

**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 11, 2023

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)

(833) 393-6684
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, par value \$0.0001 per share	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 May 11, 2023, Eyenovia, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended March 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02, including Exhibit 99.1, is being “furnished” and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 2.02, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

Item 7.01. Regulation FD Disclosure.

On May 11, 2023, the Company began using an updated corporate presentation with various investors and analysts. A copy of the presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 7.01, including Exhibit 99.2, is being “furnished” and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that Section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01, including Exhibit 99.2, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Eyenovia, Inc. Press Release, dated May 11, 2023.
99.2	Eyenovia, Inc. Updated Corporate Presentation, dated May 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: May 11, 2023

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

**Eyenovia Reports First Quarter 2023 Financial Results and Provides Business Update**

Announced FDA approval of Mydcombi™, a fixed dose combination of tropicamide and phenylephrine for mydriasis, the first FDA approved product to utilize the Optejet®

Received feedback from FDA on its Phase 3 Microline presbyopia candidate that provides a clear and efficient path forward for the program

Entered into co-development agreement with Formosa Pharmaceuticals for the potential development of new topical ophthalmic therapeutics

Company to host conference call and webcast today, May 11, at 4:30 pm ET

NEW YORK—May 11, 2023—Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company developing the Optejet delivery system for use both in combination with its own drug-device therapeutic programs for mydriasis, presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced its financial and operating results for the first quarter ended March 31, 2023.

First Quarter 2023 and Recent Business Developments

- Announced U.S. Food and Drug Administration (FDA) approval of Mydcombi, the Company's proprietary combination microdose formulation of tropicamide and phenylephrine for inducing mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired. Please see the full prescribing information at www.mydcombi.com.
 - Received feedback from FDA on its Phase 3 Microline presbyopia candidate that provides a clear and efficient path forward for the program.
 - Entered into a development collaboration agreement with Formosa Pharmaceuticals to combine Eyenovia's Optejet with Formosa's APNT nanoparticle formulation platform for the potential development of new topical ophthalmic therapeutics.
 - Announced positive results from a research study, conducted in collaboration with Tufts Medical Center, demonstrating the superiority of the Optejet versus standard eye drops in the administration of the anti-glaucoma medication latanoprost preserved with benzalkonium chloride (BAK). Optejet was found to achieve a therapeutic dose of latanoprost with significantly less exposure to excess drug and harmful preservatives than can be achieved using conventional drops. These results were presented at the Association for Research in Vision and Ophthalmology (ARVO) 2023 annual meeting in April.
-



- Continued to build out its manufacturing facilities in Redwood City, CA and Reno, NV, which is on track to come online during the third quarter of 2023.
- Licensing partners Bausch+Lomb and Arctic Vision continued to enroll patients in their respective Phase 3 studies of Micropine (US and China) and Microline (China).
- Ended the first quarter of 2023 with approximately \$18.5 million in total cash and cash equivalents. In addition, with the approval of Mydcombi, the Company has the ability to draw down an additional \$5 million on its credit facility with Avenue Capital before July 31, 2023.

Michael Rowe, Chief Executive Officer, commented, "We are proud to be delivering on our commitments in 2023 with the recently announced FDA approval of Mydcombi, our first approved product dispensed using our Optejet technology. We believe the Optejet will transform the way that topical eye drugs are developed and delivered, and this FDA approval marks a significant milestone in its evolution. It is also an important achievement in the context of our current and future partnerships, providing a template for the development of additional ophthalmic therapies administered via the Optejet in high-value ophthalmic indications."

"Regarding our pre-NDA Microline program for presbyopia, we received clear feedback from the FDA that provides an efficient path forward for the program. We are in the process of completing the build-out and validation of our Redwood City manufacturing facility and remain on track to commence the manufacture of launch batches early next year. In the interim, we plan to conduct supportive human factors testing and clinical work demonstrating the usability of the Gen-2 Optejet device, which has been optimized for in-home use."

"With one product approved, and line-of-sight toward a second, we have reached a true inflection point in the evolution of our company. Having an FDA approved product not only provides critical validation of our Optejet technology for our own advanced clinical programs, but also our partnerships as well. To that end, we continue to advance discussions with additional partners that could potentially assess the utility of Optejet in very large indications such as glaucoma and dry eye, among others. I am pleased with our progress to date and look forward to initial commercial sales of Mydcombi this summer together with continued clinical and regulatory progress for us and our partners."

First Quarter 2023 Financial Review

For the first quarter of 2023, net loss was approximately \$(5.7) million, or \$(0.15) per share compared to a net loss of approximately \$(7.3) million, or \$(0.24) per share, for the first quarter of 2022.

Research and development expenses totaled approximately \$2.5 million for the first quarter of 2023 as compared to \$3.7 million for the first quarter of 2022.



For the first quarter of 2023, general and administrative expenses were approximately \$2.9 million, compared to \$3.5 million for the first quarter of 2022.

Total operating expenses for the first quarter of 2023 were approximately \$5.5 million compared to \$7.2 million for the first quarter of 2022.

As of March 31, 2023, the Company's cash and cash equivalents were approximately \$18.5 million compared to \$22.9 million as of December 31, 2022. In addition, with the approval of Mydcombi, the Company has the ability to draw down an additional \$5 million on its credit facility with Avenue Capital before July 31, 2023.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, May 11. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international). 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.

To access the Call me™ feature, which avoids having to wait for an operator, click [here](#).

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

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics. Eyenovia is currently focused on the commercialization of Mydcombi and the late-stage development of microdosed medications for presbyopia and myopia progression. For more information, visit www.eyenovia.com.

The Eyenovia Corporate Information slide deck may be found at ir.eyenovia.com/events-and-presentations.

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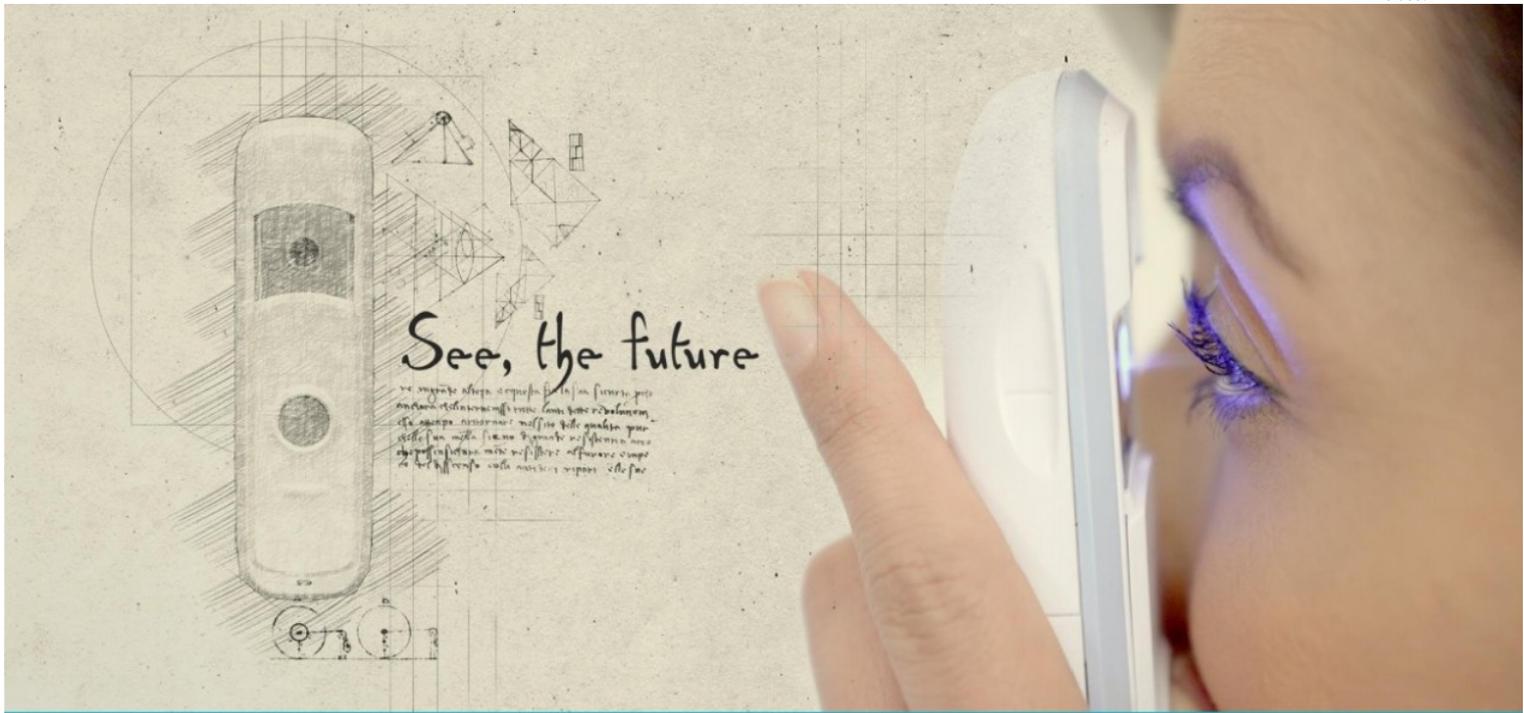
EYENOVIA, INC.
Condensed Balance Sheets

	March 31, 2023 (unaudited)	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	\$ 18,466,322	\$ 22,863,520
Deferred clinical supply costs	3,352,645	2,284,931
License fee and expense reimbursements receivable	973,677	1,183,786
Security deposits, current	119,550	119,550
Prepaid expenses and other current assets	2,011,884	1,190,719
Total Current Assets	<u>24,924,078</u>	<u>27,642,506</u>
Property and equipment, net	2,152,861	1,295,115
Security deposits, non-current	80,874	80,874
Operating lease right-of-use asset	1,508,158	1,291,592
Equipment deposits	643,513	726,326
Total Assets	<u>\$ 29,309,484</u>	<u>\$ 31,036,413</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,402,076	\$ 1,428,283
Accrued compensation	637,189	1,747,191
Accrued expenses and other current liabilities	460,143	503,076
Operating lease liabilities - current portion	472,901	484,882
Notes payable - current portion, net of debt discount of \$123,480 and \$33,885 as of March 31, 2023 and December 31, 2022, respectively	1,218,963	174,448
Convertible notes payable - current portion, net of debt discount of \$123,480 and \$33,885 as of March 31, 2023 and December 31, 2022, respectively	709,853	174,448
Total Current Liabilities	<u>4,901,125</u>	<u>4,512,328</u>
Operating lease liabilities - non-current portion	1,133,948	907,644
Notes payable - non-current portion, net of debt discount of \$648,889 and \$813,229 as of March 31, 2023 and December 31, 2022, respectively	3,730,278	4,190,938
Convertible notes payable - non-current portion, net of debt discount of \$648,889 and \$813,229 as of March 31, 2023 and December 31, 2022, respectively	3,730,278	4,190,938
Total Liabilities	<u>13,495,629</u>	<u>13,801,848</u>
Stockholders' Equity:		
Preferred stock, \$0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2023 and December 31, 2022	-	-
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 37,991,746 and 36,668,980 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	3,799	3,667
Additional paid-in capital	139,779,885	135,461,361
Accumulated deficit	(123,969,829)	(118,230,463)
Total Stockholders' Equity	<u>15,813,855</u>	<u>17,234,565</u>
Total Liabilities and Stockholders' Equity	<u>\$ 29,309,484</u>	<u>\$ 31,036,413</u>



EYENOVIA, INC.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended	
	March 31,	
	2023	2022
Operating Expenses:		
Research and development	\$ 2,521,950	\$ 3,712,584
General and administrative	2,936,886	3,474,965
Total Operating Expenses	5,458,836	7,187,549
Loss From Operations	(5,458,836)	(7,187,549)
Other Income (Expense):		
Other income (expense), net	70,993	(7,073)
Interest expense	(454,003)	(145,237)
Interest income	102,480	194
Net Loss	\$ (5,739,366)	\$ (7,339,665)
Net Loss Per Share - Basic and Diluted	\$ (0.15)	\$ (0.24)
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	37,410,587	30,008,194



See, the future

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May 2023

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, 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 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

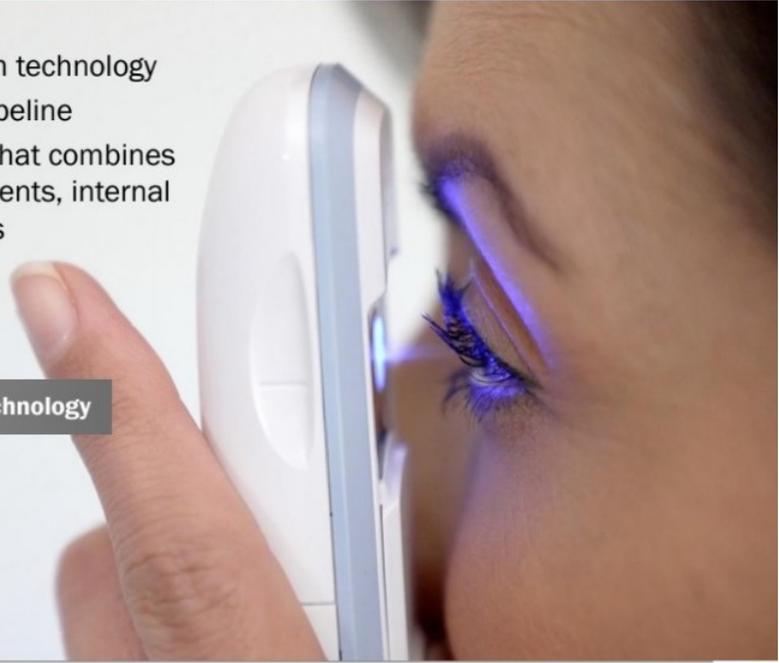
Eyenovia (NASDAQ | EYEN) is a US Based Medical Device and Ocular Therapeutics Company



- Patented digital device platform technology
- Exciting and diverse product pipeline
- Multi-faceted business model that combines partnerships, licensing agreements, internal product development and sales

Optejet® with microdose array print technology

- Horizontal delivery
- Precision dose
- Digital compliance capabilities



Today's Eyedropper Bottle

Designed for Manufacturing Ease, Not Patient Ease

Over the past 125 years, changes in eyedropper design have done little to improve the usability of topical ophthalmic medications



1800's
Glass Pipette



1900's
Glass Pipette with Bulb
and Separate Vial



Today
Integrated Bottle with Dropper Tip

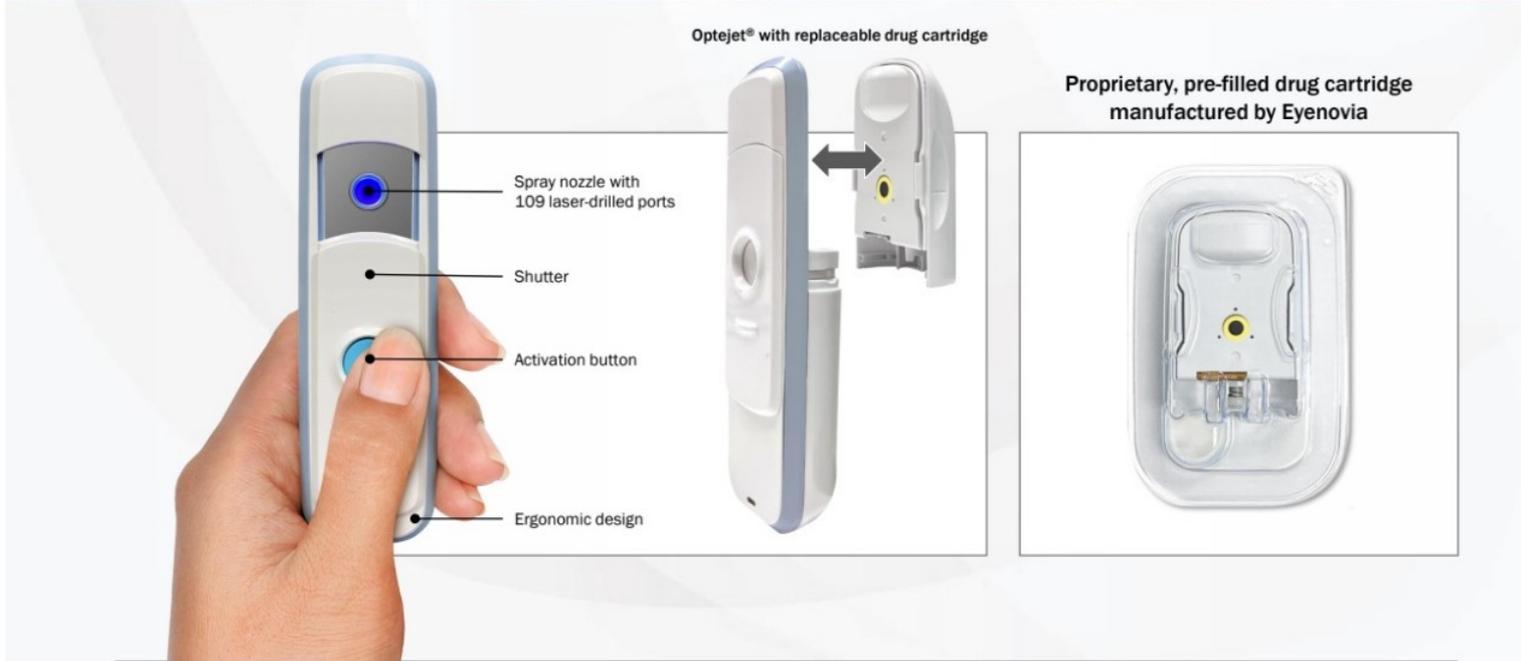
In a recent survey conducted by J. Reckner and Associates, consumers reported that **taking eye drops was among the most difficult ways to self-administer medication¹**

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1. Survey conducted in January 2023 with 100 people (19 - 65+ Age Range, Mean Age = 51YO) who regularly take eye drop medications respondents were asked to rank common drug forms from easiest to administer, to most difficult to administer on a 0-10 scale (0 meaning no difficulty, 10 meaning extremely difficult). Of the 11 medication types the respondents were asked to rank, Eye drops ranked third most difficult behind suppositories and eye ointments. The Topical Ointments were ranked the easiest to administer with an average score of 1.11, and suppositories ranked the most difficult with a score of 6.38. Comparatively, Eye Drops received an average score of 4.63.

Introducing the Optejet®

Optejet is a drug-device combination product manufactured with a sterile-filled, replaceable drug cartridge



Ergonomic Design to Improve Usability

Horizontal delivery, push button dosing and no protruding tip



Eye Dropper Bottle tips can touch the eye surface



Eye Dropper Bottle administration requires head-tilting, squeezing, and reliance on gravity



Optejet® administration can be done horizontally with the push of a button



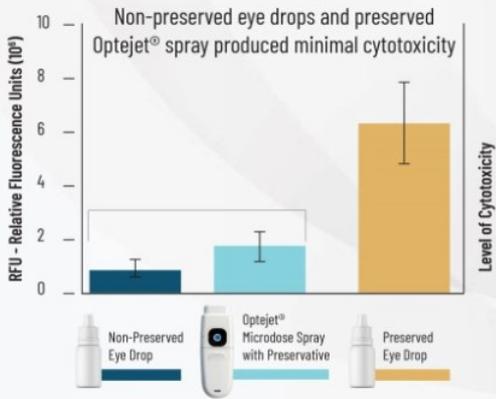
Optejet® has a recessed nozzle, protected by a shutter when not in use to prevent cross-contamination

Precision Dosing to Improve Therapeutic Index

With 80% less dose volume, reduces excessive exposure to both drugs and preservatives ^{1,2}

Minimizes Excessive Drug Exposure to Ocular Tissues

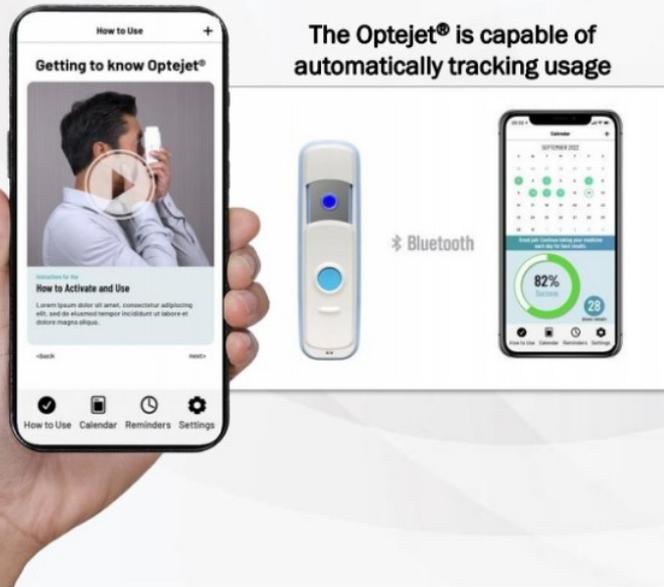
Minimizes Impact of Preservatives on Ocular Tissues



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1 Wirta D. et al, Presentation at 2019 ASCRS meeting | 2 Ianchulev T. et al, Therapeutic Delivery 2018 | 3 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. Study with Tufts University 2022, Data on File | 4 The impact of precision spray dosing of netarsudil 0.02% can be seen when compared to a single drop of the same drug.

Optejet Digital Technology to Improve Delivery of Care



Remote Patient Monitoring: More Data May Benefit All Parties

PATIENT

- Reminders to take medicine
- Ability to track compliance progress
- Confidence in medication usage

PHYSICIAN

- Ability for quicker action
- More accurate data
- Allows for better patient-physician conversation
- Remote Therapeutic Monitoring CPT Code may allow for billing

PAYER

- Less likely to have patient on second medication if compliance is the issue
- Better patient outcomes if compliance can be reinforced

Product Pipeline

US Market

	Target Market Drug	Optejet Differentiation	Addressable Population*	Status	Notes
Proprietary	Pupil dilation (Mydriasis)	Office Efficiency, ease of use, patient experience	108M	FDA Approved May 2023	 MydCombi. <small>Propipronide and phenylephrine HCl ophthalmic spray 1%/2.5%</small>
	Alternative to glasses for early presbyopia	Ease of use, convenience, less exposure to pilocarpine	3.5M	Manufacturing registration batches 1Q 2024	
Partnered	Treatment of childhood progressive Myopia	Ease of use, digital monitoring technology, pediatrics self dosing	1.9M	Ph3 study enrollment to be completed end of 2023	
Potential	Glaucoma	Digital monitoring technology, ease of use, less drug exposure	3M	Licensing discussions in process	
	Dry Eye	Ease of use, greater comfort	20M	Pre-IND Meeting planned 2H 2023	
	Post-Op Cataract	Ease of use, greater comfort	4M	Licensing discussions in process	

- MydCombi is the first and only FDA-approved FDC ophthalmic spray indicated for inducing mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired
- Pupil dilation (mydriasis) is part of a comprehensive eye exam and ocular surgery
 - Estimated 108 million dilations in US annually
 - Estimated \$250 million US market opportunity¹
- Eyedrops are the current standard of care and ripe for innovation
 - Multiple eyedrops usually needed
 - Patient discomfort and avoidance
 - Time consuming administration
 - Hygiene risk



MydCombi™ Product Overview

First and only FDA Approved Ophthalmic Spray for Mydriasis



MydCombi administered as one metered spray

Two Phase 3 clinical trials evaluated the efficacy of MYDCOMBI for achievement of mydriasis.

In MIST-1, the mean change in pupil diameter was 4.7 mm with MYDCOMBI, 4.1 mm with tropicamide, and 0.9 mm with phenylephrine at 35 minutes post-dose. MYDCOMBI was statistically superior to tropicamide administered alone and phenylephrine administered alone. In MIST-2, the mean change in pupil diameter was 4.8 mm with MYDCOMBI and 0.1 mm with placebo at 35 minutes post-dose.

MYDCOMBI provided a clinically significant effect in the proportion of eyes achieving pupil diameter of ≥ 6 mm at 35-minute post-dose in 94% of eyes compared to 78% of eyes administered tropicamide alone and 1.6% of eyes administered phenylephrine alone.

As shown in the figure, treatment differences in mydriasis were observed as early as 20 minutes.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: In patients with known hypersensitivity to any component of the formulation.

WARNINGS AND PRECAUTIONS:

Not for Injection: Topical ophthalmic use

Significant Elevations in Blood Pressure: Caution in pediatric patients less than 5 years of age, and in patients with cardiovascular disease or hyperthyroidism. In patients at high risk, monitor blood pressure post treatment.

Central Nervous System Disturbances: Caution in pediatric patients where rare incidences of central nervous system disturbances have been reported.

Intraocular Pressure: May produce a transient elevation

Rebound Miosis: Reported 1 day after administration

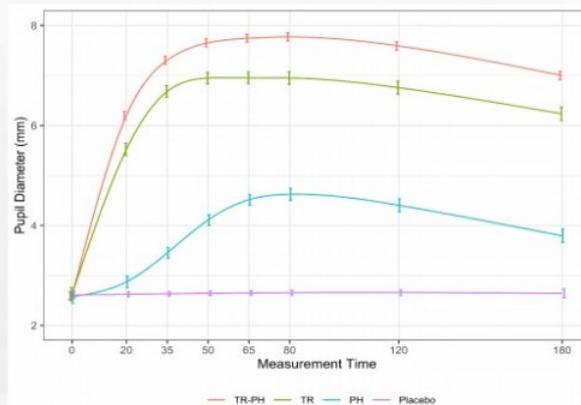
ADVERSE REACTIONS

- Most common ocular adverse reactions include transient blurred vision, reduced visual acuity, photophobia, superficial punctate keratitis, and mild eye discomfort. Increased intraocular pressure has been reported following the use of mydriatics
- Systemic adverse reactions including dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity have been reported with the use of tropicamide.

To report SUSPECTED ADVERSE REACTIONS, contact EyeNovia, Inc. At 1-833-393-6684 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch)

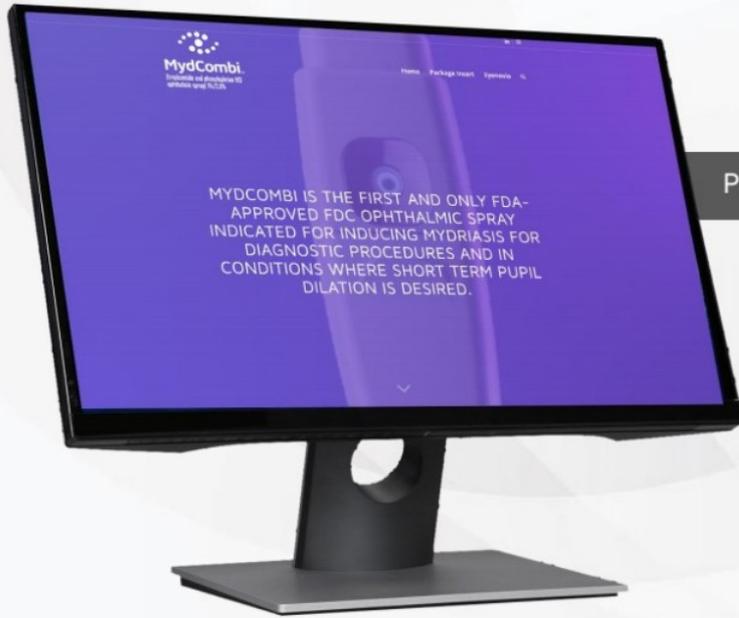
Please click here for [FULL PRESCRIBING INFORMATION](#)

MIST-1 and MIST-2 pooled, mean pupil diameter vs measurement time, by treatment group. Vertical bars show 95% confidence interval for the mean at each point.



MydCombi™ Product Availability

MydCombi.com Website

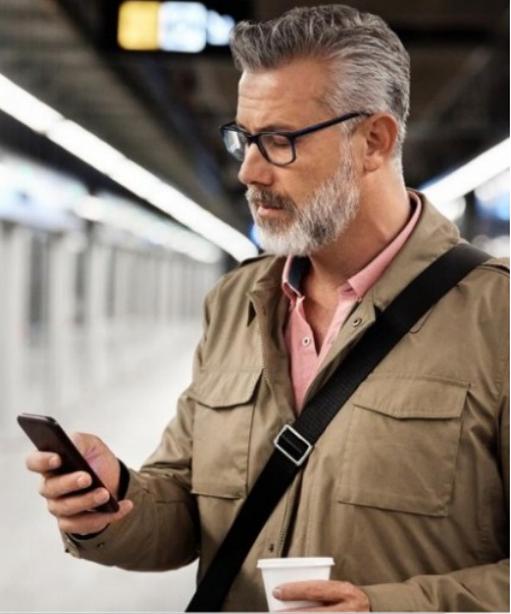


Product Availability Q3 2023

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MicroLine for Presbyopia

- Presbyopia is the age-related loss of near vision that occurs as the lens becomes inelastic (hold the menu further away)
- 18 million people aged 40 - 55 in the US have presbyopia, with roughly half never having to use glasses earlier in their lives
- MicroLine is a lifestyle product to avoid the appearance and inconvenience of reading glasses
 - Use “as needed” with rapid onset improvement of near vision
 - Easy to administer
 - Discreet - compatible with modern lifestyle



MicroLine

Phase 3 Clinical Results

- Vision-1¹ and Vision-2² clinical studies
 - 6.0x more patients achieved ≥ 3 -line gain on a vision chart in the active group vs. placebo³
 - Well-tolerated with fewer than 2% of patients reporting adverse events
 - 65% of patients reported seeing improvement in exit survey
- People prefer MicroLine over eyedrops
 - Among 100 presbyopic patients aged 40-55, 80% said they would prefer MicroLine over the traditional eyedrop bottle⁴
 - Price sensitivity tests indicate approximately \$100 for 80 doses would be well accepted



MicroLine

The Only Presbyopia Treatment with the Optejet that May Enhance Office Economics



Market Receptivity	High among optometrists who are intrigued by the ability to sell the device through their offices; high among patients who are attracted to the benefits of the device
Potential Market Size	3.5 million people ¹ @ \$250 per year = \$877M
Pricing	Approximately \$100 per cartridge (similar to Vuity on a per-use basis); market research indicates patients would use 2.5 cartridges/year on average
Reimbursement Status	Cash-pay cosmeceutical; can be purchased with HSA/FSA funds

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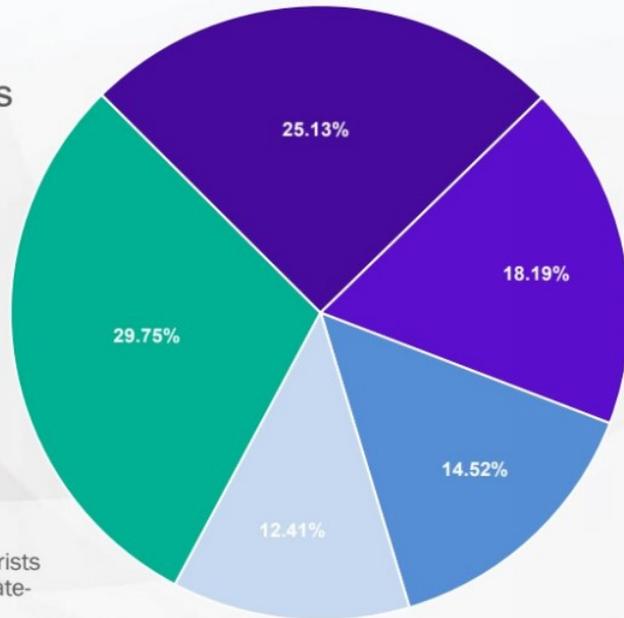
1. Population of 40-55YO in the US = 60.8MA , 35% of this population has never needed corrected visionB, assumes product will work for 33% of the remaining population
A. Published by Erin Duffin, & 30, S. (2022, September 30). *Population of the U.S. by sex and age 2021*. Statista. Retrieved February 3, 2023, from <https://www.statista.com/statistics/241488/population-of-the-us-by-sex-and-age/> | B. *What is 20/20 vision?* University of Iowa Hospitals & Clinics. (n.d.). Retrieved February 3, 2023, from <https://uhc.org/health-topics/what-2020-vision#:~:text=How%20common%20is%2020%2F20,1%20see%20very%20well%2C%20Dr.>

ODs Believe MicroLine Will Win Presbyopia Market

Optejet Delivery and Retail Component Differentiate Eyenovia from the Pack

Market Share of Presbyopia Products Predicted by Optometrists

- MicroLine - Eyenovia
- Vuity - Abbvie
- CSF-1 - Orasis
- Acelcedine - Lenz Therapeutics
- Nyxol and Pilocarpine - Ocuphire



In a market research survey consisting of 100 Optometrists across the US, they were asked to review existing and late-stage pharmacologic products for presbyopia

MicroLine NDA Timeline

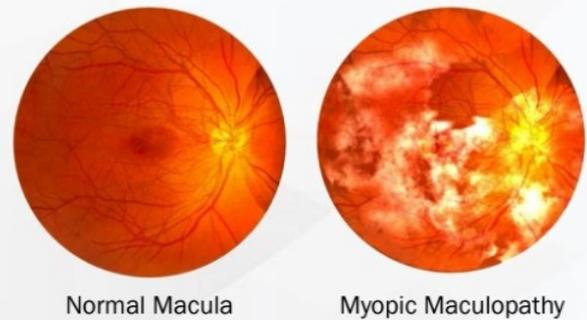
NDA Filing Targeted for Q1 2025



MicroPine for Childhood Myopic Maculopathy

- Begins in early childhood, with genetic link¹
- Elongation of sclera/retina with morbidity and vision problems²
- Urgent need for FDA-approved drug therapies to slow myopia progression
- Atropine may slow myopia progression by at least 60%³

Progression of Myopic Maculopathy



Normal Macula

Myopic Maculopathy

Affects ~25M children in the US alone, with ~5M considered to be at high risk⁴

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.

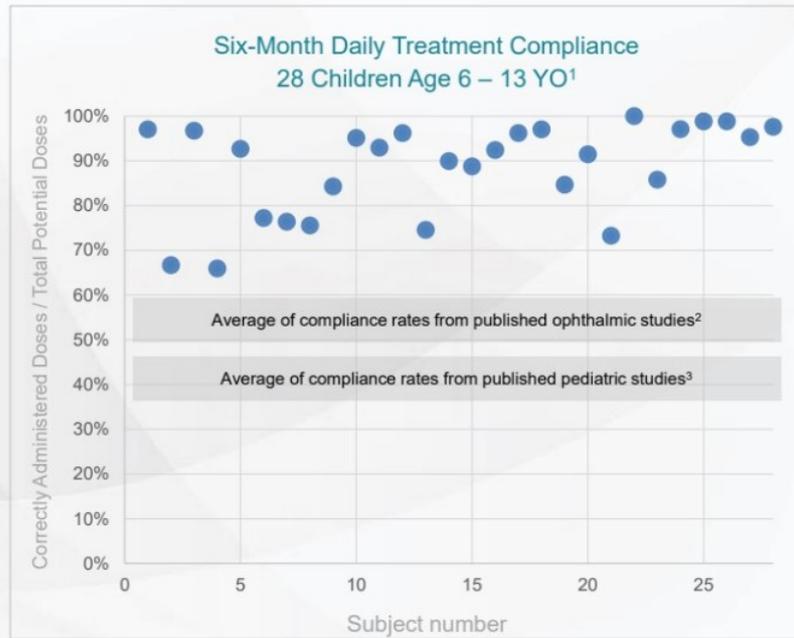
² *Eye and Contact Lens.* 2004; 30

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.

MicroPine for Childhood Myopic Maculopathy

- **Precision-dosed atropine spray developed specifically for children**
 - Easy, daily use by children¹
 - Lower drug volume exposure to enhance comfort and minimize systemic exposure
 - Potential for pairing with smart devices to track treatment adherence and provide family reminders
- **Compliance data shows promise compared with historical treatments**



MicroPine

A Pediatric Therapy Designed with Children in Mind



Market Receptivity	Very high to the device due to the potential benefits it may offer; well accepted by children in the CHAPERONE study
Potential Market Size	If one assumes the annual cost of these drugs is \$2,400, then with 1.9 million children treated ^{1,2} , a market size of over \$4.5 billion in the US alone. Potential royalty stream of several hundred million dollars
Pricing	Licensed to Bausch + Lomb
Reimbursement Status	Licensed to Bausch + Lomb; we assume will be treated like other ophthalmic prescription medications

eyenovia

1. Theophanous, C., Modjtahedi, B. S., Batech, M., Marlin, D. S., Luong, T. Q., & Fong, D. S. (2018, August 29). Myopia prevalence and risk factors in children. *Clinical ophthalmology* (Auckland, N.Z.). Retrieved February 3, 2023, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6120514/>
2. Bureau, U. S. C. (2022, April 7). Children data. *Census.gov*. Retrieved February 3, 2023, from <https://www.census.gov/topics/population/children/data.html>

Multiple Commercialization Partners



Arctic Vision – A China-based ophthalmic biotech focusing on breakthrough therapies, with a leading portfolio covering pre-clinical stage to commercial stage products



Bausch+Lomb – One of the world's largest suppliers of contact lenses, lens care products, prescription pharmaceuticals, intraocular lenses and other eye care products

Ongoing discussions with multiple partners in glaucoma and dry eye

Potential Long Term Income Stream



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



Bausch+Lomb – MicroPine licensed for the US and Canada

License agreements with a total value of over \$90M in potential payments + royalties

Formosa APNT™ Technology Collaboration

Formosa Pharma is developing a unique pipeline consisting of risk-diverse development modes, including 505(b)(2), biosimilars, and NCEs. Their proprietary APNT nanoparticle formulation platform drives their pipeline



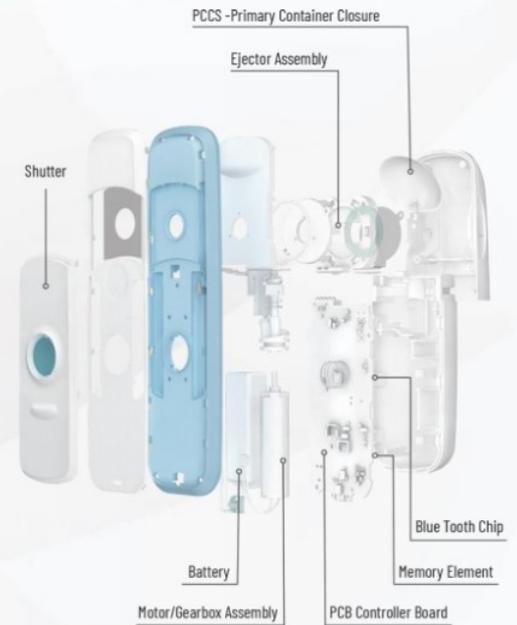
- Eyenovia gains access to Formosa's APNT™ formulation technology which opens several new and large market indications for potential expansion of our own development pipeline



- APNT™ (Active Pharmaceutical Nanoparticle Technology) works to reduce particle size leading to improved dissolution, bioavailability, and lowers the risk of contamination
- If successful, the companies will discuss an agreement for the co-development of a differentiated asset in a multi-billion-dollar market

Broad Intellectual Property Portfolio

- Key claims covered with multiple patents
 - 16 US Patents Issued; 1 pending
 - 95 foreign issued; 32 pending
 - Many in effect beyond 2031
- Clinical data and regulatory approval adds another layer of IP



Financial Snapshot (March 2023)

Nasdaq: EYEN

Common Shares Outstanding	37.9M
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Equity Grants Outstanding Under Stock Plans	5.6M
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Warrants	6.1M
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Fully Diluted Shares	49.7M
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Cash	\$18.5M
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Debt	\$10.9M
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Experienced Leadership Team



John Gandolfo
Chief Financial Officer 



Michael Rowe
Chief Executive Officer 



Bren Kern
Chief Operating Officer 



Norbert Lowe
VP, Commercial
Operations



Greg Bennett
VP, Clinical Program
Strategy and Development



Malini Batheja, PhD
VP, Pharma R&D and CMC
Regulatory



Enrico Brambilla
VP, Device R&D and
Engineering



Lauren Gidden
AVP, Quality and
Regulatory Affairs

Investment Summary

- Optejet® platform technology with ergonomic design facilitates ease of use and delivers precise doses
 - Addresses many problems of conventional eye drops
 - Protected with a strong intellectual property portfolio
- Eynovia owns a pipeline of products in large therapeutic categories
 - With multiple commercial partnerships in place and more being developed
- Poised for leadership as a technology partner and therapy provider in potentially huge markets
- **First FDA approved product May 2023**
 - MydCombi™ (tropicamide and phenylephrine HCl ophthalmic spray) 1%/2.5%
 - Validates the underlying Optejet® technology