

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K/A

(Amendment No. 1)

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 25, 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. ☐

EXPLANATORY NOTE

This Amendment No. 1 on Form 8-K/A amends the Current Report on Form 8-K filed on January 25, 2024 (the “Original 8-K”), to provide an updated version of the investor presentation furnished as Exhibit 99.1 thereto to update market size opportunity references and clarify the cost of an NDA filing for Apersure as set forth on slides 16, 17 and 28. The updated investor presentation is furnished as Exhibit 99.1 hereto and supersedes Exhibit 99.1 to the Original 8-K in its entirety. No other changes have been made to the Original 8-K or to Exhibit 99.1 furnished hereto.

Item 7.01. Regulation FD Disclosure.

On January 25, 2024, Eyenovia released an updated investor presentation, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Eyenovia is developing topical ophthalmic medications that utilize its novel, patented Optejet® drug-device dispensing platform to address large market indications with significant unmet medical needs. Numerous studies have demonstrated the ability of the Optejet to achieve efficacy with up to 80% less medication than traditional eye drops, resulting in increased local tolerability and decreased systemic exposure to both drug and preservatives. The Optejet technology is protected by a comprehensive IP portfolio, with many claims in effect beyond 2031.

Complementing its Optejet device, Eyenovia is developing its Optecare™ suite of digital applications which leverages the onboard programming and Bluetooth technology in the Optejet to track usage and boost compliance through reminders sent to the patient, which may result in improved patient outcomes. This also represents a potential additional revenue stream for eye doctors under a CPT code for “Remote Therapeutic Monitoring Treatment Management Services.”

Eyenovia currently has one commercial asset, Mydcombi for mydriasis (in-office and surgical pupil dilation), which is currently being launched commercially. Eyenovia estimates this to be a \$250 million market annually, and the updated investor presentation contains several testimonials from early adopters of the technology. Mydcombi represents the first FDA approved drug in the Optejet, providing important validation of the technology.

Eyenovia in-licensed its second asset, APP13007 for pain and inflammation following ocular surgery, from Formosa Pharmaceuticals in August of 2023. APP13007 has an FDA PDUFA date of March 4, 2024. APP13007 utilizes Formosa’s APNT™ platform which reduces an active pharmaceutical ingredient’s particle size with high uniformity and purity, ultimately enhancing bioavailability.

New clinical data in the updated investor presentation demonstrates that 91% of APP13007-treated patients were pain free through day 15, as compared to 42% for placebo. Similarly, 59% of APP13007-treated patients were free from inflammation (ACC Grade 0) through day 15, versus 16% for placebo. Importantly, the clinical profile of APP13007 allows for 2x/day dosing in a market where most approved treatments require up to 4x/day dosing. APP13007 was well tolerated in clinical trials. Eyenovia plans to launch APP13007 in 2H 2024, if approved. This would allow the company to further leverage its planned 10-person field sales force.

In addition, Eyenovia recently announced that it has re-acquired the development rights to MicroPine (precision dosed atropine spray) from Bausch+Lomb, which is currently in Phase 3 for pediatric myopia. Myopia, which typically begins in early childhood, is characterized by an elongation of the eye, resulting in significant vision loss and even blindness if not treated. It is estimated that myopia affects 25 million children in the U.S. alone, with five million of those believed to be at high risk. The Review of Myopia Management states this equates to a \$1.8 billion annual market opportunity in the U.S., with a similar opportunity in China. With myopia, treatment compliance is particularly important to slow disease progression, early indications from use of Eyenovia’s Optecare remote therapeutic monitoring suggest enhanced dosing compliance as compared to historical treatments without such monitoring.

In terms of remaining development steps for MicroPine, Eyenovia is planning to meet with FDA to discuss possible changes to the Phase 3 CHAPERONE clinical trial protocol to expedite development, including a possible interim analysis of data from ~300 patients in late 2024. If positive and statistically significant, Eyenovia plans to meet with FDA again with the goal of submitting an NDA in 2H 2026. If positive but not statistically significant, Eyenovia will continue the trial until the original enrollment target of 420 patients reaches the study endpoint. Under that scenario, the Company would plan to file an NDA in 2H 2027.

Longer term, the Company sees potential applications for the Optejet in glaucoma (annual U.S. market opportunity of \$2.7 billion), acute dry eye (\$236 million), chronic dry eye (\$2.1 billion) and eye hydration.

Eyenovia’s updated investor presentation is also available for download under “Events and Presentations” in the “Investors” section of the Company’s website, www.eyenovia.com.

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

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Eyenovia, Inc. Updated Corporate Presentation, dated January 2024</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: January 31, 2024

/s/ John Gandolfo

John Gandolfo
Chief Financial Officer



January 2024

We Are the Optejet[®] Company

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



EYEN-CO

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 and the potential for approval of APP13007; 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 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 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.



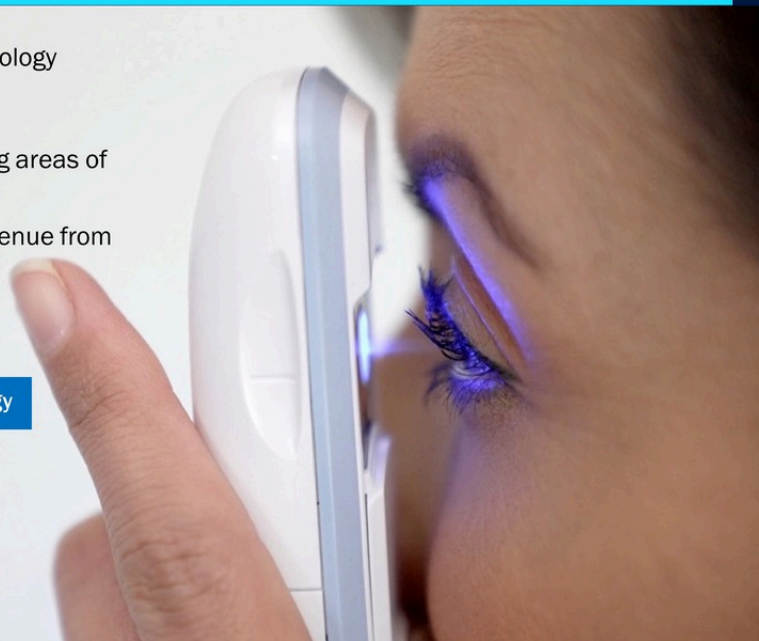
Eyenovia (NASDAQ:EYEN) is the Optejet® Company



- 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-of-use and dosing precision
- Delivers efficacy while improving tolerability and reducing side effects¹
- Digital Optecare™ capabilities²



1. Wirta DL, Walters TR, Flynn WJ, Rath 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
2. Optecare is Eyenovia's suite of digital compliance 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

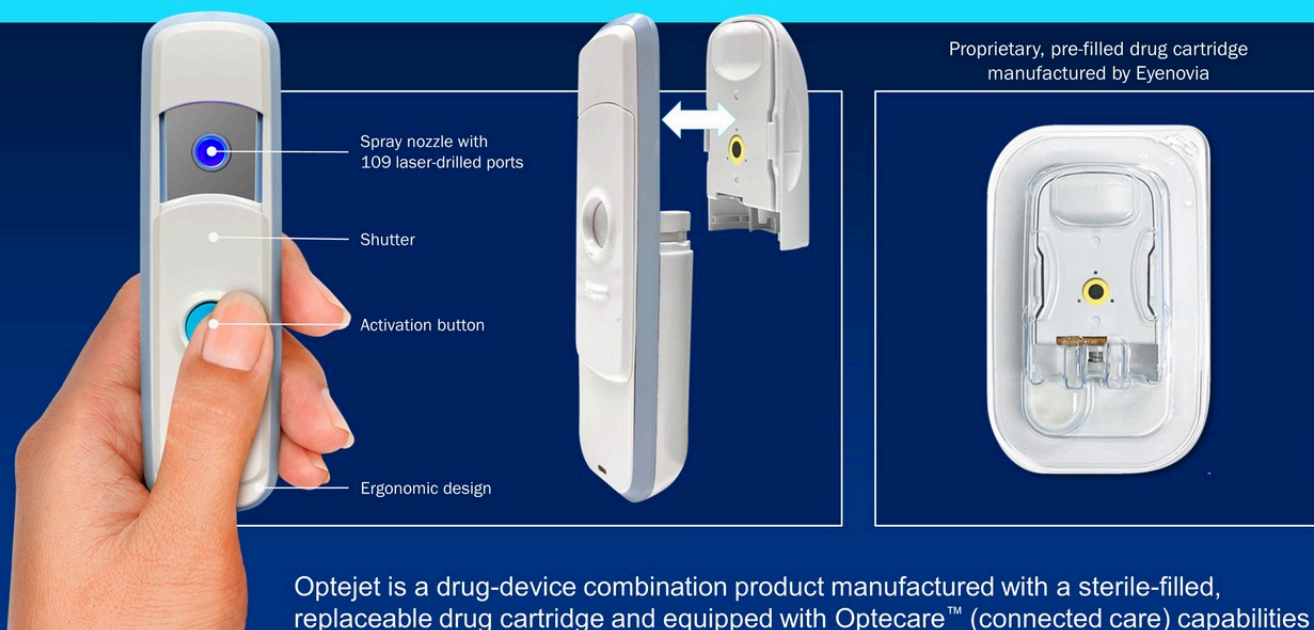
In a recent survey conducted by J. Reckner and Associates, consumers reported that taking eye drops was among the most difficult ways to self-administer medication¹



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 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 ointments. 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

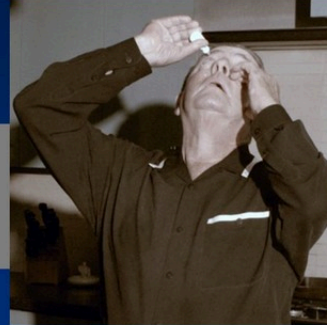
Horizontal delivery, push-button dosing and no protruding tip



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 cross-contamination



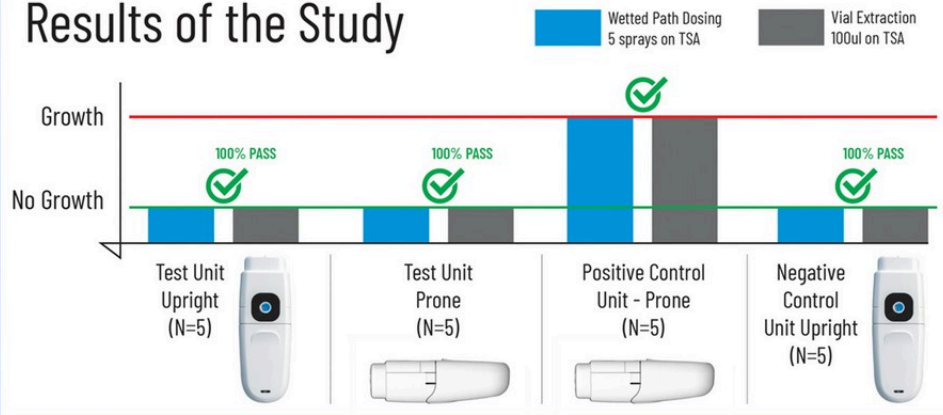
Eye Dropper Bottle administration requires head-tilting, squeezing, and reliance on gravity



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

Laboratory-Proven Cartridge Thoroughly Tested to Demonstrate Sterile Drug Delivery

Results of the Study



RESULTS: Using the 1×10^6 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

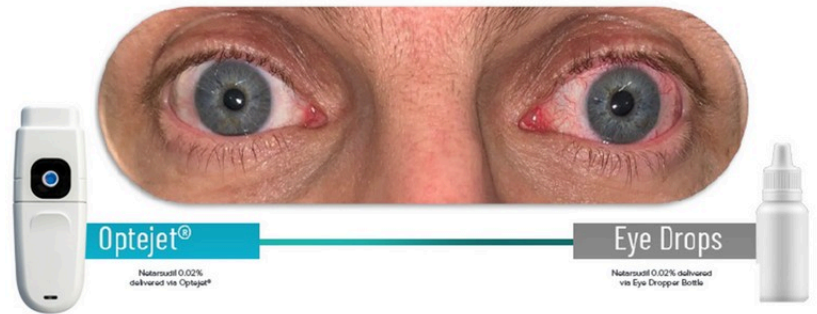
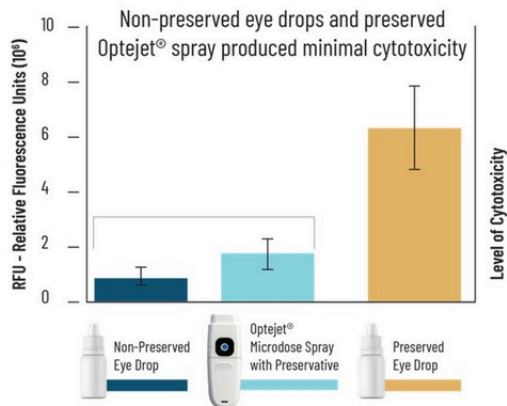
The Optejet Delivers 80% Less Drug Volume Than Eye Droppers

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

Minimizes Excessive Drug Exposure to Ocular Tissues³

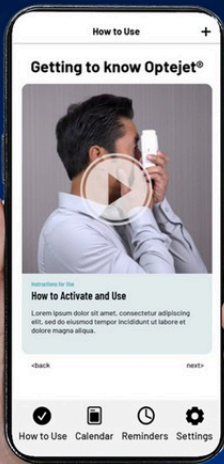


Improves Local Tolerability and Decreases Systemic Exposure⁴



¹ Wirta D. et al, Presentation at 2019 ASCRS meeting | ² Ianchulev 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.

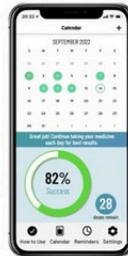
Optejet Digital Technology is Optecare™



The Optejet® is capable of automatically tracking usage



Bluetooth



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 (98980) for monthly check of compliance data

PAYER

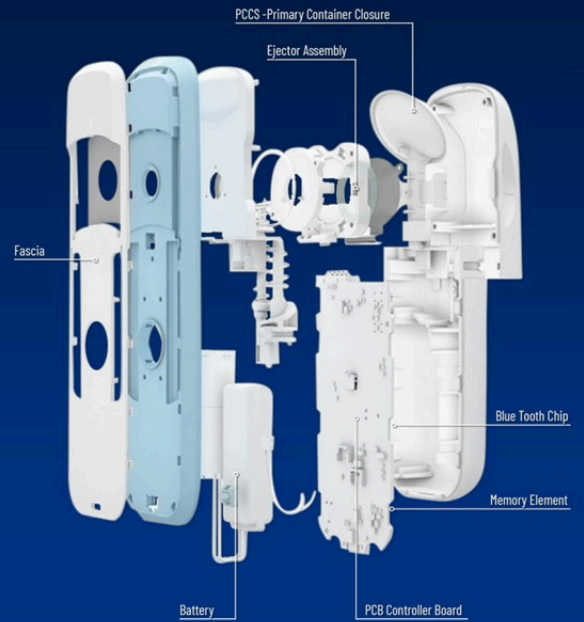
- Cost savings: Less likely to have patient on second medication if compliance is the issue
- Better outcomes: Compliance with drug therapy shown to slow disease progression¹



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



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

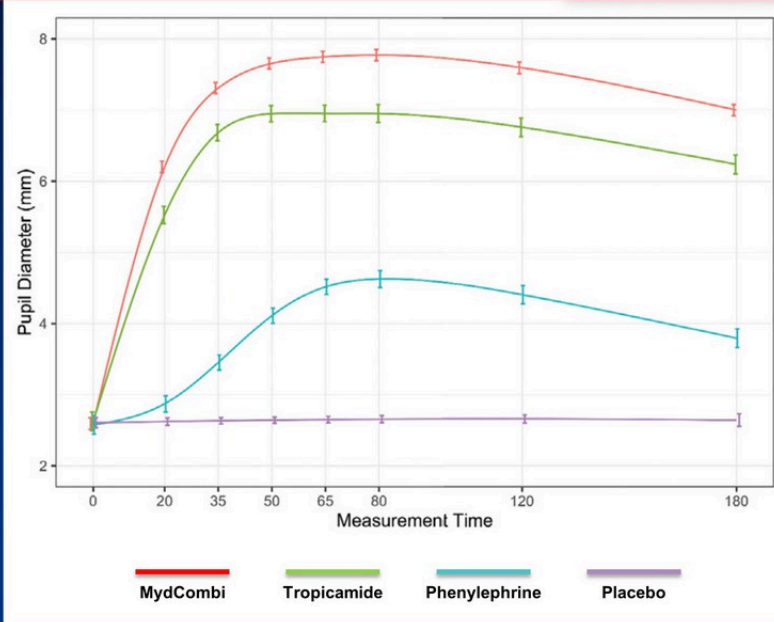


1. \$200M annual sales of pharmaceutical mydriatic products used during 108M office-based exams (\$2 * 100M) + \$50M of single bottle mydriatic agents used cataract replacement surgery (\$12.5 x 4M)

MydCombi™

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™

Speed and simplicity with each spray

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

Online ordering will be available on EyenoviaRx.com

¹Indication: 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 1-833-353-6884 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch) www.mydcombi.com for FULL PRESCRIBING INFORMATION

ernational Airport

T	TIME	DESTINATION	GATE	REMARK
2	10:46	MYDCOMBI	10	ON TIME
15	10:49	TROPICAMIDE	7	DELAYED
13	10:52	PHENYLEPHRINE	4	DELAYED
62	11:02	New York	12	CHECK IN

Take A New Route with MydCombi

An easy way to dilate patients with MydCombi's unique spray administration. Streamlining the dilation process may lead to better patient flow.

MydCombi
tropicamide and phenylephrine HCl
ophthalmic spray 1%/2.5%



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 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's no chance of contamination as MydCombi doesn't touch the patients' eyes."

Krystina Feliciano, Ophthalmic Tech
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, and the effectiveness is similar to eye drops with patients experiencing more comfort when instilled."

Dan Tran, MD
Coastal Vision Medical Group - CA



Late-Stage Development Pipeline

	Product	Indication	Targeted Product Differentiation	United States Addressable Market	Next Milestone
PROPRIETARY	APP13007	Post surgical pain and inflammation	2x day dosing in a market dominated by 4x day dosing	\$700M ¹	PDUFA March 2024
	MicroPine	Pediatric Progressive Myopia	Optejet: Ease of use, less systemic exposure, Optecare™ service	\$1.8B ²	Planned Ph3 Interim Analysis Q4 2024
	Apersure	Presbyopia	Optejet: Ease of use, convenience, low side effect incidence	\$850M ³	\$4 million NDA fee on hold pending improvement in presbyopia market



1. IQVIA Estimates of Ophthalmic Topical Steroid and Steroid Combinations Market 2023
2. Richard Edlow, O. (2020) The Myopia Management Market, Review of Myopia Management. Available at: <https://reviewofmm.com/the-myopia-management-market/>
3. Eyenovia Estimates

APP13007

(Clobetasol Propionate Nanosuspension 0.05%, BID)

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

FDA PDUFA date March 2024

➤ 2024

Post-ocular surgery treatment

- Short and mid-term revenue opportunity (\$700M market)¹
- Synergistic commercialization with MydCombi's sales force



➤ 2027

Dry eye treatment

- Potential acute dry eye product in the Optejet (\$236M market)²



1. IQVIA Estimates of Ophthalmic Topical Steroid and Steroid Combinations Market 2023

2. Eyenovia Estimates chronic dry eye is 90% and acute is 10% of total dry eye market of \$2.36B (North America Dry Eye Syndrome Market – Industry Trends and Forecast to 2030) Data Bridge Market Research. Available at: <https://www.databridgemarketresearch.com/reports/north-america-dry-eye-syndrome-market#:~:text=Data%20Bridge%20Market%20Research%20analyzes,indicates%20that%20the%20market%20value>

Technology Enables APP13007's Compelling Profile

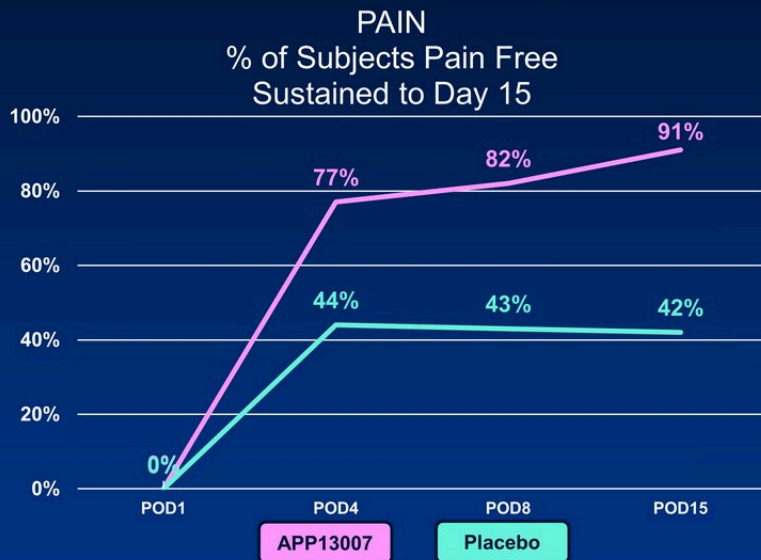
The Post-surgical Pain and Inflammation Market Was Valued at \$200m in 2022

Patented APNT nanolization provides many benefits
in topical ophthalmic drug development*

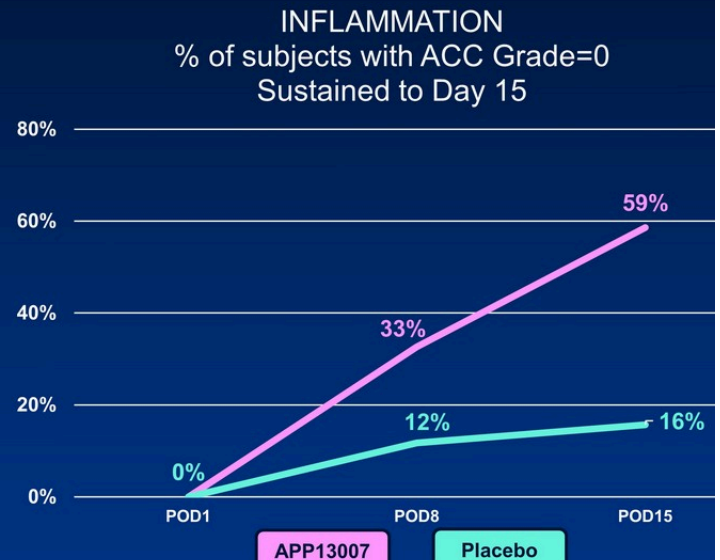


- High uniformity and purity in particle size
- Improved stability
- Improved dispersion properties
- Improved bioavailability

Rapid and Sustained Ocular Pain Relief and Clearance of Inflammation



51% of subjects in the clinical study experienced significant pain, with over half requiring rescue from placebo vs 4% with APP13007.



*Korenfeld ASCRS Presentation 2023 | A Phase 3 Study of APP13007 (Clobetasol Propionate Ophthalmic Nanosuspension 0.05%) to Treat Inflammation and Pain after Cataract Surgery

When it Comes to Post-Surgical Pain and Inflammation Management Efficacy and Twice-a-Day Dosing Matter Most



Preferred posology for post-cataract surgery: Antibiotic, NSAID and steroid once in the morning and evening¹

Post-Surgical Steroid Posology

Dexamethasone	4x daily
Difluprednate	4x daily
Fluometholone	4x daily
Loteprednol	2x-4x daily
Prednisolone	2x-4x daily
APP13007	2x daily

<https://pi.bausch.com/globalassets/pdf/Packagelabels/Pharma/RxGenerics/Dexamethasone-Sodium-Phosphate-A-9100-9100302.pdf> https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022212tbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/016851s063tbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202872tbl.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017011s047tbl.pdf



1. J. Reckner and Associates survey conducted August 2023 with 100 Ophthalmologists performing at least 10 ocular surgeries per week. Respondents were asked to consider the description of the product mentioned with the following description: "There is a new corticosteroid that may be available next year. This new steroid would be dosed twice-daily post-ocular surgery by patients. In clinical trials, it has shown to be very effective in reducing inflammation and pain and well tolerated with a low (<2%) incidence of IOP spikes over a 14-day usage period." What part of this description is most important to you?

In the Clinical Trial CPN-301, Over 99% of Patients in the Treatment Group Experienced No Incidents of Elevated IOP > 21mmHg*

All Adverse Events ≥ 2.0%	APP13007 (N=181)		Placebo (N=197)	
Adverse Events	n (%)	# of Events	n (%)	# of Events
Subjects with ≥ 1 Ocular Adverse Event	29 (16.0%)	33	34 (17.3%)	50
Anterior chamber inflammation	7 (3.9%)	7	3 (1.5%)	3
Corneal oedema	3 (1.7%)	3	10 (5.1%)	10

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 link¹
- Elongation of the eye with morbidity and vision problems²
- Urgent need for FDA-approved drug therapies to slow myopia progression

Progression of Myopic Maculopathy



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 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.

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, Vyluma, 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
- Eyenovia'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 Address Unmet Needs

- **Increased Tolerability**
 - Lower Drug Exposure
- **Ease of Use**
 - Optejet has been used for nearly 5,000 patient months in children
- **Enhanced Compliance**
 - Connected-care allows for monitoring of patient use and discussion with healthcare provider
- **Enhanced Safety**
 - Lower systemic exposure



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

The Pediatric Progressive Myopia Market is Valued at \$1.8B in the US and Similarly in China



SAFE.
EFFECTIVE.
EASY.

Only MicroPine comes
with Optecare™

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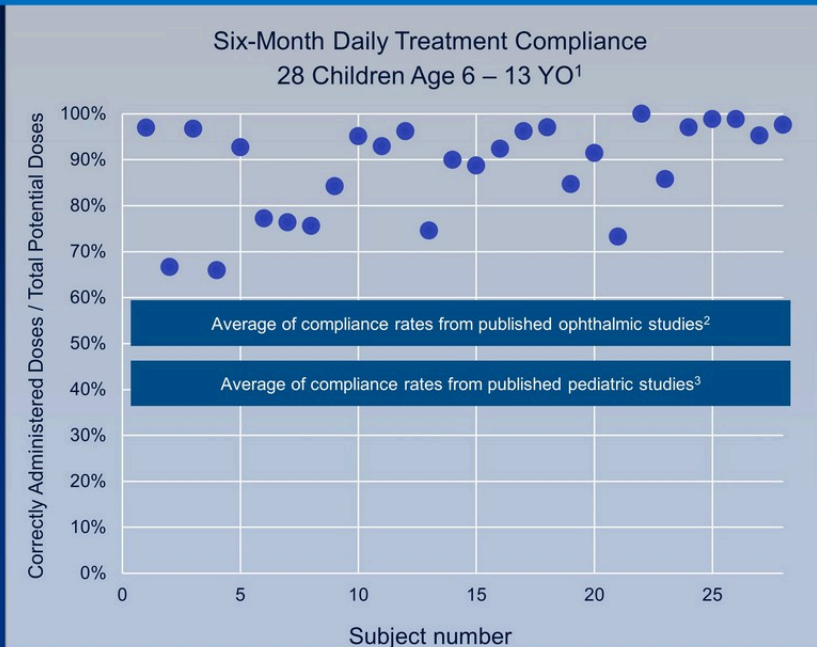
MICROPINE



Currently under investigation, not FDA approved

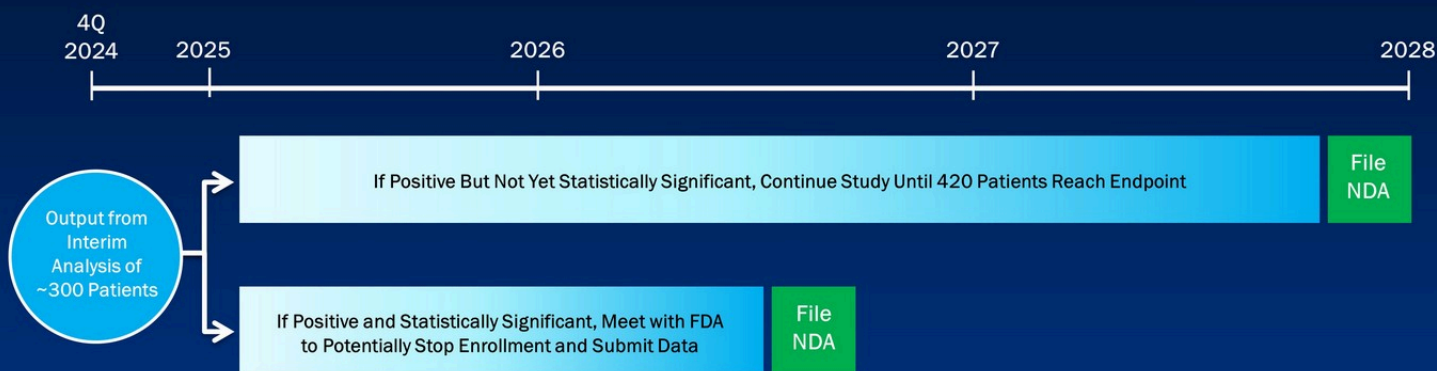
Optecare™ Designed to Improve Treatment Adherence

- 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

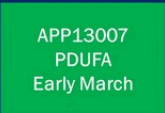


1 Data on file with Eyenovia. 2 Naito 2018: Naito T, Yoshikawa K, Namiguchi K, Mizoue S, Shiraishi A, et al. (2018) Comparison of success rates in eye drop instillation between sitting position and supine position. PLOS ONE 13(9): e0204363. Patel 1995: Patel SC, Spaeth GL. Compliance in patients prescribed eyedrops for glaucoma. Ophthalmic Surg. 1995 May-Jun;26(3):233-6. Winfield, 1990: Winfield AJ, Jessiman D, Williams A, Esakowitz L. A study of the causes 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 Feb;44(1):1-14.

MicroPine Planned Development Timeline



Eyenovia: 2024 Key Events



Additional Large-Market Opportunities

	Target Market	Targeted Product Differentiation	United States Addressable Market
POTENTIAL	Glaucoma	Optejet: Optecare™ service, Ease of use, Low side effect incidence	\$2.7B ¹
	Acute Dry Eye	Optejet: New drug class, Ease of use, Fast onset	\$236M ²
	Chronic Dry Eye	Optejet: New MOA, Ease of use, Fast onset	\$2.1B ²
	Eye Hydration	Optejet Device Registration	



1. Estimates from IQVIA Sales Data | 2. Eyenovia Estimates chronic dry eye is 90% and acute is 10% of total dry eye market of \$2.36B (North America Dry Eye Syndrome Market – Industry Trends and Forecast to 2030) Data Bridge Market Research.
Available at: <https://www.databridgemarketresearch.com/reports/north-america-dry-eye-syndrome-market#:~:text=Data%20Bridge%20Market%20Research%20analyzes,indicates%20that%20the%20market%20value.>

Financial Snapshot (September 2023)

Nasdaq: EYEN

Common Shares Outstanding	42.9M
Equity Grants Outstanding Under Stock Plans	5.3M
Warrants	13.2M
Fully Diluted Shares	61.4M
Cash	\$20.7M
Debt	\$14.1M

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

