

**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): August 10, 2022

**EYENOVIA, INC.**

(Exact Name of Registrant as Specified in its Charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-38365  
(Commission  
File Number)

47-1178401  
(IRS Employer  
Identification No.)

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

(917) 289-1117  
Registrant's Telephone Number, Including Area Code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	(Trading Symbol)	(Name of each exchange on which registered)
Common stock, \$0.0001 par value	EYEN	The Nasdaq Stock Market (Nasdaq Capital Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02. Results of Operations and Financial Condition.**

On August 10, 2022, Eyenovia, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information contained in, or incorporated into, Item 2.02, including the press release attached as Exhibit 99.1, is being furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

**Item 8.01 Other Events.**

Attached hereto as Exhibit 99.2 and incorporated herein by reference is an updated corporate presentation the Company intends to use with various investors and analysts.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Eyenovia, Inc. Press Release dated August 10, 2022</a>
<a href="#">99.2</a>	<a href="#">Eyenovia, Inc. Updated Corporate Presentation dated August 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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.**

/s/ John Gandolfo  
John Gandolfo  
Chief Financial Officer

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Date: August 10, 2022

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**Eyenovia Reports Second Quarter 2022 Financial Results**

Announced appointment of Michael Rowe as Chief Executive Officer and Board member

Mydcombi™ NDA resubmission on track for the fourth quarter of 2022

Phase 3 VISION-2 study evaluating MicroLine as an on-demand treatment for improving near vision (presbyopia) progressing as planned; topline data expected in the third quarter of 2022

Company to host conference call and webcast today, August 10, at 4:30 pm ET

NEW YORK—August 10, 2022—Eyenovia, Inc. (Nasdaq: EYEN), a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on its proprietary microdose array print (MAP™) platform technology, today announced its financial and operating results for the second quarter ended June 30, 2022.

**Second Quarter 2022 and Recent Business Developments**

- Announced the appointment of Eyenovia's former Chief Operating Officer, Michael Rowe, as the company's new Chief Executive Officer, replacing Dr. Sean Ianchulev, who has transitioned to Chairman of the Board of Directors. Mr. Rowe was also appointed as a director to Eyenovia's Board of Directors.
  - Global supply chain issues impacting the production of Mydcombi™ validation units have been resolved and the New Drug Application ("NDA") resubmission is now expected in the fourth quarter of 2022.
  - VISION-2 Phase 3 trial evaluating MicroLine as a potential, on-demand treatment for presbyopia progressing as planned, with topline data anticipated in the third quarter of 2022. If successful, the Company plans to start production of registration batches as a requirement towards filing a new drug/device combination application to the U.S. Food and Drug Administration ("FDA")
  - Announced that the Company's new manufacturing facility in Redwood City, CA is now operational, and also announced the appointment of Bren Kern as Senior Vice President of Manufacturing and Operations.
  - Appointed Dr. Ellen Strahlman and Dr. Ram Palanki as directors to the Board of Directors. Together, they bring decades of medical technology, clinical development, product launch and commercialization experience, much of it specific to ophthalmology.
  - Announced that the Company's strategic partner, Arctic Vision, enrolled the first patient in its Phase 3 clinical trial of ARVN003 (MicroLine) for presbyopia in China.
  - Ended the second quarter of 2022 with approximately \$29.4 million in total cash and cash equivalents, including \$7.9 million of restricted cash.
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Dr. Sean Ianchulev, Chairman of the Board of Directors, commented, “We achieved significant progress during the second quarter and subsequent period across both our Mydcombi and MicroLine programs, and we are very fortunate to have concluded our CEO search with the appointment of Michael Rowe who we believe is the ideal candidate to sustain our current momentum. His appointment maintains continuity while bringing significant ophthalmic operations and commercialization expertise to the role ahead of significant regulatory and clinical milestones. These include the pending resubmission of our Mydcombi New Drug Application and near completion of our second Phase 3 presbyopia trial, each of which moves us a step further to transitioning to a commercial stage company.”

Michael Rowe, Chief Executive Officer, commented, “We are nearing completion of the additional Optejet device validation testing requested by the FDA when Mydcombi was reclassified as a drug-device combination product. Global supply chain issues that have impacted most high technology manufacturers and delayed the production of our validation units have now been resolved. As a result, we now anticipate resubmitting our NDA to the FDA during the fourth quarter of 2022. If approved next year, Mydcombi for mydriasis would be the first commercial product to leverage our Optejet dispensing technology, a significant achievement for our Company. With our presbyopia program also progressing, and our Redwood City manufacturing operations up and running, this is indeed a transformational time for our Company. I am pleased with the progress made addressing these challenges during the second quarter and look forward to a productive back half of the year.”

#### **Second Quarter 2022 Financial Review**

For the second quarter of 2022, net loss was approximately \$(7.2) million, or \$(0.22) per share compared to a net loss of approximately \$(4.8) million, or \$(0.19) per share, for the second quarter of 2021.

Total license revenue was \$0.0 million for the second quarter of 2022 as compared to \$2.0 million for the second quarter of 2021.

Research and development expenses totaled approximately \$3.6 million for the second quarter of 2022 as compared to \$3.7 million for the second quarter of 2021, a decrease of approximately (2.7%).

For the second quarter of 2022, general and administrative expenses were approximately \$3.5 million, compared to \$2.3 million for the second quarter of 2021, an increase of approximately 53.8%.

Total operating expenses for the second quarter of 2022 were approximately \$7.1 million compared to \$6.0 million for the second quarter of 2021. This represents an increase of approximately 19.0%.

As of June 30, 2022, the Company’s cash and cash equivalents were approximately \$29.4 million, including \$7.9 million of restricted cash, as compared to \$27.3 million as of December 31, 2021.

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#### **Conference Call and Webcast**

The conference call is scheduled to begin at 4:30 pm ET today, August 10. Participants should dial 877-407-9039 (domestic) or 201-689-8470 (international) with the conference code 13731733. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at [www.eyenovia.com](http://www.eyenovia.com).

After the live webcast, the event will be archived on Eyenovia's website for one year.

#### **About the VISION Trials**

The VISION trials are Phase 3, double-masked, placebo-controlled, cross-over superiority trials that enroll participants with presbyopia. The primary endpoint is improvement in high-contrast binocular distance corrected near visual acuity in low light conditions. MicroLine is intended for the "on demand" improvement of near vision in people with presbyopia.

#### **About MicroLine for Presbyopia**

MicroLine (pilocarpine ophthalmic spray) is Eyenovia's investigational pharmacologic treatment for presbyopia. Presbyopia, or farsightedness, is the non-preventable, age-related hardening of the lens, which causes a gradual loss of the eye's ability to focus on nearby objects and is estimated to affect nearly 113 million Americans. Pilocarpine ophthalmic solution is known to constrict the pupil and improve near-distance vision by creating an extended depth of focus through its small aperture effect. Eyenovia believes that its administration of pilocarpine using the Company's high precision microdosing technology could provide a meaningful improvement in near vision while enhancing tolerability and usability. MicroLine has been licensed to Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

#### **About MicroPine for Progressive Myopia**

MicroPine (atropine ophthalmic spray) is Eyenovia's investigational, potentially first-in-class topical treatment for the reduction of pediatric myopia progression, also known as nearsightedness, in children ages 3-12. It has been developed for comfort and ease-of-use in children, and its microdose administration is designed to potentially result in low systemic and ocular drug exposure. MicroPine has been licensed to Bausch+Lomb, Inc. in the United States and Canada, and Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

#### **About Mydcombi™ for Mydriasis**

Mydcombi is Eyenovia's investigational, first-in-class fixed-dose-combination product (tropicamide 1% and phenylephrine 2.5% ophthalmic spray) for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 100 million office-based comprehensive eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. Developed as a micro-formulation for use without anesthetic, Eyenovia believes Mydcombi will help improve the efficacy, tolerability, and efficiency of pharmacologic mydriasis. Mydcombi has been licensed to Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

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#### **About Optejet® and Microdose Array Print (MAP™) Therapeutics**

Eyenovia's Optejet microdose formulation and delivery platform for ocular therapeutics uses high-precision piezo-print technology to deliver 6-8 µL of drug, consistent with the capacity of the tear film of the eye. We estimate the volume of ophthalmic solution administered with the Optejet is less than 20% of that delivered using conventional eyedroppers, thus reducing overdosing and exposure to drug and preservatives. Eyenovia's patented microfluidic ejection technology is designed for fast and gentle ocular surface delivery, where solution is dispensed to the ocular surface in approximately 80 milliseconds, beating the ocular blink reflex. Successful use of the Optejet has been demonstrated more than 85% of the time after basic training in a variety of clinical settings compared to 40 – 50% historically seen with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

#### **About Eyenovia, Inc.**

Eyenovia, Inc. (Nasdaq: EYEN) is an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for mydriasis, presbyopia and myopia progression. For more information, visit [Eyenovia.com](http://Eyenovia.com).

The Eyenovia Corporate Information slide deck may be found at [ir.eyenovia.com/events-and-presentations](http://ir.eyenovia.com/events-and-presentations).

#### **Forward-Looking Statements**

Except for historical information, all of the statements, expectations and assumptions contained in this press release 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. In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could still be adversely impacted by COVID-19), timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential impacts of COVID-19 and related economic disruptions on our supply chain, including the availability of sufficient components and materials used in our product candidates; the potential advantages of our product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; intellectual property risks; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; our competitive position; and other risks described from time to time in the "Risk Factors" section of our filings with the U.S. Securities and Exchange Commission, including those described in our Annual Report on Form 10-K as well as our Quarterly Reports on Form 10-Q, and supplemented from time to time by our Current Reports on Form 8-K. 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.

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**Eyenovia Contact:**

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EYENOVIA, INC.  
Condensed Balance Sheets

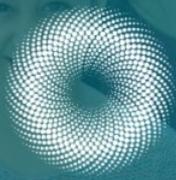
	June 30, 2022 (unaudited)	December 31, 2021
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 21,506,582	\$ 19,461,850
Deferred clinical supply costs	1,538,380	-
License fee and expense reimbursements receivable	709,234	1,805,065
Prepaid expenses and other current assets	1,858,530	721,438
Total Current Assets	25,612,726	21,988,353
Restricted cash	7,875,000	7,875,000
Property and equipment, net	1,406,666	1,271,225
Security deposits	201,407	132,539
Equipment deposits	510,239	391,941
Total Assets	\$ 35,606,038	\$ 31,659,058
<b>Liabilities and Stockholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 2,686,794	\$ 1,614,104
Accrued compensation	1,014,084	1,543,618
Accrued expenses and other current liabilities	824,302	845,719
Deferred rent - current portion	27,462	18,685
Notes payable	7,429,131	7,150,368
Total Current Liabilities	11,981,773	11,172,494
Deferred rent - non-current portion	13,528	19,949
Total Liabilities	11,995,301	11,192,443
Stockholders' Equity:		
Preferred stock, \$0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2022 and December 31, 2021	-	-
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 33,623,053 and 28,426,616 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	3,363	2,844
Additional paid-in capital	128,405,445	110,683,077
Accumulated deficit	(104,798,071)	(90,219,306)
Total Stockholders' Equity	23,610,737	20,466,615
Total Liabilities and Stockholders' Equity	\$ 35,606,038	\$ 31,659,058



EYENOVIA, INC.

Condensed Statements of Operations  
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
<b>Operating Income</b>				
Revenue	\$ -	\$ 2,000,000	\$ -	\$ 4,000,000
Cost of revenue	-	(800,000)	-	(1,600,000)
Gross Profit	-	1,200,000	-	2,400,000
<b>Operating Expenses:</b>				
Research and development	3,586,866	3,684,647	7,299,450	8,007,296
General and administrative	3,534,590	2,297,492	7,009,555	4,541,482
Total Operating Expenses	7,121,456	5,982,139	14,309,005	12,548,778
Loss From Operations	(7,121,456)	(4,782,139)	(14,309,005)	(10,148,778)
<b>Other Income (Expense):</b>				
Other income, net	33,376	18,567	26,303	37,152
Interest expense	(153,436)	(78,047)	(298,673)	(83,195)
Interest income	2,416	220	2,610	1,754
	-	-	-	-
<b>Net Loss</b>	\$ (7,239,100)	\$ (4,841,399)	\$ (14,578,765)	\$ (10,193,067)
Net Loss Per Share - Basic and Diluted	\$ (0.22)	\$ (0.19)	\$ (0.46)	\$ (0.40)
Weighted Average Number of Common Shares Outstanding				
- Basic and Diluted	33,644,867	25,927,303	31,836,582	25,630,572



eyenovia

Making it Possible | August 2022



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 estimate 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.

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



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:**

- Planned NDA submission 4Q 2022

**MicroPine for pediatric progressive myopia:**

- Phase 3 CHAPERONE IND transferred to Bausch+Lomb

**MicroLine for presbyopia / improved near vision:**

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

### DEVELOPMENT AND COMMERCIALIZATION PARTNERSHIPS

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

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

**Bausch Health** – MicroPine in the US and Canada

### PLATFORM TECHNOLOGY

for potential pipeline expansion into further high-value ophthalmic indications

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

Potential pipeline expansion activities leveraging Optejet® technology are ongoing



**Michael Rowe**  
CEO



**John Gandolfo**  
CFO



**Bren Kern**  
SVP, Operations



**Malini Batheja**  
VP, Pharmaceutical R&D



**Beth Scott**  
VP, Regulatory and Medical Affairs



**Norbert Lowe**  
VP, Commercial



**Greg Bennett**  
VP Clinical Operations



- ↓ 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 unintentionally 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

<sup>1</sup>Abelson, M., 2020. The Hows And Whys Of Pharmacokinetics. ReviewofOphthalmology.com; accessed 11/3/20

<sup>2</sup>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.

## ■ Precise, Physiological Dosing

Directly coats the cornea, reducing overexposure to drug as well as preservative toxicity.<sup>1</sup> 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).<sup>2,5</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>

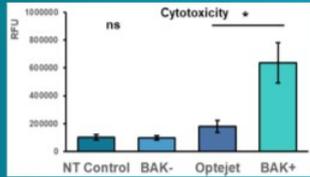
## ■ Compliance and Adherence

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



## 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<sup>1</sup>



## Qualified as a Multidose Preservative-Free Container

Passed 10<sup>6</sup> microbial ingress challenge test demonstrating integrity of the container in normal use

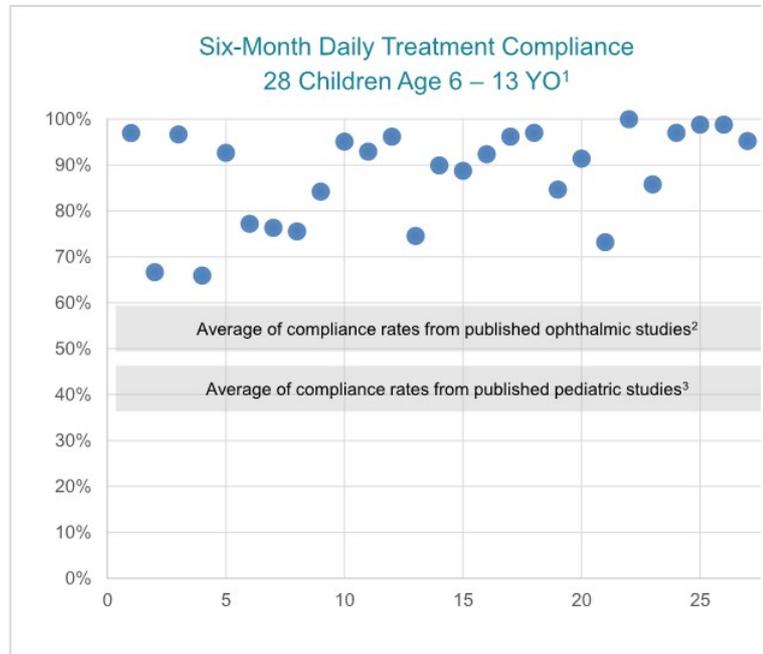


**Provides unmatched flexibility in formulation selection**

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<sup>2,3</sup>



<sup>1</sup>Data on file with Eyenovia.  
<sup>2</sup>Naito, 2018; Patel, 1995; Winfield, 1990  
<sup>3</sup>Matsui, 1997

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

**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™ is a cash-pay diagnostic

- 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

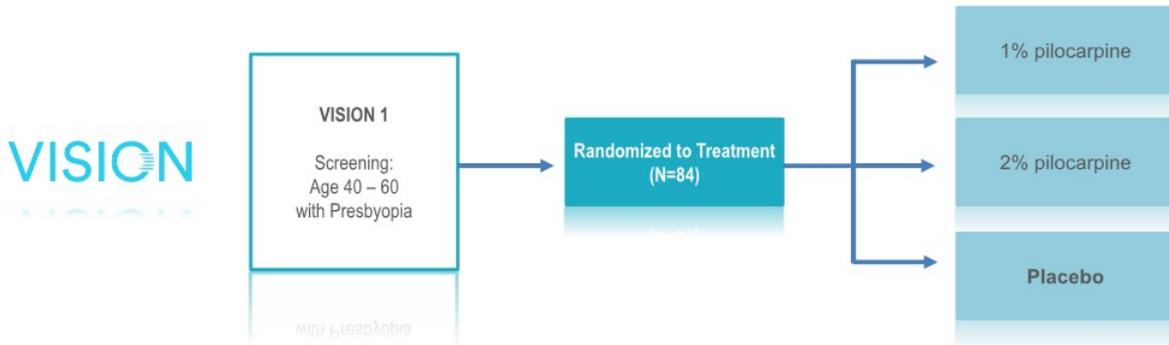


**18 million** people 40-55 years of age who never previously needed glasses suffer from presbyopia in the US alone

Presbyopia is a **7.7 billion dollar**<sup>1</sup> market

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

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



## Key Safety Outcomes

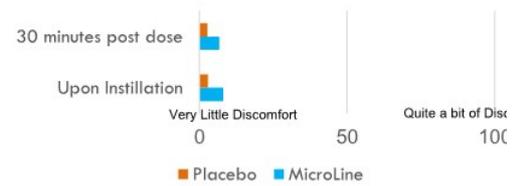
All AEs were Transient in Nature

	MicroLine	Placebo
Moderate Hyperemia <sup>1</sup>	2%	0%
Instillation Discomfort	2%	0%
Brow ache	2%	0%



Exit survey: Percent reporting significant improvement in near vision

## Patient Comfort Assessment



<sup>1</sup> Resolved by 3 hours post-dose

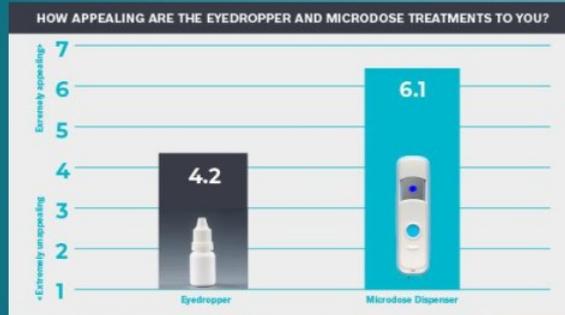
<sup>2</sup> Cohort of subjects with baseline DCNVA < 0.6 logMAR

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

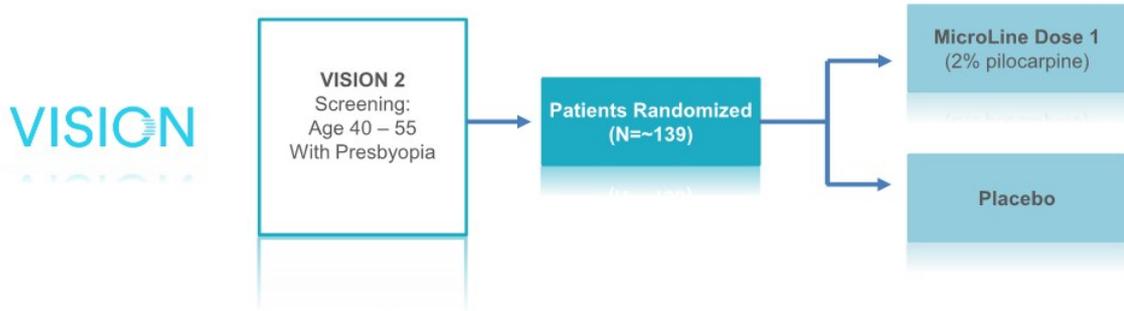
- ✓ Most likely users were between 40 and 55 years old in the top half of household incomes
- ✓ A price of approximately \$100 for 80 doses is not expected to be an issue
- ✓ Lack of side effects, especially headache, was deemed "very important"

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

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

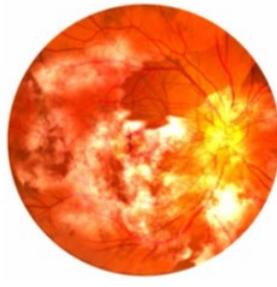


Topline data anticipated 2H 2022

## Progression of Myopic Maculopathy



Normal Macula



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
  - 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>

- Clinically meaningful and significant effectiveness 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

→ 36mo



**Chaperone Study – Multi-year single Phase III Trial anticipated to complete in 2025**

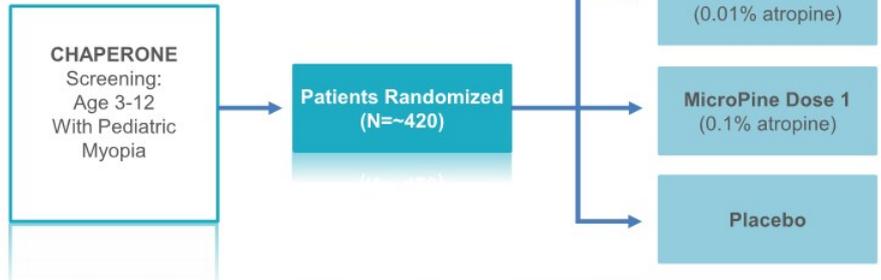
Primary Endpoint: Proportion of subjects with <math><0.5</math> diopter change in refractive error (myopia progression) from baseline through 36 months.

→ 12mo

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



Enrollment completion expected Q4 2022\*

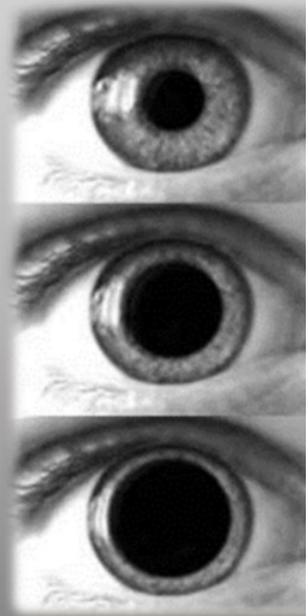


## ➤ Diagnostic mydriasis (pupil dilation) is part of the comprehensive eye exam

- 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<sup>1</sup>

## ➤ There are several issues with the current standard of care

- Three different eyedrops
- Patient discomfort and avoidance
- Excess chair time
- Hygiene risk



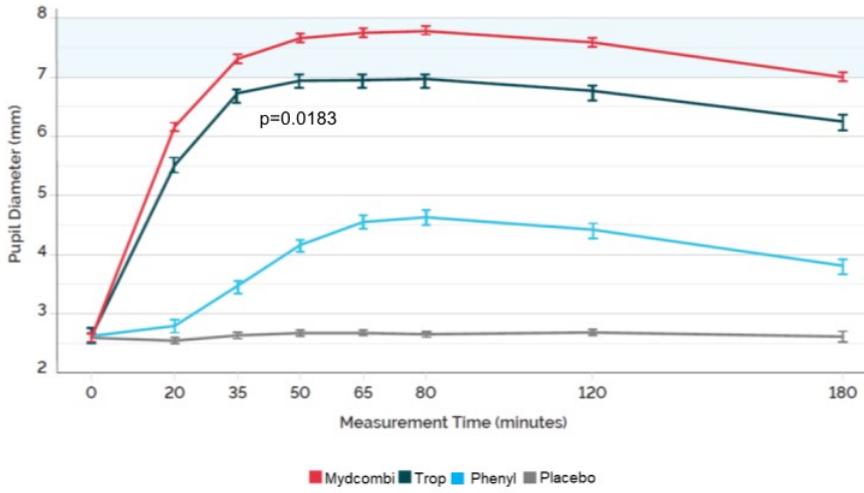


# MydCombi™

(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<sup>1</sup>
- Touch-free, comfortable application does not require anesthetic 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. 60% of patients quickly achieved clinically significant mydriasis at 20 minutes and nearly 95% did so at 35 minutes post-dosage<sup>2</sup>

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



**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.



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 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<sup>1,2</sup>

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

Territory: **US and Canada**

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



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

15 U.S. Patents Issued; 12 Pending

87 O.U.S. Patents Issued; 36 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**

<b>Common Shares Outstanding</b>	33.6M
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<b>Equity Grants Outstanding Under Stock Plans</b>	5.0M
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<b>Warrants</b>	6.1M
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<b>Fully Diluted Shares</b>	44.7M
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<b>Cash</b>	\$29.4M
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<b>Debt</b>	\$12.0M
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**Sean Ianchulev, MD, MPH**  
Chairman  
Co-Founder of Eyenovia



**Kenneth Lee Jr.**  
Lead Director  
General partner of Hatteras  
Venture Partners



**Charles Mather IV**  
Independent Director  
Managing Director, Equity  
Capital Markets at Suntrust  
Robinson Humphrey



**Julia Haller, MD**  
Independent Director  
Ophthalmologist-in-Chief  
Wills Eye Hospital



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



**Rachel Jacobson**  
Independent Director  
President of 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