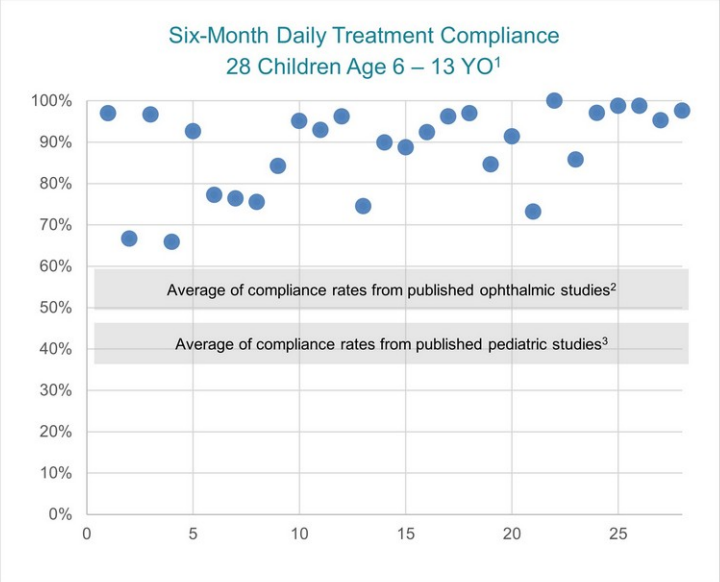
Provides unmatched flexibility in formulation selection

[1]Tufts University Study 2022, Data on File
[2]Study completed 2022, Data on File

Meaningful 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]



[1] Data on file with Eyenovia.
[2]Naito, 2018; Patel, 1995; Winfield, 1990
[3]Matsui, 1997

Optejet® Platform | Potential High-Value Opportunities

Estimated Gross Margins Based on $100/Month Price[1]

80% - 92%

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
- 180-dose cartridge allows for amortization of COGS over multiple months of therapy
- MicroLine has strong potential as a cash-pay cosmeceutical while MydCombi™ will be a cash-pay diagnostic

[1] Estimates for "at scale" (250,000 annual units minimum)

Presbyopia | There Exists a Significant Unmet Need

- Presbyopia is the age-related loss of near vision that occurs as the lens becomes inelastic
- Majority of people aged 40 – 55 have never needed glasses prior to having difficulty with near vision
- Having to wear glasses can be an inconvenience and an unwanted outward signal of aging
- An alternative which is less obvious and more convenient is seen as valuable
- Eyenovia's **MicroLine** is intended to be that inconspicuous, convenient alternative
- **MicroLine** provides near vision without the appearance and inconvenience of reading glasses

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

Presbyopia is a **7.7 billion dollar**[1] market

[1] Estimate from DelveInsight Presbyopia report; December 2020

- Effective at temporarily 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

VISION 1 and VISION 2 Study Design

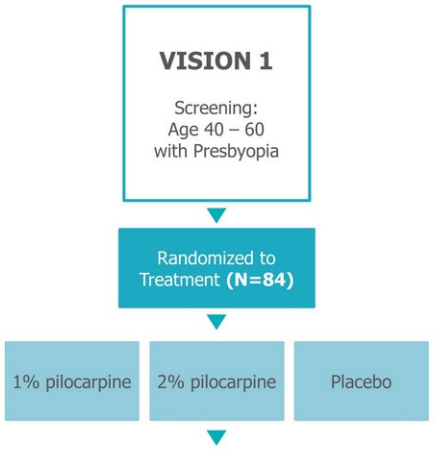
Phase 3 double-masked, placebo-controlled, cross-over superiority trial

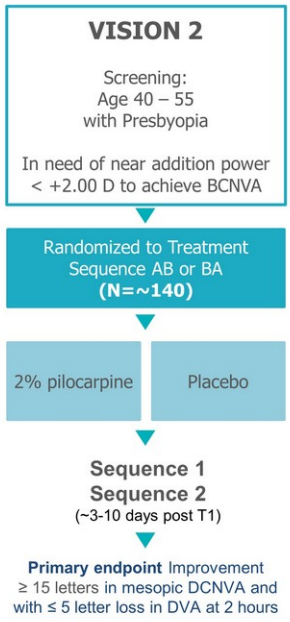
Microdosed pilocarpine and placebo ophthalmic sprays

Study Design was chosen for efficiency to 'Dose on Demand'

DCNVA:
Distance Corrected Near Visual Acuity

DVA:
Distance Visual Acuity





1 AGN-190584 and Rapid Visual Acuity Improvement in Presbyopia on Day 1 of Treatment: Results from the Phase 3 Studies, G Waring
2. Data on File (VISION1/VISION 2 Combined Results)

Combined VISION-1 and VISION-2 Results
MicroLine (Pilocarpine 2% Spray) was Comfortable and Well-tolerated

6.0x

More patients achieved ≥ 3-line gain in the active group vs placebo[2]

2:1

Proportion of Patients Reporting Improvement in Near Vision

Exit survey: Percent reporting meaningful improvement in near vision

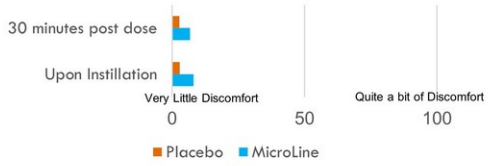
Key Safety Outcomes

All AEs were Transient in Nature

	MicroLine	Placebo
Moderate Hyperemia[1]	0.9%	0%
Instillation Discomfort	1.7%	0%
Brow ache	2.2%	0%

Safety Population: 229 Subjects

Patient Comfort Assessment



1 Resolved by 3 hours post-dose
2 Cohort of subjects with baseline DCNVA < 0.6 logMAR

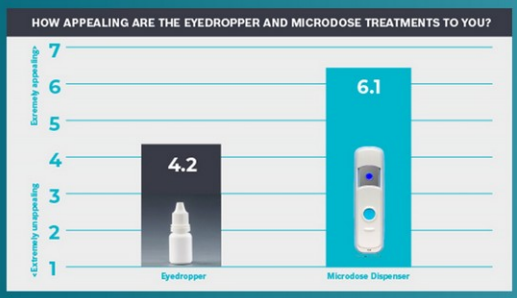
Post-Study Surveys Indicates Strong Preference for MicroLine

MARKET RESEARCH 1 - June 2021

PRESBYOPIA FOCUS GROUPS DESCRIBE A BETTER OPTIONS

The ideal product profile would include:

- ✓ No risk of headaches
- ✓ Lower risk of red eye/other side effects
- ✓ It's futuristic and "cool"
- ✓ Convenience



MARKET RESEARCH 2 - December 2020

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 $100 for 80 doses is not expected to be an issue
- ✓ Lack of side effects, especially headache, was deemed "very important"

MARKET RESEARCH 3 - May 2022

Among 100 presbyopic patients aged 40-55

- ✓ 4 out of 5 patients said they would prefer the Optejet device over the traditional eyedrop bottle

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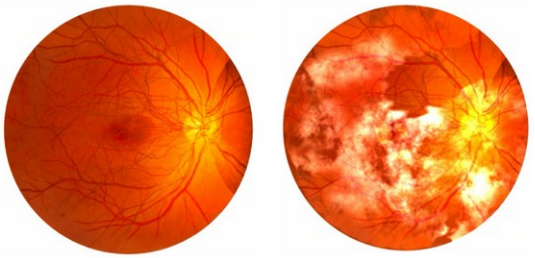
Progression of Myopic Maculopathy



Normal Macula | Myopic Maculopathy

Affects ~25M children in the US alone, with ~5M considered to be at high risk[4]

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

[1] Jones LA, Sinnott LT, Mutti DO, Mitchell GL, Moeschberger ML, Zadnik K. Parental history of myopia, sports and outdoor activities, and future myopia. Invest Ophthalmol Vis Sci. 2007 Aug;48(8):3524-32.
[2] Eye and Contact Lens. 2004; 30
[3] Chia A, Chua WH, Cheung YB, et al. Atropine for the treatment of childhood Myopia: Safety and efficacy of 0.5%, 0.1%, and 0.01% doses (Atropine for the Treatment of Myopia 2). Ophthalmology 2012;119:347-354
[4] Theophanous C. Myopia Prevalence and Risk Factors in Children. Clinical Ophthalmology. December 2018. U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2019.

- Clinically meaningful and significant efficacy at preventing myopia progression versus placebo
- Ability for children to reliably use, once daily per eye
- Comfortable to instill, minimal impact on the ocular surface
- Minimal local side effects and systemic absorption
- Potential for tracking adherence and providing dosing reminders for purpose of improving treatment success

Chaperone Study Design

36mo

Chaperone Study – Multi-year single Phase III Trial anticipated to complete in 2026

Primary Endpoint: Proportion of subjects with <0.5 diopter change in refractive error (myopia progression) from baseline through 36 months.

12mo

Patients are then re-randomized to the same or an alternative treatment arm and followed for an additional 12 months.

Enrollment completion expected 2023*

CHAPERONE

CHAPERONE
Screening:
Age 3-12
With Pediatric
Myopia

Patients Randomized (N=~420)

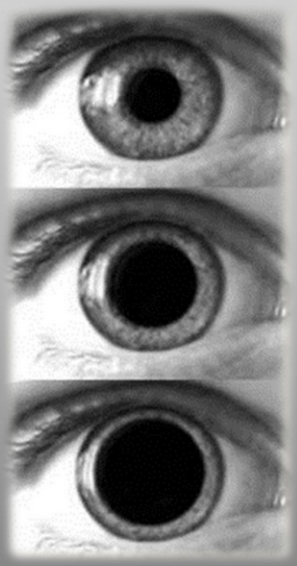
- **MicroPine Dose 1** (0.01% atropine)
- **MicroPine Dose 1** (0.1% atropine)
- **Placebo**

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

Diagnostic Mydriasis

- **Diagnostic 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 opportunity[1]

- **There are several issues with the current standard of care**
  - Three different eyedrops
  - Patient discomfort and avoidance
  - Excess chair time
  - Hygiene risk



[1] $200M annual sales of pharmaceutical mydriatic products used during 100M office-based exams ($2 * 100M) + $50M of single bottle mydriatic agents used cataract replacement surgery ($12.5 x 4M)

MydCombi™ among the first drug-device combination products for pupil dilation

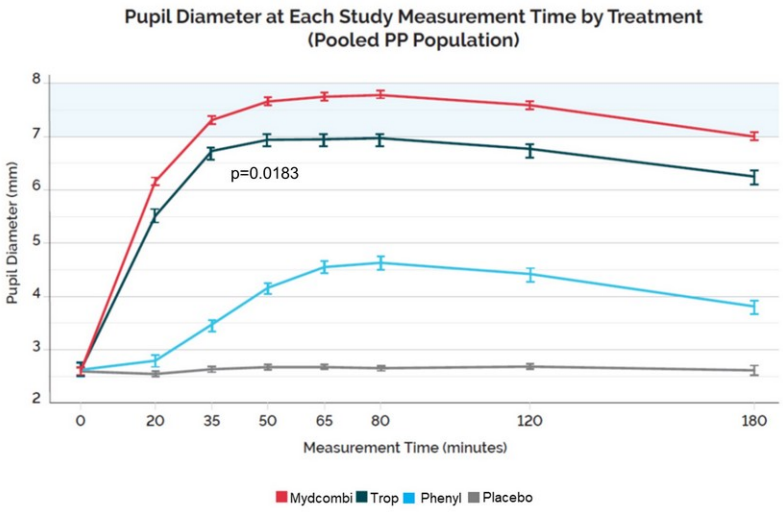
MydCombi™

(tropicamide and phenylephrine HCl ophthalmic spray) 1%/2.5%

- If approved, the only fixed drug combination of the two leading mydriatic medications in the US
- Device administered with the push of a button, saving up to ten minutes of technician time[1]
- Touch-free, comfortable application does not require anesthetic with fewer than 1% of patients experiencing stinging discomfort[2]
- Lower drug and preservative exposure, including systemic absorption of phenylephrine, which can be problematic in hypertensive patients[2,3]
- Reliable in numerous patient practices. 60% of patients quickly achieved clinically significant mydriasis at 20 minutes and nearly 95% did so at 35 minutes post-dosage[2]

[1] Denion E. et al, A 5-Minute Interval between Two Dilating Eye Drops Increases Their Effect. Optom Vis Sci. 2017 Aug
[2] Wirta, D. Presented at ASCRS Annual Meeting, 2019, San Diego CA
[3] Abelson, M., 2020. The Hows And Whys Of Pharmacokinetics. ReviewofOphthalmology.com; accessed 11/3/20

MydCombi has a Superior Mydriatic Effect vs. Single Agents



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.

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

Strategic Partnerships to Potentially Extend Commercial Reach

arctic VISION

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**

Arctic Vision Announces First Patient Enrolled in Phase III Clinical Trial of ARVN003 for Presbyopia – July 4, 2022

- ARVN003 (MicroLine) is expected to be the first approved drug for presbyopia in China
- This is the first clinical trial approved in China for presbyopia drugs

Strategic Partnerships to Potentially Extend Commercial Reach

BAUSCH + LOMB | 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 approximately 5M[1,2]

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

Territory: **US and Canada**

[1] Theophanous C. Myopia Prevalence and Risk Factors in Children. Clinical Ophthalmology. December 2018.
[2] U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2019.

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

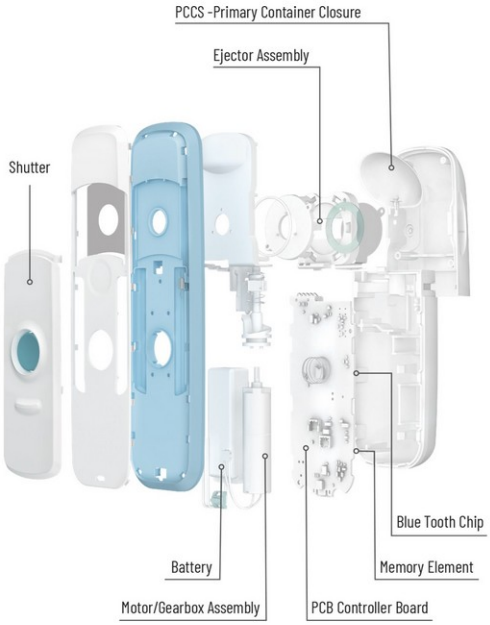
18 U.S. Patents Issued; 8 Pending

89 O.U.S. Patents Issued; 33 Pending

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

Various patents in effect until late 2031

Provisional patents filed to bring protection through 2040



Nasdaq: EYEN	
Common Shares Outstanding	35.5M
Equity Grants Outstanding Under Stock Plans Includes Options and RSUs	5.7M
Warrants	6.1M
Fully Diluted Shares	47.3M
Cash	$25.3M[1]
Debt	$11.1M

1. $7.9M of the cash balance is restricted. All figures as of September 30 2022.

Board of Directors

Sean Ianchulev, MD, MPH
Chairman
Co-Founder of Eyenovia

Charles Mather IV
Independent Director
Managing Director, Equity Capital Markets at STRH

Stephen Benjamin, JD
Independent Director
Former President, The US Conference of Mayors

Rachel Jacobson
Independent Director
President, The Drone Racing League

Ellen Strahlman, MD, MS
Independent Director
Partner, Reillen Group

Ram Palanki, PharmD
Independent Director
EVP, REGENXBIO

Michael Rowe
Director
CEO of Eyenovia