
**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): March 30, 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)**

**(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 March 30, 2023, Eyenovia, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal year ended December 31, 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>
<u>99.1</u>	<u>Eyenovia, Inc. Press Release, dated March 30, 2023.</u>
<u>99.2</u>	<u>Eyenovia, Inc. Updated Corporate Presentation dated March 2023.</u>
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: March 30, 2023

/s/ John Gandolfo

John Gandolfo

Chief Financial Officer



Eyenovia Reports Fourth Quarter 2022 Financial Results and Provides Business Update

Announced FDA acceptance of Mydcombi New Drug Application (NDA) and PDUFA action date of May 8, 2023

Announced positive results from Microline Phase 3 program as a potential treatment for presbyopia and received feedback from the FDA outlining a clear path forward for the program

Entered into co-development agreement with Formosa Pharmaceuticals

Company to host conference call and webcast today, March 30th, at 4:30 pm ET

NEW YORK—March 30, 2023—Eyenovia, Inc. (Nasdaq: EYEN), a pre-commercial 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 fourth quarter and full-year ended December 31, 2022.

Fourth Quarter 2022 and Recent Business Developments

- Announced U.S. Food and Drug Administration (FDA) acceptance of the Mydcombi NDA and Prescription Drug User Fee Act (PDUFA) action target date of May 8th, 2023.
- Announced positive results from Microline Phase 3 program as a potential treatment for presbyopia and received encouraging feedback from FDA outlining a clear path forward for the program.
- Entered into a development collaboration agreement with Formosa Pharmaceuticals to combine Eyenovia's Optejet® dispensing technology with Formosa's APNT nanoparticle formulation platform for the potential development of new topical therapeutics in high-value ophthalmic indications with significant unmet medical needs.
- Manufacturing facility in Redwood City is operational and producing clinical supply; legacy Reno facility is currently being inspected by the FDA as part of the Mydcombi review process; second facility in Reno anticipated to come online during the third quarter 2023.
- Development partner Arctic Vision continues to enroll patients in its Phase 3 study of Microline (ARVN003) as a potential treatment for presbyopia in China.
- Ended the fourth quarter of 2022 with approximately \$22.9 million in total cash and cash equivalents.

Michael Rowe, Chief Executive Officer, commented, “We continue to make significant progress with our two lead programs, Mydcombi and Microline. Specifically, we are preparing for our May 8th PDUFA date for Mydcombi which, if approved, would validate the Optejet dispensing technology that is core to all of our proprietary and partnered programs, and would transition us to a commercial stage company. We are in the middle of a FDA inspection of our manufacturing facility as part of that review process.”



“Regarding Microline, having completed our VISION 2 study, we recently received feedback from the FDA which outlines a clear path forward for the program. Importantly, the feedback is in line with our expectations, and our development timeline for the program remains unchanged. Presbyopia represents a very significant market opportunity for our company, and the agency’s feedback is very encouraging.”

“Finally, our co-development agreement with Formosa represents an opportunity to significantly expand our pipeline and will serve as a model for any future partnerships. We are in advanced discussions with additional potential partners to leverage the Optejet in high-value indications, and we are optimistic that we will sign one or more partnership agreements this year.”

Fourth Quarter and Full Year 2022 Financial Review

For the fourth quarter of 2022, net loss was approximately \$[6.1] million, or \$[0.17] per share compared to a net income of approximately \$3.0 million, or \$0.11 per share, for the fourth quarter of 2021. For the full-year 2022, net loss was approximately \$[28.0] million, or \$[0.83] per share on approximately 33.6 million weighted average shares outstanding, and this compares to a net loss of approximately \$[12.8] million, or \$[0.49] per share, for the full year 2021 on approximately 26.3 million weighted average shares outstanding.

Research and development expenses totaled approximately \$2.2 million for the fourth quarter of 2022 as compared to \$3.3 million for the fourth quarter of 2021, a decrease of approximately 33%. For the full-year 2022, research and development expenses decreased approximately 10% to \$13.4 million, versus \$14.9 million for the full-year 2021. The decrease was driven primarily by lower direct clinical and non-clinical expenses, as well as deferral of costs related to future delivery of clinical supply to our partners.

For the fourth quarter of 2022, general and administrative expenses were approximately \$3.2 million, compared to \$3.7 million for the fourth quarter of 2021, a decrease of approximately 13.3%. For the full-year 2022, general and administrative expenses were \$13.5 million, an increase of 28% as compared to \$10.6 million for the full-year 2021. The full year increase was driven by staff additions, higher professional fees, and an increase in stock-based compensation.

Total operating expenses for the fourth quarter of 2022 were approximately \$5.4 million compared to \$6.9 million for the fourth quarter of 2021. This represents a decrease of approximately 22.7%. Total operating expenses for the full-year 2022 were \$26.9 million, representing an increase of 6% versus \$25.4 million for the full-year 2021.

As of December 31, 2022, the Company’s unrestricted cash and cash equivalents were approximately \$22.9 million, as compared to \$27.3 million in unrestricted and restricted cash as of December 31, 2021.



Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, March 30th. Participants should dial 1-877-407-9039 or 1-201-689-8470. A live webcast of the conference call will also be available [here](#) and on the investor relations page of the Company's corporate website at 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.



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 ~8 μ L 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. 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, future versions with smart electronics and mobile e-health technology are being designed to track and enhance patient compliance.

About Eyenovia, Inc.

Eyenovia, Inc. (Nasdaq: EYEN) is a pre-commercial ophthalmic 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.

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

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.

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EYENOVIA, INC.
Balance Sheets

	December 31,	
	2022 (unaudited)	2021
Assets		
Current Assets:		
Cash and cash equivalents	\$ 22,863,520	\$ 19,461,850
Deferred clinical supply costs	2,284,931	-
License fee and expense reimbursements receivable	1,183,786	1,805,065
Security deposits, current	119,550	-
Prepaid expenses and other current assets	1,190,719	734,942
Total Current Assets	<u>27,642,506</u>	<u>22,001,857</u>
Restricted cash	-	7,875,000
Property and equipment, net	1,295,115	1,271,225
Security deposits, non-current	80,874	119,035
Operating lease right-of-use asset	1,291,592	-
Equipment deposits	726,326	391,941
Total Assets	<u>\$ 31,036,413</u>	<u>\$ 31,659,058</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,428,283	\$ 1,614,104
Accrued compensation	1,747,191	1,543,618
Accrued expenses and other current liabilities	503,076	845,719
Deferred rent - current portion	-	18,685
Operating lease liabilities - current portion	484,882	-
Notes payable - current portion, net of debt discount of \$33,885 and \$349,632 as of December 31, 2022 and 2021, respectively	174,448	7,150,368
Convertible notes payable - current portion, net of debt discount of \$33,885 and \$0 as of December 31, 2022 and 2021, respectively	174,448	-
Total Current Liabilities	<u>4,512,328</u>	<u>11,172,494</u>
Deferred rent - non-current portion	-	19,949
Operating lease liabilities - non-current portion	907,644	-
Notes payable - non-current portion, net of debt discount of \$813,229 and \$0 as of December 31, 2022 and 2021, respectively	4,190,938	-
Convertible notes payable - non-current portion, net of debt discount of \$813,229 and \$0 as of December 31, 2022 and 2021, respectively	4,190,938	-
Total Liabilities	<u>13,801,848</u>	<u>11,192,443</u>
Stockholders' Equity:		
Preferred stock, \$0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2022 and 2021, respectively	-	-
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 36,668,980 and 28,426,616 shares issued and outstanding as of December 31, 2022 and 2021, respectively	3,667	2,844
Additional paid-in capital	135,461,361	110,683,077
Accumulated deficit	(118,230,463)	(90,219,306)
Total Stockholders' Equity	<u>17,234,565</u>	<u>20,466,615</u>
Total Liabilities and Stockholders' Equity	<u>\$ 31,036,413</u>	<u>\$ 31,659,058</u>



EYENOVIA, INC.
Statements of Operations

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2022 (unaudited)	2021 (unaudited)	2022 (unaudited)	2021
Operating Income				
Revenue	\$ -	\$ 10,000,000	\$ -	\$ 14,000,000
Cost of revenue	-	-	-	(1,600,000)
Gross Profit	-	10,000,000	-	12,400,000
Operating Expenses:				
Research and development	2,202,354	3,291,510	13,378,680	14,850,874
General and administrative	3,169,928	3,655,172	13,532,835	10,569,653
Total Operating Expenses	5,372,282	6,946,682	26,911,515	25,420,527
Loss From Operations	(5,372,282)	3,053,318	(26,911,515)	(13,020,527)
Other Income (Expense):				
Extinguishment of PPP 7(a) loan	-	-	-	463,353
Other income, net	100,510	115,147	197,090	164,027
Interest expense	(904,247)	(185,349)	(1,380,058)	(387,756)
Interest income	52,623	162	83,326	2,516
Net Loss	\$ (6,123,396)	\$ 2,983,278	\$ (28,011,157)	\$ (12,778,387)
Net Loss Per Share - Basic				
Basic	\$ (0.17)	\$ 0.11	\$ (0.83)	\$ (0.49)
Diluted	\$ (0.17)	\$ 0.10	\$ (0.83)	\$ (0.49)
Weighted Average Number of Common Shares Outstanding				
Basic	36,701,880	27,959,123	33,649,747	26,324,081
Diluted	36,701,880	30,019,966	33,649,747	26,324,081



Forward-looking Statements

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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.

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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**



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

Optejet® with replaceable drug cartridge



Spray nozzle with
109 laser-drilled ports

Shutter

Activation button

Ergonomic design



Proprietary, pre-filled drug cartridge
manufactured by Eyenovia



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



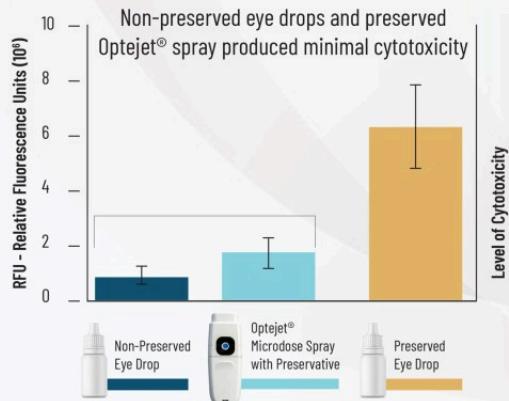
Optejet® has a recessed nozzle, protected by a shield when not in use to prevent cross-contamination

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

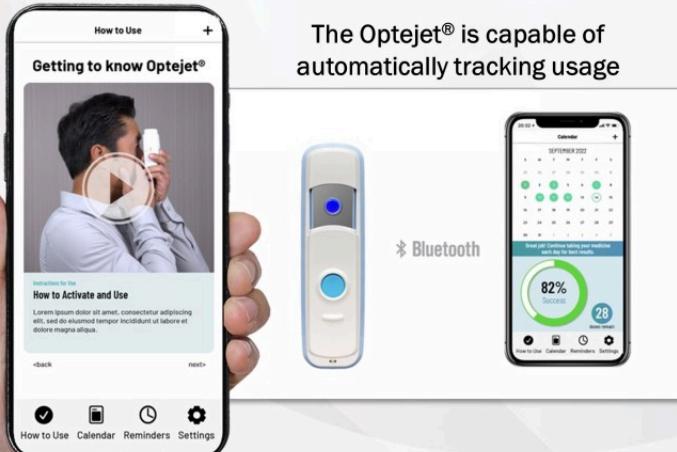


Banerjee, P. et al. In Vitro Cell Toxicity Comparing Microdose vs Drop Delivery of Latanoprost with BAK in Human Conjunctival Cells. ePoster at ESCRS-ECONET September 10-13, 2022.



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



The Optejet® is capable of automatically tracking usage

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 Benefit	Addressable Population*	Status	Notes
Proprietary	Pupil dilation (Mydriasis)	Office Efficiency, ease of use, patient experience	108M	PDUFA May 8, 2023	 MydCombi. Brimonidine and phenylephrine HCl ophthalmic spray 1% / 2.5%
	Alternative to glasses for early presbyopia	Ease of use, convenience, less exposure to pilocarpine	3.5M	Pre-NDA Meeting March 28, 2023	
Partnered	Treatment of childhood progressive Myopia	Ease of use, digital monitoring technology, pediatrics self dosing	1.9M	Ongoing Ph3 Study Completion expected 2026	
Potential	Glaucoma	Digital monitoring technology, ease of use, less drug exposure	3M	Active Discussions	
	Dry Eye	Ease of use, greater comfort	20M	Pre-IND Meeting planned 2H 2023	
	Post-Op Cataract	Ease of use, greater comfort	4M	Active Discussions	



* Estimate 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

MydCombi™ for Pupil Dilation / Mydriasis

- 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



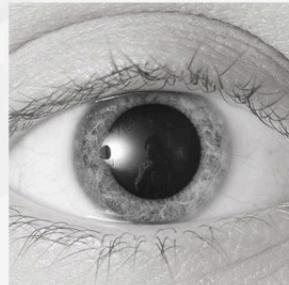
1. \$200M annual sales of pharmaceutical mydriatic products used during 108M office-based exams (\$2 * 100M) + \$50M of single bottle mydriatic agents used cataract replacement surgery (\$12.5 x 4M)

MydCombi™ Product Overview

- If approved, the only fixed drug combination of the two leading mydriatic medications in the US
- Administered with the push of a button, saving up to ten minutes of technician time¹
- Touch-free, comfortable application with no anesthetic
 - Fewer than 1% of patients reported stinging discomfort²
- Lower drug and preservative exposure, including absorption of phenylephrine²
- Single spray of tropicamide/phenylephrine from Optejet® results in 3 out of 4 patients achieving necessary dilation within 15 minutes³



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



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 Chayet, A. et al, Evaluation of 2 mydriatic dosing regimens delivered by micro-array print technology for comparison of pupil dilation speed, ePoster ASCRS 2022

MydCombi™

Cash-Pay Diagnostic With Unique Benefits for the Office and Patient



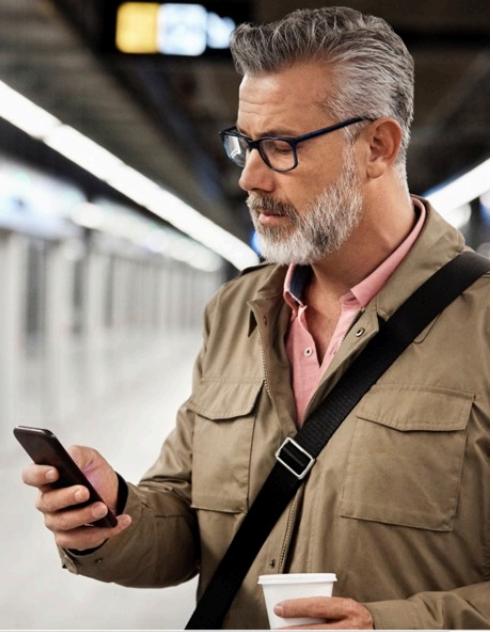
Market Receptivity	Strong among optometrists and ophthalmic technicians, who will be the principal users
Potential Market Size	108M ^{1,2,3} potential procedures includes 104M in-office @ \$1.80 and 4M surgeries @ \$18 (surgical centers often discard bottles after single use) equals \$250M
Pricing	Premium to current standard of care, offset through improved office throughput and patient satisfaction
Reimbursement Status	Cash-pay diagnostic. Office purchases directly like other diagnostic agents. No insurance company involvement.



1. Wilson, F. A., Stimpson, J. P., & Wang, Y. (2015). Inconsistencies exist in national estimates of Eye Care Services Utilization in the United States. *Journal of ophthalmology*. Retrieved February 3, 2023, from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4546761/> | 2. Lindstrom, R. L. (2021, February 1). Future of cataract surgery seems promising. *Healio*. Retrieved February 3, 2023, from <https://www.healio.com/news/ophthalmology/20210126/future-of-cataract-surgery-seems-promising> | 3 Charles, S. (2017). The Future of Surgical Retina in the Era of Medical Retina. *Retinalphysician.com*. Retrieved February 3, 2023, from <https://www.retinalphysician.com/issues/2017/may-2017/the-future-of-surgical-retina-in-the-era-of-medical-retina>

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 \geq 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 in 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

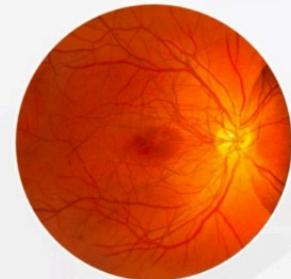


1. Population of 40-55YO in the US = 60.8MA , 35% of this population has never needed corrected visionB, assumes product will work for 33% of the remaining population
A. Published by Erin Duffin, & 30, S. (2022, September 30). *Population of the U.S. by sex and age* 2021. Statista. Retrieved February 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://uihc.org/health-topics/what-2020-vision#:~:text=How%20common%20is%2020%2F20,t%20see%20very%20well%2C%20Dr>

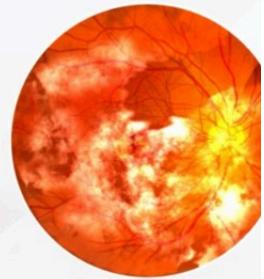
MicroPine for Childhood Myopic Maculopathy

- 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.

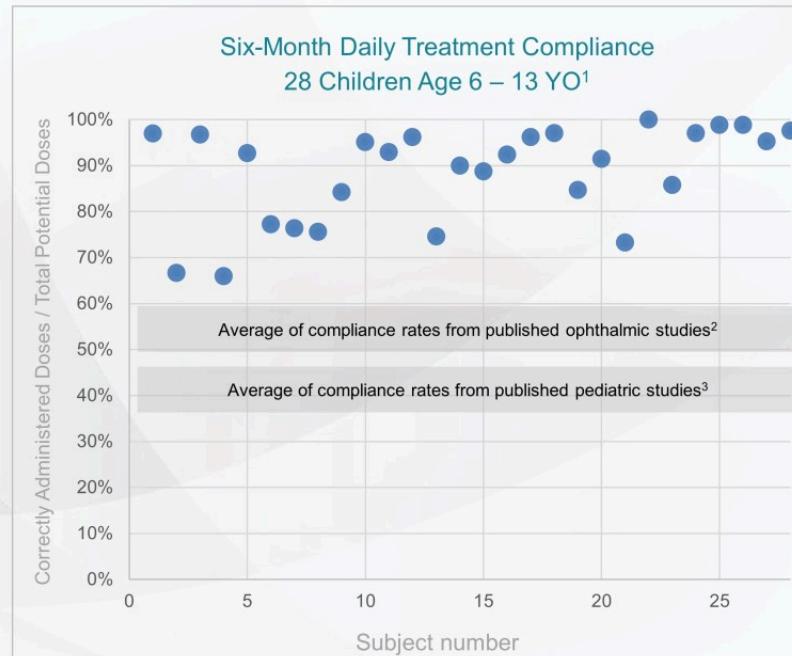
² Eye and Contact Lens. 2004; 30

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

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 chronic ophthalmic indications

Potential Long Term Income Stream



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

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



Bausch+Lomb – MicroPine licensed for the US and Canada.

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
 - 18 US Patents Issued; 8 pending
 - 89 foreign issued; 33 pending
 - Many in effect beyond 2031
- Clinical data and regulatory approval adds another layer of IP



Financial Snapshot (December 2022)

Nasdaq: EYEN

Common Shares Outstanding 33.6M

Equity Grants Outstanding Under Stock Plans 5.0M

Warrants 6.1M

Fully Diluted Shares 44.7M

Cash \$29.4M

Debt \$12.0M

Experienced Leadership Team



John Gandolfo
Chief Financial Officer [in](#)



Michael Rowe
Chief Executive Officer [in](#)



Bren Kern
Chief Operating Officer [in](#)



Malini Batheja, PhD
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

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
- Eyenovia 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 product FDA PDUFA date - May 8, 2023
 - Will validate the underlying technology