

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): June 4, 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:

- 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 7.01. Regulation FD Disclosure.**

On June 4, 2024, Eyenovia, Inc. (the “Company”) will begin 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 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 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

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	<a href="#">Eyenovia, Inc. Updated Corporate Presentation, dated June 2024.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**EYENOVIA, INC.**

Date: June 4, 2024

/s/ John Gandolfo  
John Gandolfo  
Chief Financial Officer

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June 2024

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# We Are the Optejet<sup>®</sup> Company

Developing and commercializing ophthalmic therapeutics with Optecare<sup>™</sup> 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 estimates of market opportunities for our products, product candidates and platform technology. These statements are based on current estimates and projections about our business based, in part, on assumptions made by management. These statements are not a guarantee of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements of 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 and our licensees' clinical trials, including, but not limited to, the costs, design, initiation and enrollment, timing, progress and results of such trials; our licensees' ability to submit applications for, obtaining and maintaining regulatory approvals for Mydcombi, clobetasol propionate and our product candidates; the potential advantages of Mydcombi, clobetasol propionate and our product candidates and platform technology and potential revenues from licensing transactions; the rate and degree of market acceptance and clinical utility of clobetasol propionate and our product candidates; our estimates regarding the potential market opportunity for Mydcombi, clobetasol propionate and our product candidates; reliance on third parties to develop and commercialize Mydcombi™, clobetasol propionate and our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for Mydcombi, clobetasol propionate and our product candidates; property risks; changes in legal, regulatory, legislative and geopolitical environments in the markets in which we operate and the effect 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.



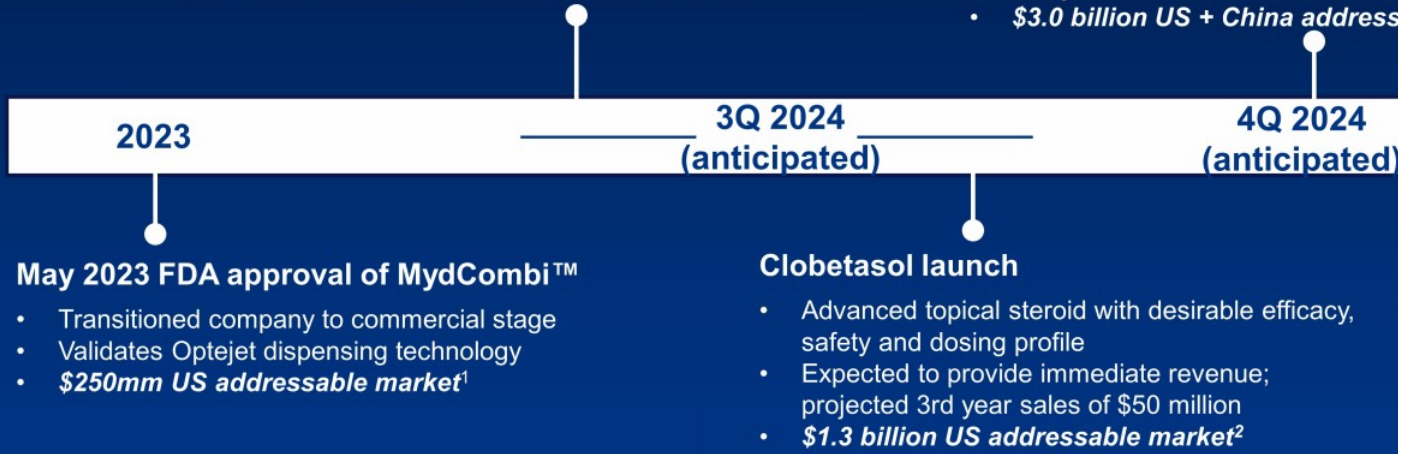
# Eyenovia Corporate Highlights

## Optejet® Gen-2 FDA meeting

- To confirm regulatory pathway towards drug/device approval
- Expands licensing opportunities with other companies
- Patent projection through 2041
- Applications in acute dry eye, chronic dry eye, and glaucoma
- **Combined >\$8.8 billion US addressable market**

## MicroPine Phase 3 interim results

- Currently only FDA-approved treatment for progressive myopia are contact lenses
- Potential to unmask if data safety committee determines efficacy is positive
- **\$3.0 billion US + China addressable market**



## May 2023 FDA approval of MydCombi™

- Transitioned company to commercial stage
- Validates Optejet dispensing technology
- **\$250mm US addressable market<sup>1</sup>**

## Clobetasol launch

- Advanced topical steroid with desirable efficacy, safety and dosing profile
- Expected to provide immediate revenue; projected 3rd year sales of \$50 million
- **\$1.3 billion US addressable market<sup>2</sup>**



1. \$200M annual sales of pharmaceutical mydriatic products used during 108M office-based exams (\$2 x 100M) + \$50M of single bottle mydriatic agents used cataract replacement surgery  
2. Source: IQVIA topical ophthalmic steroid and steroid combination market

# MicroPine

Atropine Ophthalmic Metered Spray

**Our Premier Near-Term Opportunity in the  
Multi-Billion Dollar Pediatric Progressive Myopia M**





# Asset Highlights



## \$3.0B market in the U.S. and China

One of the largest markets in global eyecare



## Optejet Technology

Easy to use and self-administer with digital capability to track adherence and compliance



## Unmet Medical Need

Current options are not appropriate for all patients and do not eliminate progression risk



## Major Clinical Milestone expected in

CHAPERONE Data Monitoring C  
Review expected in

## Strong IP, Non-Sub

Unique FDA form with d  
method patents thro

## Manu

CMO manufactures drug  
Device and Sterile Fill a  
by



## Facing the Myopia Epidemic

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

## MYOPIA: A GLOBAL EPIDEMIC



An overview of the problem and efforts to address it.

BY NEESURG MEHTA, MD; AND ANGIE WEN, MD

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 link or environmental factors<sup>1</sup>
- Elongation of the eye with morbidity and vision problems<sup>2</sup>
- Currently no FDA-approved drug therapies to slow myopia progression

### Progression of Myopic Maculopathy

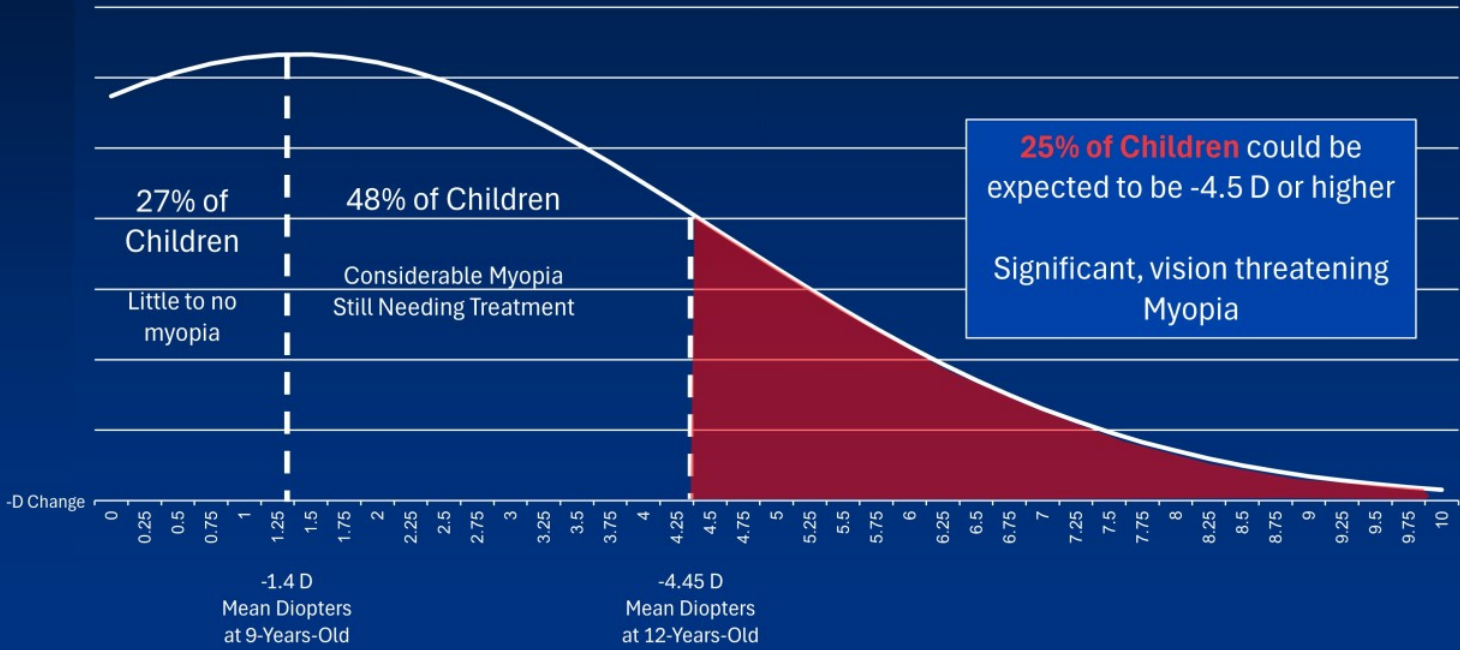


<sup>1</sup> Jones LA, Sinnott LT, Mutti DO, Mitchell GL, Moeschberger ML, Zadnik K. Parental history of myopia, sports and outdoor activities, and future myopia. Invest Ophthalmol Vis Sci. 2007 Aug;48(8):3524-30.  
<sup>2</sup> Eye and Contact Lens. 2004; 30

<sup>3</sup> 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.

# Approximately 25% of Myopic Children are at High Risk for Vision Loss Without Effective Intervention

Predicted Myopic Progression Rates of Untreated 9-Year-Old Children Over 3 Years



Donovan L. et al., Myopia progression rates in urban children wearing single-vision spectacles. Optom Vis Sci. 2012 Jan;89(1):27-32.

# Only FDA-Approved Treatment Today are Lens

## Approved Devices



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.<sup>1</sup>



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)<sup>2</sup>

## Efficacy

“Evaluating children who were prescribed 1 day at the study’s initiation, 23% of eye year six displayed a total refractive change than -0.25D (spherical equivalent)...”

Approximate cost to patient \$1800 per year for visits and [\$700 lens cost to physician]

“Essilor® Stellest® lenses slow down myopia progression by 67% on average, compared to single vision lenses...”

Approximate cost to patient \$1800 to \$2600 per year depending on lens type [\$200 lens cost to physician]



1. Optometry and Vision Science 94(6):638-646, June 2017
2. Int J Health Sci (Qassim). 2013 Nov;7(3):291-9. doi: 10.12816/0006057

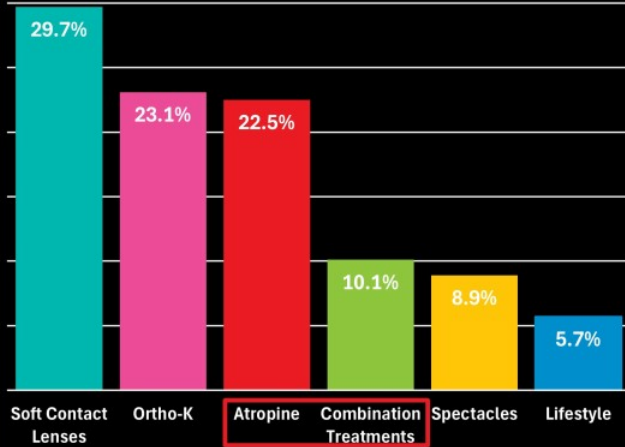




# Eye Doctors are using Off-Label Atropine from Compounding Pharmacies to Treat Myopia Patients

OPTOMETRISTS (N = 316)

Which of the following is your preferred and most used myopia management treatment?



eyesON

The 2023 Myopia Report

Published April 2023

WHICH TREATMENT INTERVENTIONS DO YOU PRESCRIBE TO MANAGE PROGRESSIVE MYOPIA IN CHILDREN AND ADOLESCENTS' N=293



Published Jan 2024

# MicroPine

## The Premier Drug+Device Product for Progressive Myopia



### Target Product Profile

- 60% reduction in myopia progression with minimal rebound after one year
- One spray per each eye daily; easy enough for children to use without supervision
- Comfortable to instill with minimal impact on ocular surface
- Minimal local side effects and very low systemic exposure
- Optecare™ compliance system provides dosing reminders and product use history for doctor to improve treatment success
- Estimated NSP of \$200/month with COGS below \$20/month



# CHAPERONE

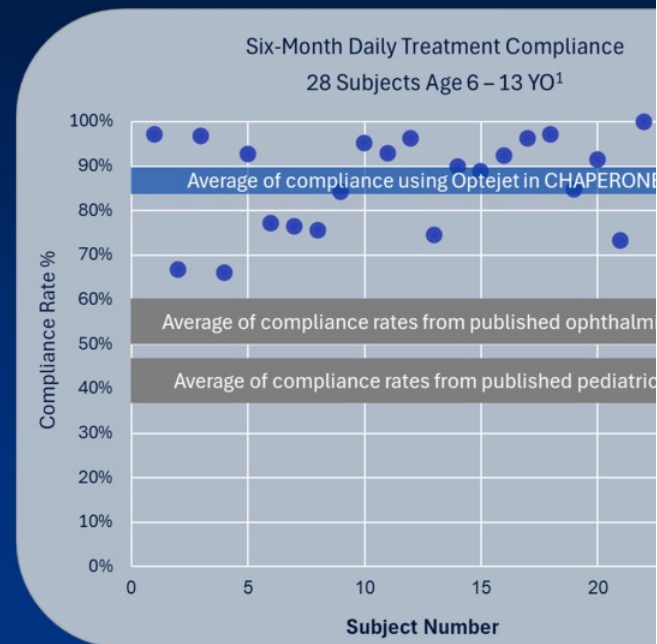
## The Single Phase 3 Trial Required for FDA Approval

- Three arms dosed with 8 microliter ophthalmic spray: placebo, 0.01% and 0.05% atropine
- Myopic children in the U.S. between the ages of 3 and 13 at risk for progression
- MicroPine given as one spray in each eye at night
- Three years to efficacy endpoint – myopia progression of less than 0.5 diopters
- Masked data to date indicates very low rate of SAEs (fewer than 1 per 1,000 patient-months of therapy); all SAEs were judged not related to treatment by investigators. Therapy compliance appears higher than what has been seen historically with eye drop studies.

# Treatment Compliance via the Optecare™ System

## What Makes MicroPine Special

- Only MicroPine comes with built-in Optecare™ technology to track and communicate patient compliance data
- In CHAPERONE, the daily treatment compliance of the first 28 subjects was well above what was predicted
- Treatment adherence and compliance is typically a primary determinant of therapy success
- Payers are strongly motivated to include therapies on formulary that improve outcomes<sup>1</sup>



<sup>1</sup> Data on file with Eyenovia. <sup>2</sup> Naito 2018: Naito T, Yoshikawa K, Namiguchi K, Mizoue S, Shiraishi A, et al. (2018) Comparison of success rates in eye drop instillation between sitting position and supine position. F e0204363. Patel 1995: Patel SC, Spaeth GL. Compliance in patients prescribed eyedrops for glaucoma. Ophthalmic Surg. 1995 May-Jun;26(3):233-6. Winfield, 1990: Winfield AJ, Jessiman D, Williams A, Esakowitz of non-compliance by patients prescribed eyedrops. Br J Ophthalmol. 1990 Aug;74(8):477-80. 3. Matsui, 1997: Matsui DM. Drug compliance in pediatrics. Clinical and research issues. Pediatr Clin North Am. 1997 F

# Potential Peak Sales of Over One Billion Dollars

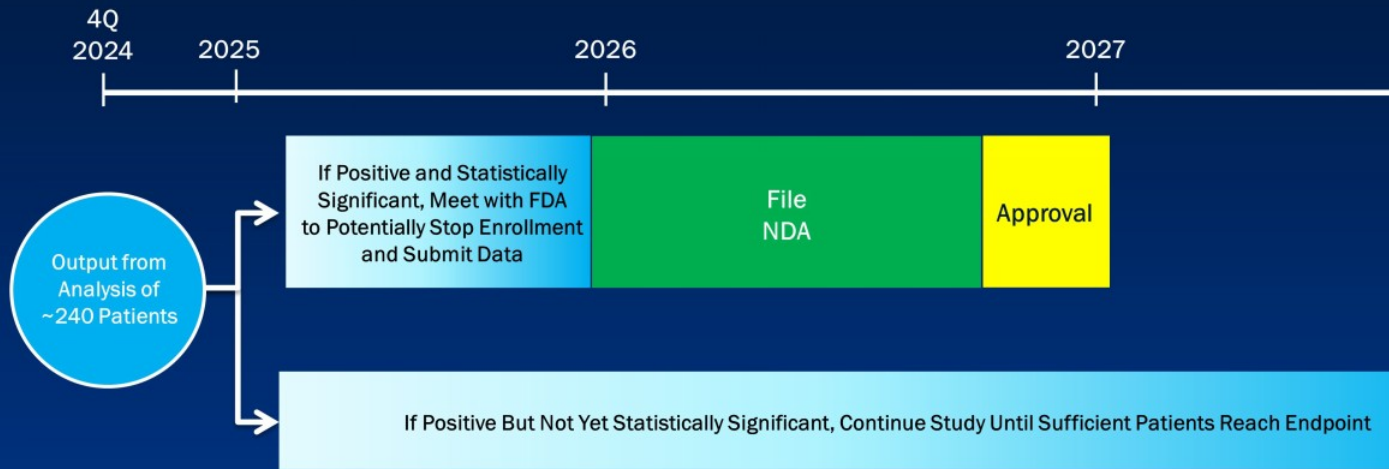
	2027	2028	2029	2030	2031	2032	2033	2034	2035
Number of Potential Users	5,000,000	5,050,000	5,100,500	5,151,505	5,203,020	5,255,050	5,307,601	5,360,677	5,414,278
Approx. Market Share	0.5%	1%	2%	4%	6%	7%	8%	9%	10%
Cartridge Units	150,000	375,000	937,500	1,640,625	2,460,938	3,076,172	3,537,598	4,068,237	4,678,446
Product Price (Net of Rebates)	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00	\$200.00
Gross Sales	\$30,000,000	\$75,000,000	\$187,500,000	\$328,125,000	\$492,187,500	\$615,234,375	\$707,519,531	\$813,647,461	\$935,694,450

## Assumptions

- Potential users based on number of children at high risk of progressive myopia in the U.S.
- \$400 net monthly price less up to 50% rebates (typical for new products in ophthalmology)
- Eight cartridges per year per patient ("cartridge stretching")
- Base could be sold to physicians at cost as a possible practice builder



# MicroPine Planned Development Timeline



**Optejet®**

Digital Ophthalmic Metered Spray Device

**The Only FDA-Approved Ophthalmic  
Digital Drug Delivery Platform**





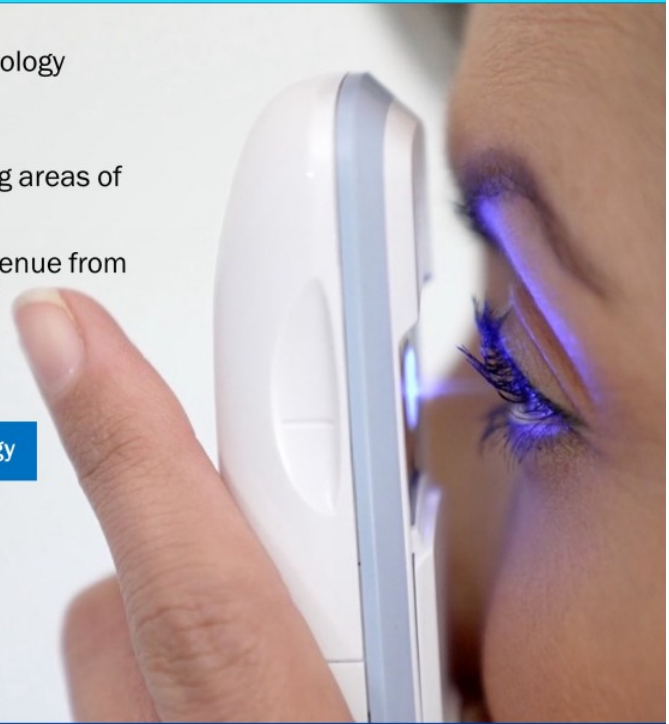
# Introducing the Optejet® Gen-2



- 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-of-use and dosing precision
- Delivers efficacy while improving tolerability and reducing side effects<sup>1</sup>
- Digital Optecare™ capabilities<sup>2</sup>



1. 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 D  
2. Optecare is Eyenovia's suite of digital compliance and adherence capabilities



# The Optejet<sup>®</sup> Consists of a Replaceable Cartridge (COGS of \$20) and Durable Base



Proprietary, pre-filled drug cartridge manufactured by Eyeon



Optejet uses technology similar to that of Inkjet printers to “print” microdroplets onto the eye, using  $\frac{1}{4}$  of the dose of conventional eye drops to maintain efficacy and minimize tolerability issues



# Ergonomic Design to Improve Usability

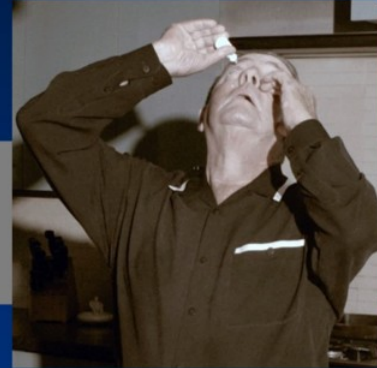
Horizontal delivery, push-button dosing and no protruding tip



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 cross-contamination

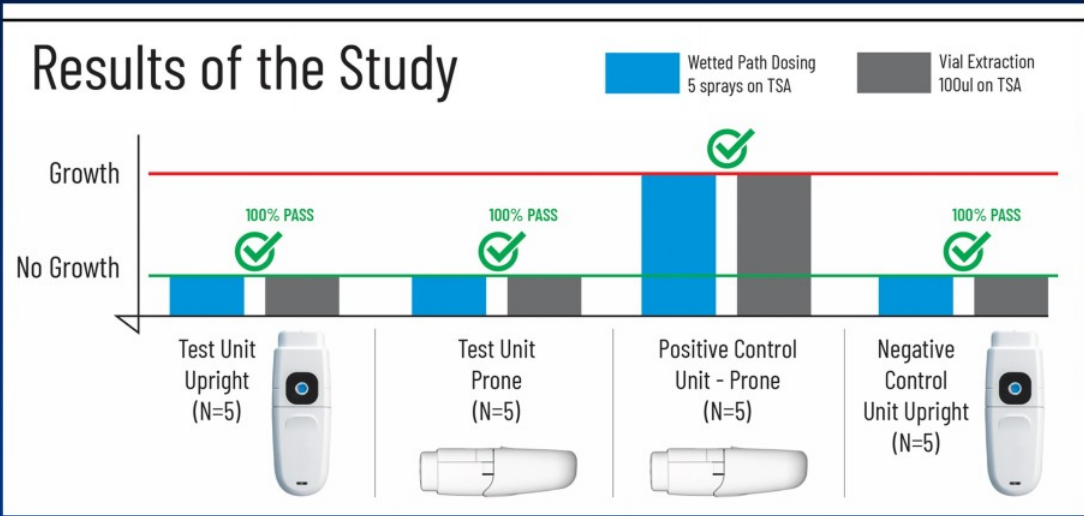


Eye Dropper Bottle administration requires head-tilting, squeezing, and reliance on gravity



Optejet administration horizontally with t

# Device Thoroughly Tested to Ensure Sterile Drug Delivery



**RESULTS:** Using the microbial growth challenge protocol, Optejet met 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



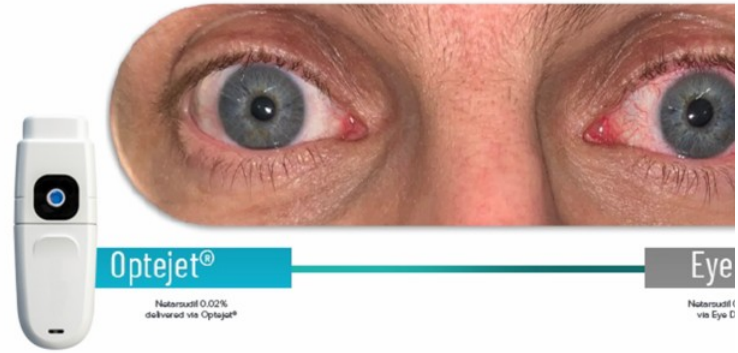
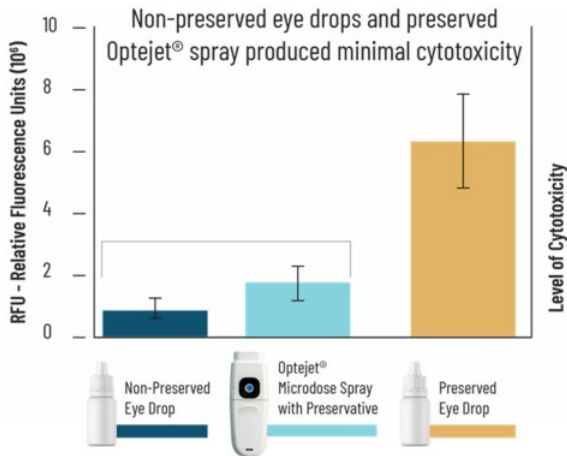
# The Optejet Delivers 80% Less Drug Volume Than Eye Drop

Sufficient for efficacy while improving benefits from reducing excessive exposure to both drugs and preserva

Minimizes Excessive Drug Exposure to Ocular Tissues<sup>3</sup>

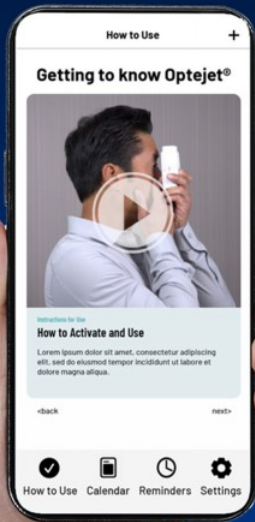


Improves Local Tolerability and Decreases Systemic Exposure<sup>4</sup>



1 Wirta D. et al, Presentation at 2019 ASCRS meeting | 2 Ianchulev T. et al, Therapeutic Delivery 2018 | 3 Hamrah, P. et al, Cytotoxicity Evaluation for BAK-preserved Latanoprost Delivered By 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 dr

# 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 service

### PHYSICIAN

- Ability for quicker action with more accurate data
- Opportunity for billing: CPT Code (98967) for monthly check of compliance data

### PAYER

- Cost savings: Less likely to have patient on second medication if compliance is tracked
- Better outcomes: Compliance with drug therapy shown to slow disease progression<sup>1</sup>

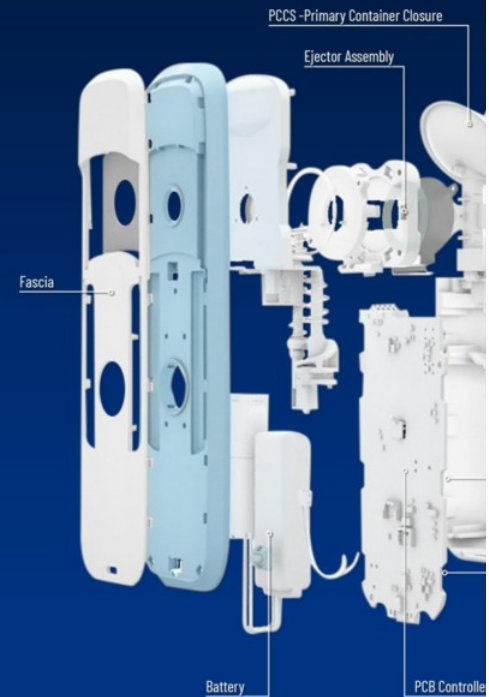


<sup>1</sup> Shu YH et al. Topical Medication Adherence and Visual Field Progression in Open-angle Glaucoma



# 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 2041
- Clinical data and regulatory approval adds another layer of IP





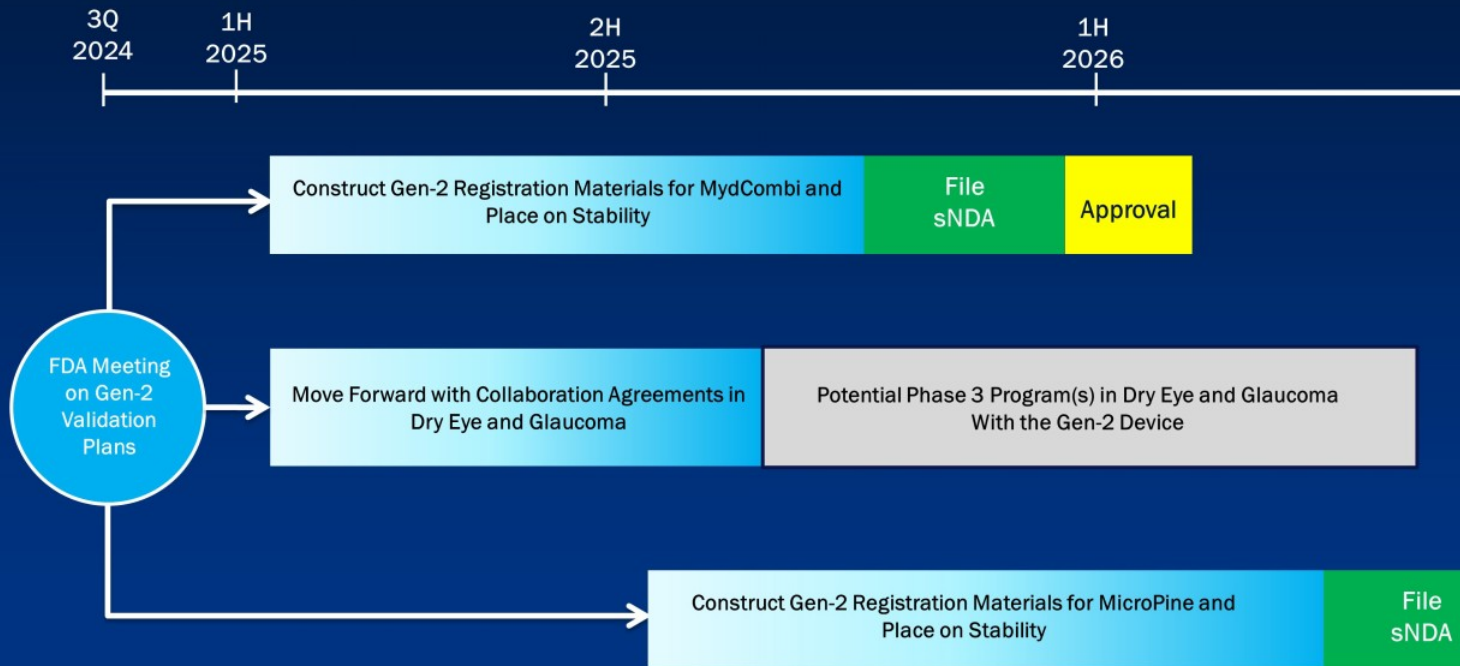
# Multiple Licensing Opportunities in Large Mark

	Target Market	Targeted Product Differentiation	United Addressal
POTENTIAL OPPORTUNITIES	Glaucoma	Optejet: Optecare™ service, Ease of use, Low side effect incidence	\$2.
	Acute Dry Eye	Optejet: New drug class, Ease of use, Fast onset	\$0.
	Chronic Dry Eye	Optejet: New MOA, Ease of use, Fast onset	\$5.
	Presbyopia	Optejet: Ease of use, consumer preference, low side effects	\$0



1. 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. [https://www.transparencymarketresearch.com/sample/sample.php?flag=5&rep\\_id=26096](https://www.transparencymarketresearch.com/sample/sample.php?flag=5&rep_id=26096))

# Gen-2 Planned Development Timeline



# Clobetasol Propionate

Ophthalmic Suspension 0.05%

**FDA-APPROVED**

**For the treatment of post-operative inflammation and  
following ocular surgery**



This presentation is not an advertisement for clobetasol propionate.

# Safety Information

**IMPORTANT SAFETY INFORMATION:** Clobetasol Propionate Ophthalmic Suspension 0.05% is indicated for the treatment of post-inflammatory and pain following ocular surgery. **CONTRAINDICATIONS:** Most active viral diseases of the cornea and conjunctiva, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal infections of ocular structures. **WARNINGS AND PRECAUTIONS:** Intraocular Pressure (IOP) Increase: Prolonged use of corticosteroids may result in increased IOP with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. If this product is used for 10 days or longer, IOP should be monitored. Cataracts: Prolonged use of corticosteroids may result in posterior subcapsular cataract formation. Delayed Healing: The use of steroids after cataract surgery may delay healing and increase the incidence of bleb leakage. Corneal and Scleral Melting: In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication order should be made by a physician only after examination of the eye with the aid of magnification, such as slit lamp biomicroscopy, and where appropriate, fluorescein staining. Bacterial Infections: Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, the use of corticosteroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be reevaluated. Viral Infections: Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. The use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex virus infections). Fungal Infections: Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungal infections must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate. **ADVERSE REACTIONS:** Ocular adverse reactions occurring in  $\geq 1\%$  of subjects in clinical studies who received clobetasol propionate ophthalmic suspension 0.05% included eye inflammation (2%), corneal edema (2%), anterior chamber inflammation (2%), macular edema (2%), intraocular pressure elevation (1%), photophobia (1%) and vitreous detachment (1%). Many of these reactions have been the consequence of the surgical procedure. **PLEASE GO TO [CLOBETASOLBID.COM](http://CLOBETASOLBID.COM) FOR FULL PRESCRIBING INFORMATION.**



# Ophthalmology's First New Steroid in 15 Years

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

Expected to Provide Near-Term Revenue to Fund Optejet Projects



**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

Guaranteed access for all patients regardless of insurance status



\* <https://www.formosapharm.com>



# Clobetasol Utilizes APNT\* Technology

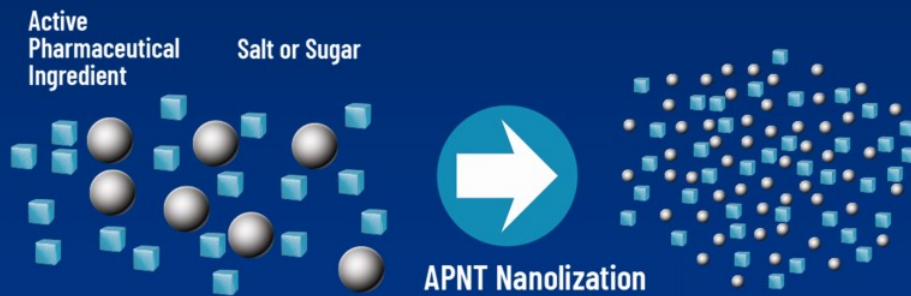
Clobetasol Propionate Suspension 0.05%, BID

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

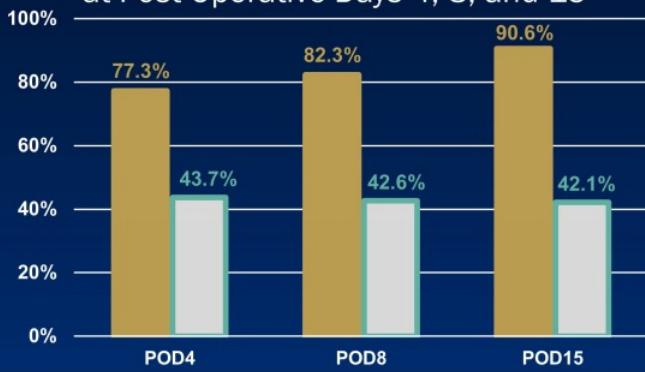


\* <https://www.formosapharm>



# Rapid and Sustained Ocular Pain Relief and Clearance of Inflammation

Percent of Patients with Complete Resolution of Pain at Post-Operative Days 4, 8, and 15



## STUDY 1

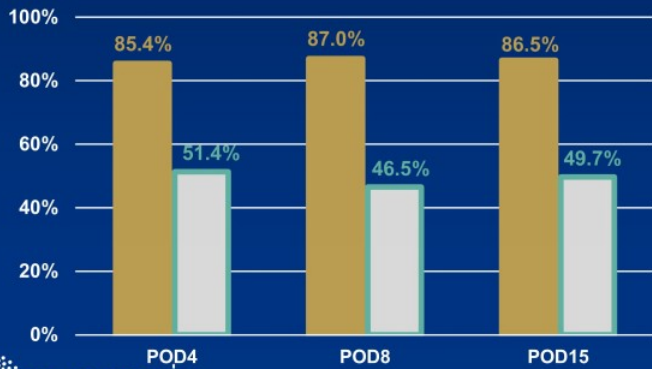
Clobetasol Propionate

N=181

Placebo

N=197

Percent of Patients with Anterior Chamber Inflammation Clearance at Post-Operative Days 8 and 15



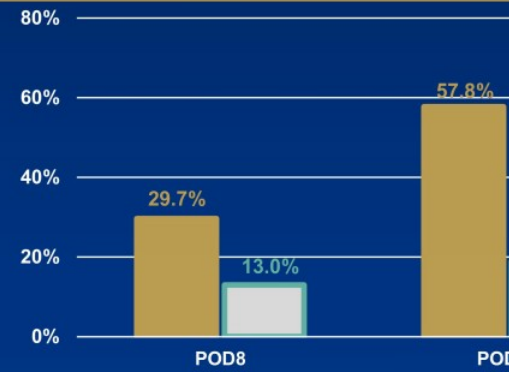
## STUDY 2

Clobetasol Propionate

N=185

Placebo

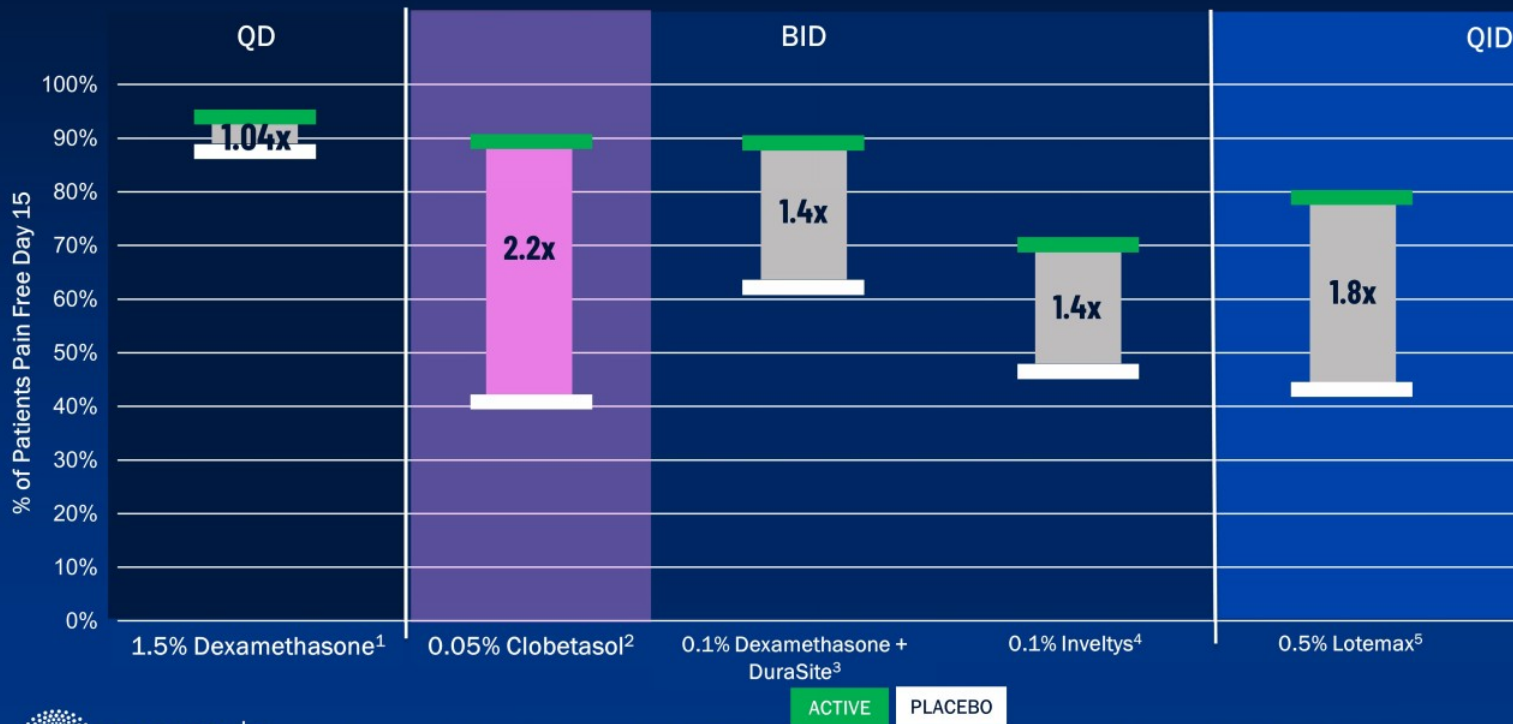
N=185



# Ratio of Patients Pain-Free at Day 15 Post-Op

## Summary of Published Studies

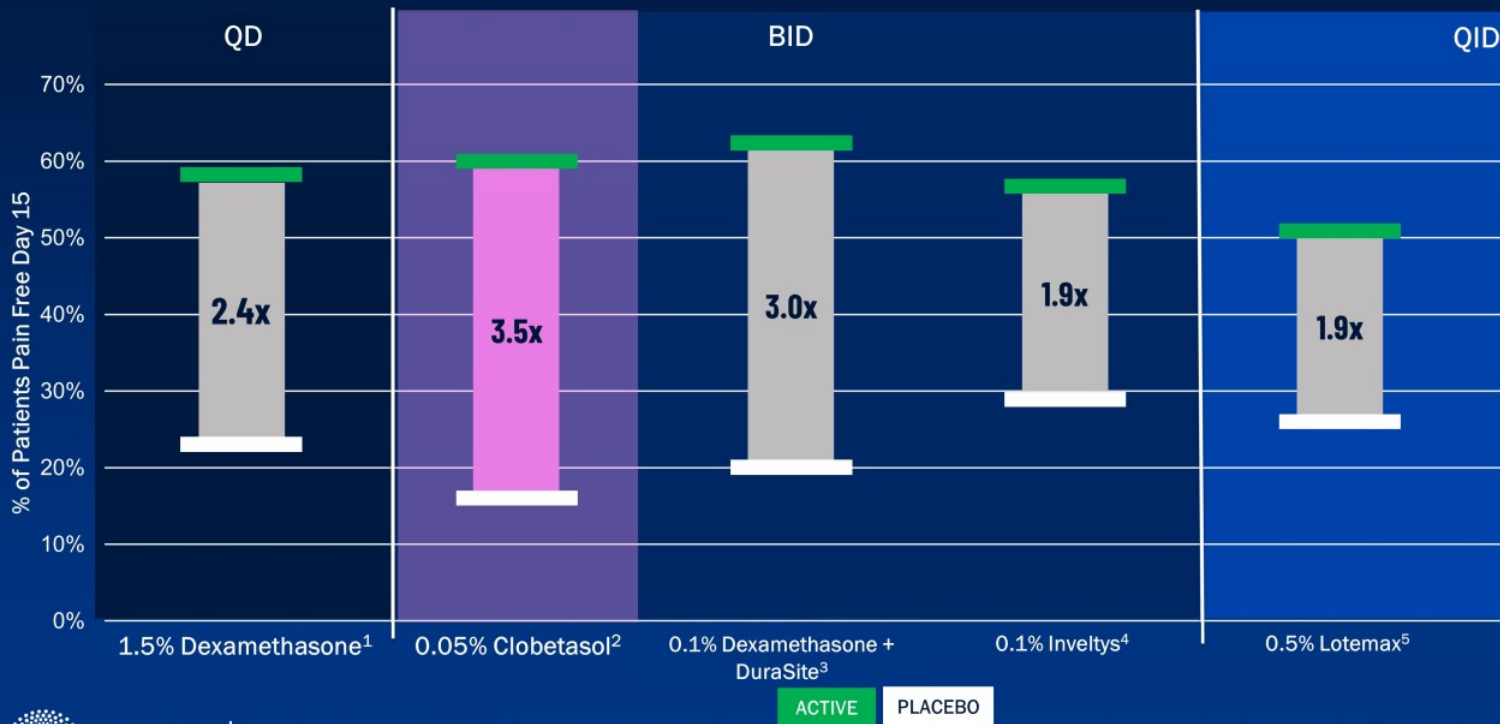
*A Larger Separation Between Active and Placebo Groups May Not Be Indicative of Relative Efficacy*



1. <https://www.sec.gov/Archives/edgar/data/1953530/000119312523206201/d5199544424b3.htm> 2. <https://clobetasolbid.wpenginepowered.com/wp-content/uploads/2024/03/Clobetasol-Prescribing-Information-Compared-to-Vehicle-for-Treatment-of-Inflammation-and-Pain-Associated-With-Cataract-Surgery> 3. <https://www.clinicaltrials.gov/study/NCT03192150?tab=results> 4. Inveltys Package Insert <https://www.inveltys.com/information.pdf> 5. Lotemax package insert <https://clinicaltrials.gov/study/NCT01060072?> 6. Durezol package insert <https://clinicaltrials.gov/study/NCT01060072?> Head-to-head comparisons are not anticipated.

# Ratio of Patients with No Inflammation Day 15 Post Op (ACC G Summary of Published Studies

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



1. <https://www.sec.gov/Archives/edgar/data/1953530/000119312523206201/d5199544424b3.htm> 2. <https://clobetasolbid.wpenginepowered.com/wp-content/uploads/2024/03/Clobetasol-Prescribing-Information-Compared-to-Vehicle-for-Treatment-of-Inflammation-and-Pain-Associated-With-Cataract-Surgery> 3. <https://www.clinicaltrials.gov/study/NCT03192150?tab=results> 4. Inveltys Package Insert <https://www.inveltys.com/information.pdf> 5. Lotemax package insert <https://clinicaltrials.gov/study/NCT01060072?> 6. Durezol package insert <https://clinicaltrials.gov/study/NCT01060072?> Head-to-head comparisons are not anticipated.

# Low Rate of Adverse Reactions with Clobetasol All of Which Occurred in 2% or Fewer Patients<sup>1</sup>

Many of these reactions may have been consequences 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%)



1. <https://clobetasolbid.wpenginepowered.com/wp-content/uploads/2024/03/Clobetasol-Prescribing-Information.pdf>

# 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 sales
- 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

## Pre-Surgical

## Post-Surgical



Avenova

MydCombi



Clobetasol

Avenova



- Cleans Lids and Lashes
- Kills Most Pathogens

- Hygienic Dilation (No Touch)
- Effective and Well-Tolerated

- New Steroid in Ophthalmology for Pain and Inflammation
- Efficacious and Well-Tolerated
- Twice-a-day Dosing

- Cleans
- Kills Mo



See [NovaBay.com](http://NovaBay.com) and [Eyenovia.com](http://Eyenovia.com) for additional product information.

**MydCombi™**

Ophthalmic Spray

(1% tropicamide and 2.5% phenylephrine)

**FDA-APPROVED**

**For short-term in-office or pre-surgical pupil dilation**



This presentation is not an advertisement for MYDCOMBI.



# Safety Information

**IMPORTANT SAFETY INFORMATION:** MYDCOMBI (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5% is indicated to induce mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired. **CONTRAINDICATIONS:** Known hypersensitivity to any component of the formulation. **WARNINGS AND PRECAUTIONS:** FOR TOPICAL OPHTHALMIC USE. NOT FOR INJECTION. This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of a psychotic reaction and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be considered. Mydriatics may produce a transient elevation of intraocular pressure. Significant elevations of intraocular pressure have been reported. Caution in patients with elevated blood pressure. Rebound miosis has been reported one day after installation. Remove contact lenses before using. **DRUG INTERACTIONS:** **Atropine and Other Anticholinergic Drugs:** May exaggerate the adrenergic pressor response. **Cholinergic Agonists and Ophthalmic Cholinesterase Inhibitors:** May interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors. **Potent Inhalation Anesthetic Agents:** May potentiate cardiovascular depression of some inhalation anesthetic agents. **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 tropicamide. **PLEASE GO TO MYDCOMBI.COM FOR FULL PRESCRIBING INFORMATION**



# MydCombi™

Modern Mydriasis: An Easy Way to Dilate

The only FDA-approved fixed-dose combination of the leading pupil dilating drugs and validation of the Optejet™ delivery platform

Quickly achieves clinically necessary dilation and reliable time to resolution.<sup>1</sup> Well tolerated. In clinical studies 97% of patients reported zero side effects<sup>1</sup>

Transitioned Eyenovia to a commercial stage company along with the creation of an internal sales force and distribution channels

Introduced easy drug delivery and the Optejet™ experience to patients, physicians, and technicians in a \$250MM addressable market<sup>2</sup>

**Indication:** MYDCOMBI (tropicamide 1% and phenylephrine HCl 2.5%) ophthalmic spray is indicated to induce mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired. **IMPORTANT SAFETY INFORMATION. CONTRAINDICATIONS:** Known hypersensitivity to any component of the formulation. **WARNINGS AND PRECAUTIONS. FOR TOPICAL OPHTHALMIC USE. NOT FOR INJECTION.** This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of psychotic reaction and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be considered. Mydriatics may produce a transient elevation of intraocular pressure. Significant elevations in blood pressure have been reported. Caution in patients with elevated blood pressure. Rebound miosis has been reported one day after installation. Remove contact lenses before using. **DRUG INTERACTIONS.** Atropine-like Drugs: May exaggerate the adrenergic pressor response. Cholinergic Agonists and Ophthalmic Cholinesterase Inhibitors: May interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors. Potent Inhalation Anesthetic Agents: May potentiate cardiovascular depressant effects of some inhalation anesthetic agents. **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 1-833-393-6694 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch) www.mydcombi.com for FULL PRESCRIBING INFORMATION



1. Wirtz 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 1;12(3):1-10.
2. \$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™

## The First FDA-Approved Product with Optejet® Techno





# The Office-Based and Surgical Pupil Dilation Market \$250 Million Opportunity<sup>1</sup> 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

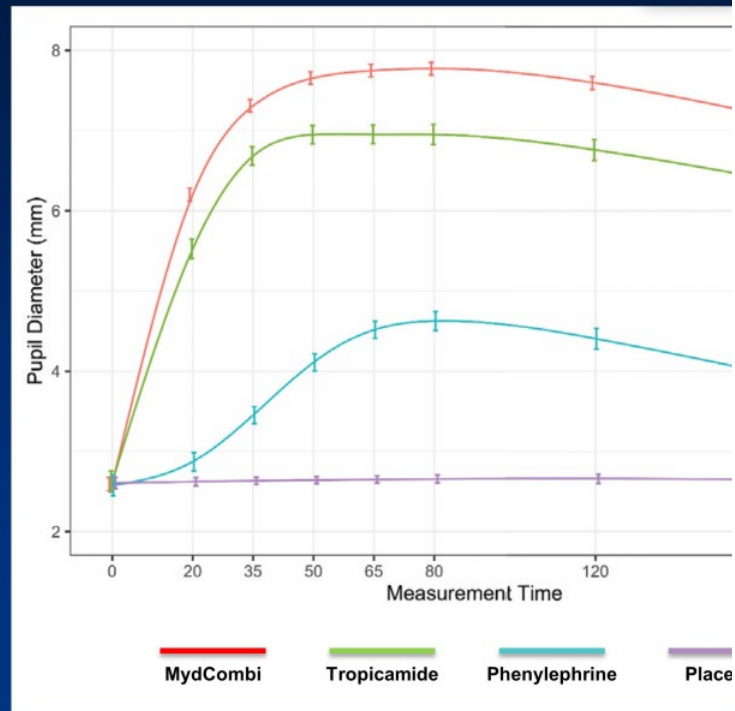


1. \$200M annual sales of pharmaceutical mydriatic products used during 108M office-based exams (\$2 \* 100M) + \$50M of single bottle mydriatic a used cataract replacement surgery (\$12.5 x 4M)

# MydCombi™

First and only FDA-approved ophthalmic spray for mydriasis

- Two Phase 3 clinical trials evaluated the efficacy of MYDCOMBI for achievement of mydriasis.
- Pupil dilation achieved by 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  $\geq 6$  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 after dosing.





# Financial Snapshot (March 2024)

## Nasdaq: EYEN

Common Shares Outstanding	47.4M
Equity Grants Outstanding Under Stock Plans	6.3M
Convertible Notes	2.3M
Warrants	10.9M
Fully Diluted Shares	66.9M
Cash	\$8.0M
Debt	\$15.6M



# 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, Pharm R&D and  
CMC Regulatory



**Enrico Brambilla**  
VP, Device R&D and  
Engineering



**Lauren Gidden**  
VP, Quality and  
Regulatory Affairs



**Rob Richardson**  
VP, Manufacturing

