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 19, 2024

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:

- $\hfill\square$ 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 240.14d-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:

	(Trading	(Name of each exchange
(Title of each class)	Symbol)	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 \Box

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. \square

Item 7.01. Regulation FD Disclosure.

On March 19, 2024, Eyenovia, Inc. (the "Company") began using an updated corporate presentation with various investors and analysts. A copy of the presentation 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 7.01, including Exhibit 99.1, 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 99.1, 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	Eyenovia, Inc. Updated Corporate Presentation, dated March 2024
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 19, 2024

/s/ John Gandolfo John Gandolfo Chief Financial Officer



March 2024

We Are the Optejet® Company

Developing and commercializing ophthalmic therapeutics with Optecare[™] services in large markets with high unmet needs



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 products, 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 products and product candidates; the potential advantages of our products, product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our products and product candidates; our estimates regarding the potential market opportunity for our products and product candidates; reliance on third parties to develop and commercialize our product candidates; the risk of defects in, or returns of, our products; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our products and 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 (NASDAQ:EYEN) is the Optejet® Company



- · Patented digital device platform technology
- · Unique, class-leading drug products
- High-value product pipeline addressing areas of significant medical and market need
- Multi-faceted business model with revenue from direct sales and licensing agreements

Optejet® with microdose array print technology

- Designed to address issues with ease-ofuse and dosing precision
- Delivers efficacy while improving tolerability and reducing side effects¹
- Digital Optecare[™] capabilities²



1. Wirta DL, Walters TR, Flynn WJ, Rathi S, lanchulev T. Mydriasis with micro-array print touch-free tropicamide-phenylephrine fixed combination MIST: pooled randomized Phase III triais. Ther Deliv. 2021 Mar;12(3):201-22. Optecare is Eyenovia's suite of digital compilance and adherence capabilities

Today's Eyedropper Bottle

Designed for manufacturing ease, not patient use

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



L. 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 most difficult to administer on a 0-10 scale (0 meaning no difficulty, 10 meaning extremely difficult). Of the 11 medication types ranked, eye drops were the third most difficult behind suppositories and eye interments. The topical ointments were ranked the easiest to administer with an average score of 1.1, and suppositories ranked the most difficult with a score of 6.48. Eye drops received an average score of 4.6.

Introducing the Optejet®

Optejet® with replaceable drug cartridge



Ergonomic Design to Improve Usability

Horizontal delivery, push-button dosing and no protruding tip



Eye Dropper Bottle tips can touch the patient's eye surface and medication can drip down their face



Optejet has a recessed nozzle, protected by a shutter when not in use to prevent crosscontamination



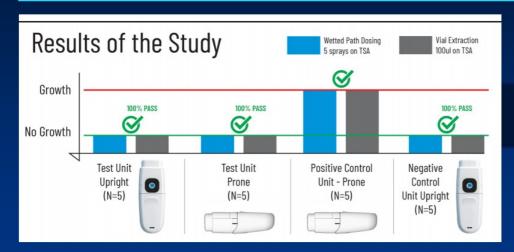
Eye Dropper Bottle administration requires head-tilting, squeezing, and reliance on gravity



Optejet administration can be done horizontally with the push of a buttor



Laboratory-Proven Cartridge Thoroughly Tested to Demonstrate Sterile Drug Delivery



RESULTS: Using the 1x10⁶ microbial growth challenge protocol, Optejet met the passing criteria.

- All test units did not show growth for the 28-day simulated use
- All positive control units showed growth
- All negative control units did not show growth



Vhitcomb., J. & Lam, P. (2023, October 11-14). Demonstration of Microbial Integrity for a Multi-Dose Ophthalmic Spray Drug Device. American Academy of Optometry, New Orleans, LA, United States.

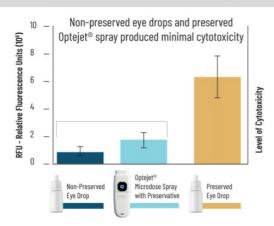
The Optejet Delivers 80% Less Drug Volume Than Eye Droppers

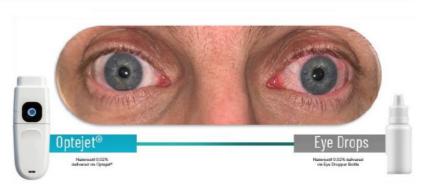
Sufficient for efficacy while improving benefits from reducing excessive exposure to both drugs and preservatives 1,2

Minimizes Excessive Drug Exposure to Ocular Tissues³



Improves Local Tolerability and Decreases Systemic Exposure⁴







1 Wirta D. et al, Presentation at 2019 ASCRS meeting | 2 lanchulev T. et al, Therapeutic Delivery 2018 | 3 Hamrah, P. et al. Cytotoxicity Evaluation for BAK-preserved Latanoprost Delivered By Drop vs. Microdose Array Print Technology. ARVO 2023 poster. New Orleans, LA| 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 is Optecare™



The Optejet® is capable of automatically tracking usage



OPTECARE:

Multiple Benefits for All Stakeholders

PATIENT

- Reminders to take medicine
- Ability to track compliance progress
- Opportunity for brand-specific encouragement
- May be monetized through App subscription

- PHYSICIAN

 Ability for quicker action with more accurate data
- Opportunity for billing: CPT Code (98980) for monthly check of compliance data

PAYER

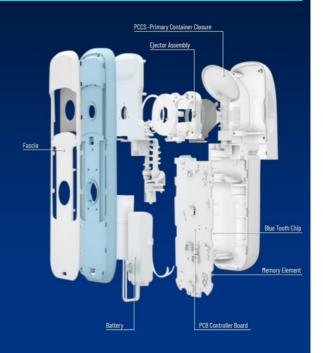
- Cost savings: Less likely to have patient on second medication if compliance is the issue
- Better outcomes: Compliance with drug therapy shown to slow disease progression1



1 Shu YH et al. Topical Medication Adherence and Visual Field Progression in Open-angle Glaucoma. J Glaucoma 2021

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





MydCombi[™] The First FDA-Approved Product with Optejet[®] Technology



The Office-Based and Surgical Pupil Dilation Market \$250 Million Opportunity¹ in the United States

- The leading pupil dilation drugs are tropicamide and phenylephrine, both used individually and together and delivered as eye drops
- There are approximately 108 million office-based dilations performed annually in the United States
- The current process suffers from a number of shortfalls:
 - Multiple eyedrops are usually needed
 - Patient discomfort and avoidance
 - Time-consuming administration and slow recovery to "normal"
 - Cross-contamination risk



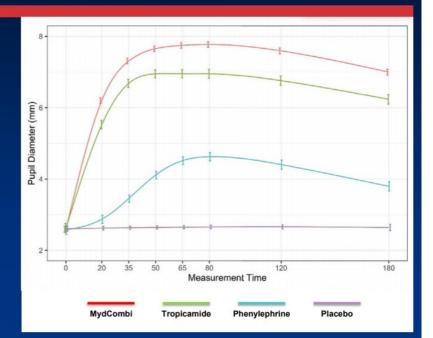


\$200M annual sales of pharmaceutical mydriatic products used during 108M office-based exams (\$2 * 100M) + \$50M of single bottle mydriatic agents
used cataract replacement surgery (\$12.5 x 4M)

MydCombi™

First and only FDA approved ophthalmic spray for mydriasis

- Two Phase 3 clinical trials evaluated the efficacy of MYDCOMBI for achievement of mydriasis.
- MYDCOMBI was statistically superior to tropicamide administered alone and phenylephrine administered alone.
- Nearly all (94%) subject eyes achieved clinically significant effect by achieving pupil diameter of ≥ 6 mm at 35-minute post-dose compared to 78% of eyes administered tropicamide alone and 1.6% of eyes administered phenylephrine alone.
- Clinically effective mydriasis was observed as quickly as 20 minutes.





MydCombi[™]

Modern Mydriasis: An Easy Way to Dilate

The only FDA approved fixed-dose combination of the leading pupil dilating drugs

Quickly achieves clinically necessary dilation and reliable time to resolution¹

Well tolerated. In clinical studies 97% of patients reported zero side effects¹

Soon to listed by leading Optometry buying group Vision Source (visionsource.com) and available on EyenoviaRx.com

Indication: HYDCONBI (trapicamide TV; and phenylophrine HC 25%) ophthalmic spray is indicated to induce mydriasis for reutine diagnostic procedures and in conditions where short term pupil dialation is desired. HYDCANS HALL WIGHARD AND PRECADIONS. FOR TOPICAL OPHISALTION USE. AND PRECADIONS. FOR TOPICAL OPHISALTION USE. AND PRECADIONS. FOR TOPICAL OPHISALTION USE. AND PRECADIONS. FOR TOPICAL OPHISALTION. Hope preparation may cause ONS disturbances which may be designed on in pediatric patients. The possibility of psychotic rescion and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be considered. Hydriatics may produce a transient elevation of intraocular pressure. Significant elevation in blood pressure have been reported. Caudion in patients with elevated blood pressure Rebound moists have been reported caudion in patients with elevated blood pressure should be considered. Hydriatics may produce a transient elevation of intraocular pressure. Significant elevations in blood pressure have been reported. Caudion in patients with elevated blood possible should be considered on day after installation. Remove contense before using Degle BEREATIONS.
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Wirta DL, Walters TR, Flynn WJ, Rathi S, Ianchulev T. Mydriasis with micro-array print touch-free tropicamide-phenylephrine fixed combination MIST; pooled randomized Phase III trials. Ther Deliv. 2021 Mar;12(3):201-214

Testimonials



"My staff and the patients love the technology. MydCombi provides good dilation without the burning associated with in-office dilation."

Edward Rubinchik, MD SmartEyeCare - NY



"MydCombi is a no brainer. Patients tolerated the medication better due to the Optejet device, and it saves our technicians work up time vs. using three eye drops."

Ed Yung, MD

Pacific Eye Institute - CA



"MydCombi is easier to use for patients with difficult eye anatomies than eye drops. There' no chance of contamination as MydCombi doesn't touch the patients' eyes."

Krystina Feliciano, Ophthalmic Tech

Krystina Feliciano, Ophthalmic Te New York Eye Surgery Center



"Patients are dilating faster and get back to normal faster. It's easy to use by my technicians." Aleksandra Wianecka, OD Vision Source Signature Eyecare - NY



"MydCombi has been a fantastic addition to our office in the age of streamlined medicine and has been welcomed by our patients." Nathan Radcliffe, MD New York Eye Surgery Center



"MydCombi is easy to handle, an the effectiveness is similar to eye drops with patients experiencing more comfort when instilled." Dan Tran, MD Coastal Vision Medical Group - C



Clobetasol Propionate Ophthalmic Suspension 0.05% Eyenovia's Second FDA-Approved Product

An Important Advancement in Ocular Post-Surgical Pain and Inflammation Control







Ophthalmology's Newest Steroid: Clobetasol

Physicians now have access to a well characterized steroid with an advantageous profile



Available 2H 2024

Clobetasol Propionate Ophthalmic Suspension 0.05%, BID



Strong efficacy in pain relief and inflammation reduction

Simplicity for patients with twice-a-day dosing

Safety and tolerability with low incidence of IOP spikes

Patented APNT Science

Ease of Access Regardless of Insurance with Value Pricing



* https://www.formosapharma.com/technology/

Clobetasol Utilizes APNT Technology

Clobetasol Propionate Suspension 0.05%, BID

Active Pharmaceutical Nanoparticle Technology:

Increases dissolution • Stable and excellent dispersion properties

Increases bioavailability

Active ingredient is milled down with salts and sugars to nanoparticle size







* https://www.formosapharma.com/technology/

Rapid and Sustained Ocular Pain Relief and Clearance of Inflammation Percent of Patients with Complete Resolution of Pain Percent of Patients with Anterior Chamber Cell Count at Post-Operative Days 4, 8, and 15 at Post-Operative Days 8 and 15 STUDY 1 82.3% 77.3% 80% 60% Clobetasol Propionate 60% 43.7% 42.6% N=181 40% 42.1% 40% 15.7% 20% 20% 11.7% Placebo N=197 0% 0% POD15 POD4 POD8 POD15 POD8 100% STUDY 2 86.5% 80% 60% Clobetasol **Propionate** 60% 51.4% 49.7% N=185 46.5% 40% 29.7% 40% 20% 13.0% Placebo 20%

N=185

0%

POD4

eyenovia

POD8

POD15

0%

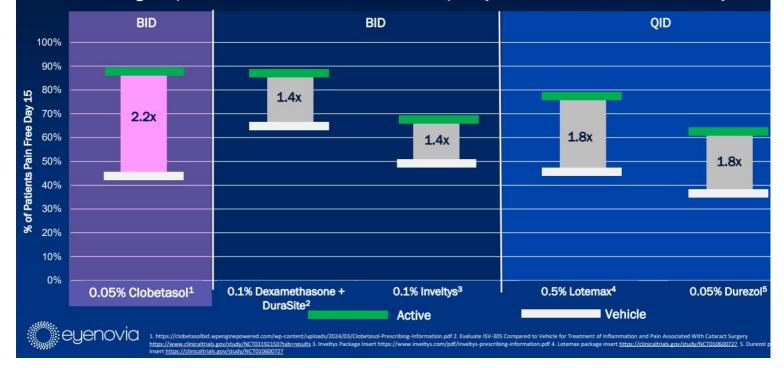
POD8

POD15

Ratio of Patients Pain Free at Day 15 Post-Op

Summary of Published Studies

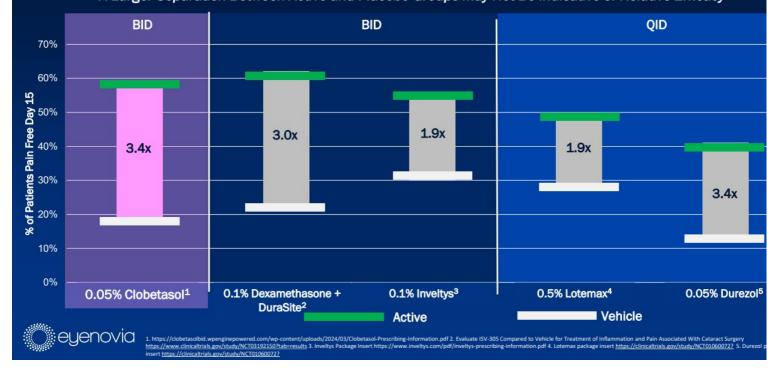
A Larger Separation Between Active and Placebo Groups May Not Be Indicative of Relative Efficacy



Ratio of Patients with No Inflammation Day 15 Post Op (ACC Grade = 0)

Summary of Published Studies

A Larger Separation Between Active and Placebo Groups May Not Be Indicative of Relative Efficacy



Very Low Rate of Adverse Reactions All of Which Occurred in 2% or Fewer Patients

Many of these reactions may have been the consequence of the surgical procedure

- Eye Inflammation (2%)
- Corneal Edema (2%)
- Anterior Chamber Inflammation (2%)
- Cystoid Macular Edema (2%)

- Intraocular Pressure Elevation (1%)
- Photophobia (1%)
- Vitreous Detachment (1%)



https://clohetasolhid.wpaggipapawarad.com/wp.content/uploads/2024/02/Clohetasol-Brassribing Information pdf

Distributed and Priced for Immediate, Broad Access

- ✓ Two Avenues of Distribution
 - ✓ Direct Ordering from EyenoviaRx.com
 - ✓ E-Prescribing from MedVantx Specialty Pharmacy
- ✓ Competitive Pricing Regardless of Insurance Status
- ✓ Non-Substitutable
- ✓ No Call-Backs to Physicians (Cost Savings to Practice)



Clobetasol: The New Generation of Ophthalmic Steroic

- Powerful Efficacy for Pain and Inflammation Relief Post-Ocular Surgery
- Simple BID Dosing Regimen
- Adverse Events Infrequent
- Competitive Pricing Regardless of Insurance



Late-Stage Development Pipeline

PROPRIETARY	Product	Indication	Targeted Product Differentiation	United States Addressable Market	Next Milestone
	MicroPine	Pediatric Progressive Myopia	Optejet: Ease of use, less systemic exposure, Optecare™ service	\$1.8B ²	Planned Ph3 Interim Analysis Q4 2024
	Apersure (MicroLine)	Presbyopia	Optejet: Ease of use, convenience, low side effect incidence	\$850M ³	NDA on hold pending market conditions



Zafar, S. et al. (2020) Presorbing patterns and costs associated with postoperative eye drop use in Medicare beneficiaries undergoing cataract surgery', Ophthalmology, 127(5), pp. 573–581, doi:10.1016/j.ophtha.2019.11.00 Richard Ediow, O. (2020) The Myopia Management Market, Review of Myopia Management. Available at: https://reviewofmm.com/the-myopia-management-market/ Eyerovia Estimates



experts around the world are tacking the challenge of myopia on multiple fronts. An overview of current behavioral, pharmacological, and optical approaches.

MYOPIA: A GLOBAL EPIDEMIC



FORBES > INNOVATION > HEALTHCARE

The Growing Global Epidemic Of Childhood Myopia: Is Atropine The Answer?

Progressive Myopia is a Global Epidemic That Can Lead to Vision Loss and Blindness if Not Controlled

- Begins in early childhood, with genetic link¹
- Elongation of the eye with morbidity and vision problems²
- Urgent need for FDA-approved drug therapies to slow myopia progression

Common Laren Schen Facel Plant

Progression of Myopic Maculopathy

Affects ~25M children in the US alone, with ~5M considered to have high myopia risk³



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 Eva and Contract Lens. 2004: 30

³ 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, 201

Treatment Options and Medical Need

Approved Devices

Soft (MiSight) and Hard (Ortho-K) contact lenses are used to correct nearsightedness and slow the progression of myopia in children

Over 75% of optometrists, however, feel that using contact lenses in patients under 10 years of age is not appropriate. Microbial keratitis being a serious concern for contact lens wearers.1

Stellest Specialty Glasses are also used to correct vision and slow axial elongation

A 2012 study showed that two thirds of children did not comply with wearing their vision correcting spectacles due to various reasons (Dislike, Lost/Broken, Feel Unnecessary, Teasing)2

Drugs in Clinical Trials

- Atropine eyedrops have been observed to slow myopia progression in children³
- Multiple companies (Sydnexis and Ocumension) are in clinical trials using atropine drops ranging in concentrations from 0.01% to 0.03%. These trials are expected to be completed from 2024-2027
- Evenovia's MicroPine ophthalmic spray is in trial evaluating atropine sulfate solution concentrations at 0.1%, and 0.01%. MicroPine delivers ~8µL of drug horizontally and can track adherence. Eyenovia's trial is expected to be completed in 2029

Adherence to therapies is a primary determinant of treatment success. Extensive review of the literature reveals that in developed countries adherence to therapies averages 50%.3

Optejet Designed to Addre **Unmet Needs**

- **Increased Tolerability**
 - Lower Drug Exposure
- Ease of Use
 - Optejet has been used for no 5,000 patient months in chil
- **Enhanced Compliance**
 - Connected-care allows for monitoring of patient use ar discussion with healthcare provider
- **Enhanced Safety**
 - Lower systemic exposure



- Vision Science94(6):638-646, June 2017
 (Qassim). 2013 Nov;7(3):291-9. doi: 10.12816/0006057

 YH, Cheung YB, et al. Aftopine 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

 2011 May;26(3):155-9. doi: 10.5001/omj.2011.38

Pediatric Progressive Myopia

A Potential Market Valued at \$1.8B in the US and Similarly in China

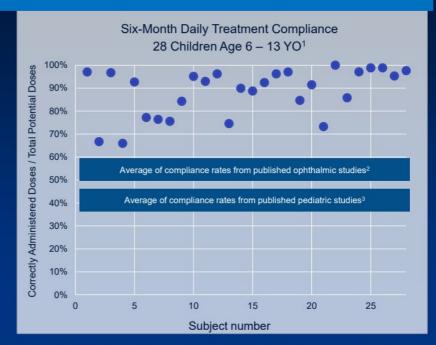




Currently under investigation, not FDA approved

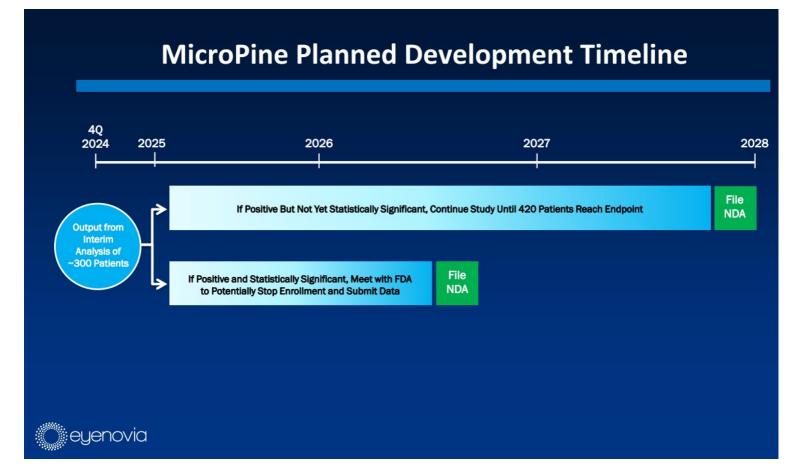
Optecare[™] **Designed to Improve Treatment Adherence**

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





Data on file with Eyenovia. 2 Nato 2015: Nato T, Yoshikawa K, Namiguchi K, Mizoue S, Shiraishi A, et al. (2018) Comparison of success rates in eye drop instillation between sitting position and supina position. PLOS ONE 13(9): 0204363. Patel 1995: Patel SC, Speeth GL. Compliance in patients prescribed eyedrops for glaucoma. Optimalismic Surg. 1995 May-Jun-26(3):233-6. Winfield, 1):990: Winfield AJ, Jessiama D, Williams A, Esakowitz L A study of the causes from-compliance by patients prescribed eyedrops. Br J Optimalismic 1999 Aug/14(8):477-80. 3. Matsu., 1997: Matsu DM. Drug compliance in pediatrics. Clinical and research issues. Pediatr (in North Am. 1997 Feb.34(1):1-14.

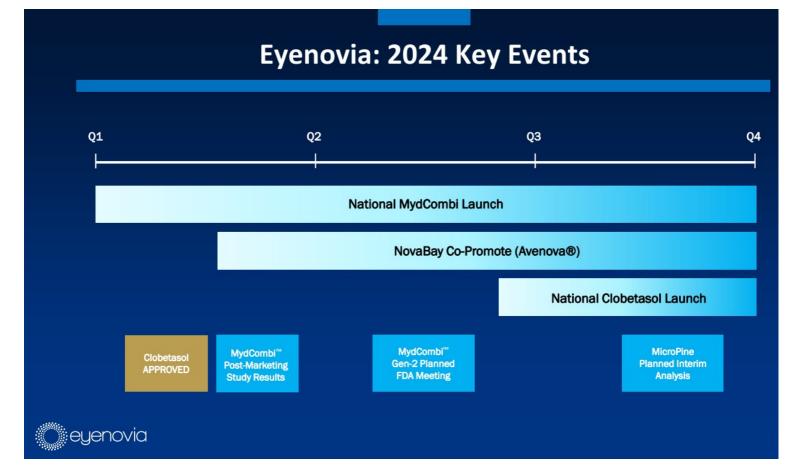


NovaBay Co-Promotion

- NovaBay and Eyenovia are co-promoting Avenova and Clobetasol
- NovaBay salesforce will support Clobetasol sales in geographies not covered by Eyenovia's salesforce
- Eyenovia will promote Avenova with their salesforce
- No additional promotional cost, with each company earning a percentage of incremental sales

Avenova fits within Eyenovia's promotional framework, providing a superior experience for doctors and patients before and after ocular surgery





Additional Large-Market Opportunities

	Target Market	Targeted Product Differentiation	United States Addressable Market
	Glaucoma	Optejet: Optecare™ service, Ease of use, Low side effect incidence	\$2.7B ¹
TIAL	Acute Dry Eye	Optejet: New drug class, Ease of use, Fast onset	\$610M ²
POTENTIAL	Chronic Dry Eye	Optejet: New MOA, Ease of use, Fast onset	\$5.5B ²
	Eye Hydration	Optejet Device Registration	



Estimates from IQVIA Sales Data | 2. Eyenovia Estimates chronic dry eye is 90% and acute is 10% of total dry eye market of \$6.1B (Dry Eye Disease Market (Jan 2024) Transparency Market Research. Available at: ps://www.transparencymarketresearch.com/sample/sample.php?flag=S&rep_id=26096)

Financial Snapshot (December 2023)

Nasdaq: I	EYEN
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Common Shares Outstanding	45.6M
Equity Grants Outstanding Under Stock Plans	5.5M
Warrants	10.9M
Fully Diluted Shares	62.0M
Cash	\$14.8M
Debt	\$15.6M



Experienced Leadership Team



John Gandolfo Chief Financial Officer



Michael Rowe Chief Executive Officer



Bren Kern Chief Operating Officer





















Norbert Lowe











