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): September 19, 2023

EYENOVIA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware (State or other jurisdiction of incorporation)

001-38365 (Commission File Number)

47-1178401 (IRS Employer Identification No.)

295 Madison Avenue, Suite 2400, New York, NY 10017 (Address of Principal Executive Offices, and Zip Code)

(833) 393-6684 Registrant's Telephone Number, Including Area Code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

□ Pre-commencement communications pursuant to Rule 142-120 under the Exchange Act (17 CFR 240.144-2(b)) □ Pre-commencement communications pursuant to Rule 142-120 under the Exchange Act (17 CFR 240.144-2(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
		(Nasdag 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 \boxtimes

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 September 19, 2023, 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

<u>Exhibit</u> No.	Description
<u>99.1</u>	Evenovia, Inc. Updated Corporate Presentation, dated September 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

EYENOVIA, INC.

Date: September 20, 2023

/s/ John Gandolfo John Gandolfo Chief Financial Officer



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September 2023

Forward-looking Statements

Except for historical information, all the statements, expectations and assumptions contained in this presentation are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our product candidates and platform technology. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements due to numerous factors discussed from time to time in documents which we file with the U.S. Securities and Exchange Commission.

In addition, such statements could be affected by risks and uncertainties related to, among other things: risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment, timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential advantages of our product candidates and platform technology 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 ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; intellectual property risks; changes in legal, regulatory, legislative and geopolitical environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and our competitive position.

Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.

Eyenovia at a Glance

Eyenovia (NASDAQ | EYEN) is a US based medical device and ocular therapeutics company



Today's Eyedropper Bottle Designed for manufacturing ease, not patient ease

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







1800's Glass Pipette 1900's Glass Pipette with Bulb and Separate Vial

Today Integrated Bottle with Dropper Tip

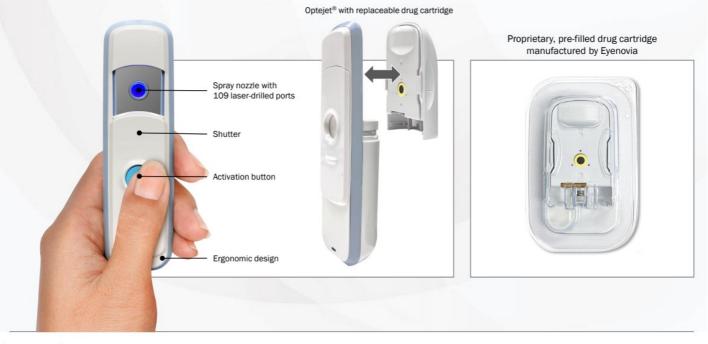
In a recent survey conducted by J. Reckner and Associates, consumers reported that taking eye drops was among the most difficult ways to self-administer medication¹

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1. Survey conducted in January 2023 with 100 people (19 - 65+ Age Range, Mean Age = 51YO) who regularly take eye drop medications. Respondents were asked to rank common drug forms from easiest to 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 beinds 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 is a drug-device combination product manufactured with a sterile-filled, replaceable drug cartridge



Ergonomic Design to Improve Usability Horizontal delivery, push button dosing and no protruding tip



Eye Dropper Bottle tips can touch the eye surface



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

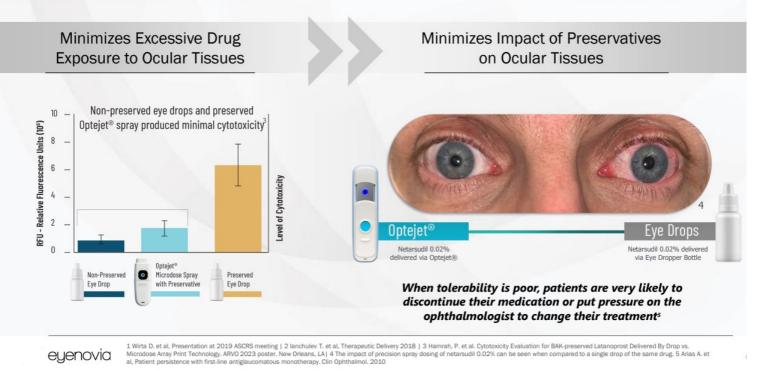


Eye Dropper Bottle administration requires head-tilting, squeezing, and reliance on gravity

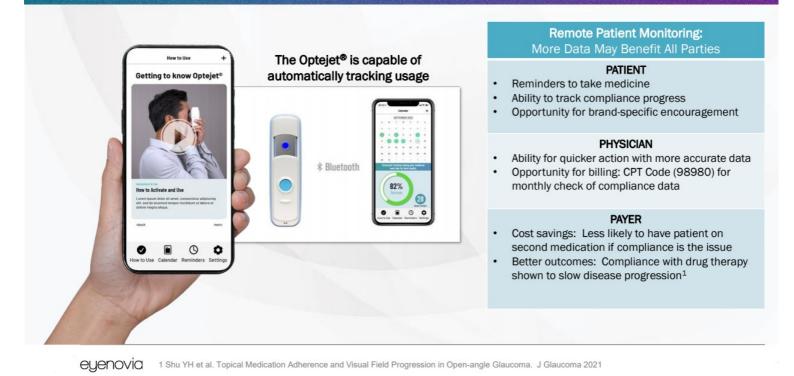


Optejet administration can be done horizontally with the push of a button

Minimal Sufficient Dosing May Improve Therapeutic Index With 80% less dose volume, reduces excessive exposure to both drugs and preservatives ¹²



Optejet Digital Technology to Improve Delivery of Care



Product Pipeline

US and China Markets

	Target Market	Optejet Targeted Differentiation	United States Addressable Population	United States Market \$USD*	China Addressable Population	US Status	Licensee
٣	Pupil dilation (Mydriasis)	Ease of use, well tolerated, less systemic absorption, fast recovery time	Procedures: 108M ¹	\$250M	650M ⁸	MydCombi Datase of Prices Eyenovia Commercializing	USA eyenovia China Oarctic Vision
PROPRIETARY	Ocular Surgery Pain and Inflammation	Eyedrop: 2X day dosing, low AE incidence ¹⁰	Procedures: 7M ²	\$200M	N/A	PDUFA March 2024	USA eyenovia
4	Alternative to glasses for early presbyopia	Ease of use, convenience, low side effect incidence	7M ³	\$1B	12M ⁹	Manufacturing registration batches 1Q 2024	USA eyenovia China o arctic Vision
	Eye Hydration	High technology delivery system	117M ⁴	\$3.1B	N/A	FDA device registration discussions	USA _{eyenovic}
PARTNERED	Treatment of childhood progressive Myopia	Ease of use, digital monitoring technology, pediatrics self-dosing	3M ⁵	\$4.5B	50M ⁹⁴	USA Ph3 study enrollment may be completed in 2024	USA BAUSCH+LOMB China Orctic
POTENTIAL		Digital monitoring technology, ease of use, low side effect incidence	3M ⁶	\$3B	20M ⁹	Biocompatibility testing of potential partner's drug product	
TEN	Dry Eye	New drug class, ease of use, fast onset	31M ⁷	\$3.6B	235M ⁹	Pre-IND meeting planned 2H 2023; exploring partnership options	

MydCombi[™] For pupil dilation and mydriasis



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

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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)



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

Reliable time to peak efficacy and dilation resolution

In clinical studies 97% of patients reported zero side effects¹

To check on availability in your area, please go to MydCombi.com



Indication: HYDCOHBI (tropicamide 1% and phenylephrine HCI 2.5%) ophthalmic spray is indicated to induce mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired. HPORTANT SAFETY INFORMATION. CONTRAINDICATIONS: FOR INFORMATION CONTRAINDICATIONS: FOR INFORMATION. Attropic and behavioral disturbances in blod pressure have been reported. Caution in patients with elevated blood pressure. Rebound miceis has been reported one day atter installation. Renove contact lenses before using. DRUG INTERACTIONS. Attropine-like Drugs: May exaggerate the adrenergic pressor response. Cholinergic Agoints and Dynthalmic Cholinesterase inhibitors. May interfere with the antihypertensive action of carbachol, pilocarpine, or pophralmic cholinesterase inhibitors. Potent Inhalation Ansthetic Agents. May potentiate cardiovascular depressant effects of some inhalation anesthetic agents. ADVERSE REACTIONS, Not common ocular adversere rectains include transities agents. Adversere actions include transities adversere actions include transities adversere actions include transities adversere actions include tr

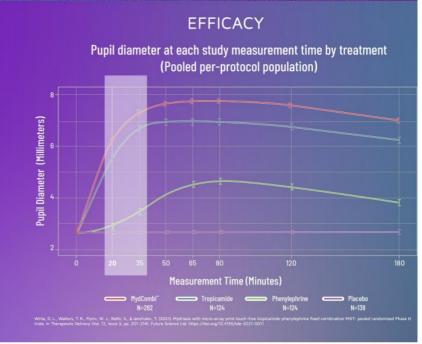


1. Wirta DL, Walters TR, Flynn WJ, Rathi S, lanchulev T. Mydriasis with micro-array print touch-free tropicamide-phenylephrine fixed combination MIST: pooled randomized Phase III trials. Ther Deliv. 2021 Mar;12(3):201-214.

MydCombi Product Overview 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 early as 20 minutes.



AP13007 is Formosa's APNT[™] formulation of clobetasol propionate ophthalmic nanosuspension

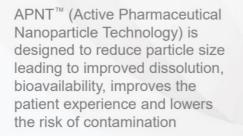
Active

Ingredient

Pharmaceutical

Salt or Sugar

APNT Nanolization





- CPN-301, A Multicenter, Randomized, Double-Masked, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of APP13007 for the Treatment of Inflammation and Pain after Cataract Surgery
- 395 subjects of which 180 on active, 197 on placebo completed the study
 - Mean age 68 YO
 - ~40% male, ~ 60% female
 - Multiple races/ethnicity represented
- 107 subjects (100 on placebo, 7 on active) rescued during the 14-day study for insufficient pain or inflammation control

PRIMARY EFFICACY ENDPOINTS

APP13007 was statistically and clinically significantly superior to placebo (p<0.001) for both primary efficacy endpoints:

- Proportion of subjects with anterior chamber cell (ACC) count = 0 (ACC Grade=0) at POD8 maintained through POD15
- Proportion of subjects with Ocular Pain Grade = 0 at POD4 maintained through POD15

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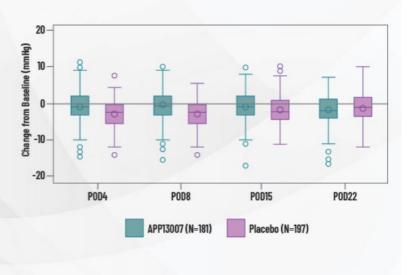
1. Korenfeld M, Walters T, Martel J, Nunez D, Wang L. A Phase 3 Study of APP13007 (Clobetasol Propionate Ophthalmic Nanosuspensio 0.05%) to Treat Inflammation and Pain after Cataract Surgery. ASCRS presentation. San Diego. May 5-8 2023

APP13007 Results from the first of two completed phase 3 studies ¹

- Adverse events occurred in 21% of active and 20% of placebo subjects
 - There was one serious adverse event in the placebo arm
- Adverse events occurring in the study eye in 2% of subjects or more:
 - Anterior chamber inflammation (4% in active, 2% in placebo)
 - Corneal oedema (2% in active, 5% in placebo)
 - Eye pain (2% in placebo)
- There was one report of IOP elevation (21mmHg or greater and CFB of 10mmHg) in the active group
 - IOP change from baseline was not significantly different between the two groups at any study visit



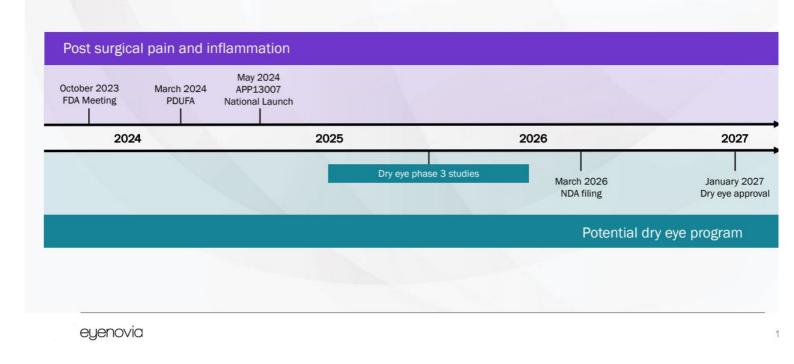
1. Data on File, Formosa Pharmaceuticals



FDA PDUFA date in March 2024 for the Treatment of Inflammation and Pain after Cataract Surgery



AP13007 A potential for multiple indications



Apersure[™] for Presbyopia

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

- Vision-1¹ and Vision-2² clinical studies
 - − 6.0x more patients achieved \ge 3-line gain on a vision chart in the active group vs. placebo^{3,5}
 - Well-tolerated with fewer than 2% of patients reporting moderate hyperemia⁴, instillation discomfort, or brow ache
- People prefer Apersure over eyedrops
 - Among 100 presbyopic patients aged 40-55, 80% said they would prefer Apersure over the traditional eyedrop bottle⁵
 - Price sensitivity tests indicate approximately \$100 for 80 doses would be well accepted



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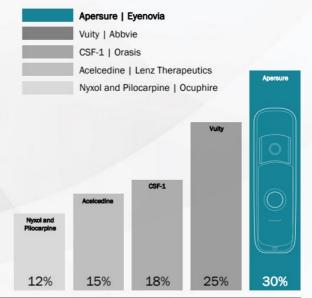
1. https://clinicaltrials.gov/ct2/show/NCT04657172 | 2. https://clinicaltrials.gov/ct2/show/NCT05114486 3. Cohort of subjects with baseline DCNVA < 0.6 logMAR | 4. Resolved by 3-hours post dose | 5. Data on file

Apersure[™] is the invisible second pair of glasses

- Existing and future presbyopia eye drops do not fit with the business model of optometrists who use eye glass frames as a revenue source for their practice
- With Apersure, optometrists can sell this Optejet based product alongside glasses as an additional benefit for their patients
 - Easy and neat application
 - · Discreet on-demand dosing that lasts for 4 hours
- In a market research survey consisting of 100 Optometrists across the US, Apersure was predicted to have the largest market share of approved and potential products

1. VISION-1 & 2 Studies, data on file, 2, 3. Survey conducted in May 2022 by

Market Share of Products Predicted by Optometrists



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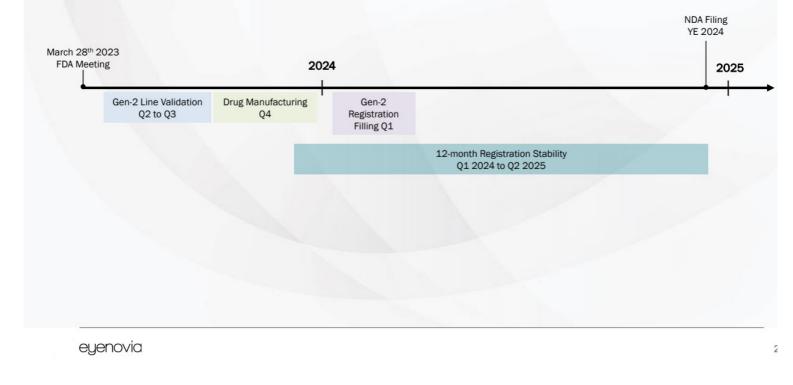
1





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





MicroPine for Delaying Progression of Myopia in Children

- Begins in early childhood, with genetic link¹ .
- · Elongation of sclera/retina with morbidity and vision problems²
- Urgent need for FDA-approved drug ٠ therapies to slow myopia progression
- Atropine may slow myopia progression • by at least 60%³



Progression of Myopic Maculopathy

Normal Macula

Myopic Maculopath

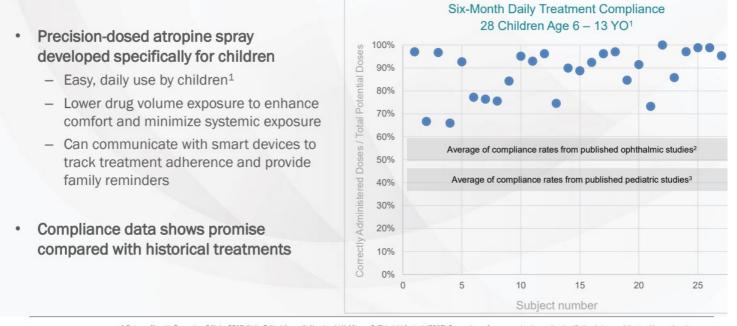
Affects ~25M children in the US alone, with ~5M considered to have high myopia risk

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ities, and future myopia. Invest Ophthalmol Vis Sci. 2007 Aug;48(8):3524-32.

¹ Jones LA, Sinnott LT, Mutti DO, Mitchell GL, Moeschberger ML, Zadnik K. Parental history of myopia, sports and outdoor activities, ² Eye and Contact Lens. 2004; 30 ³ Ohia 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% ⁴ Theophanous C. Myopia Prevalence and Risk Factors in Children. Clinical Ophthalmology. December 2018. U.S. Census Bureau, (es (Atropine for the Treatment of Myopia 2). Ophthalmology 2012;119:347-354 nt Population Survey, Annual Social and Economic Supplement, 2019.

MicroPine for Delaying Progression of Myopia in Children



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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, J, Jessiman D, Williams A, Esakovitz 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.

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



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

2

BAUSCH+LOMB

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

Licenses – MicroPine licensed for the US and Canada

O arctic VISION

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

Licenses – MicroPine, MicroLine and MydCom licensed for Greater China and South Korea; clinical study enrollment underway

License agreements with a total value of over \$90M in potential payments + royalties Ongoing discussions with multiple partners in glaucoma and dry eye

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2

Broad Intellectual Property Portfolio



Financial Snapshot (June 2023)*

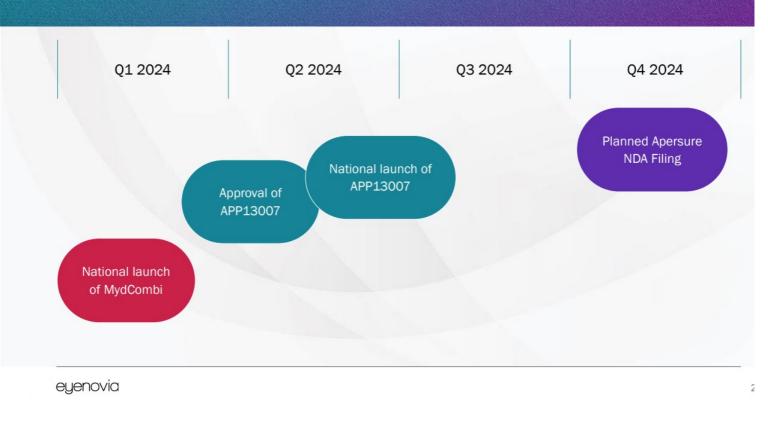
Common Shares Outstanding	38.2M
Equity Grants Outstanding Under Stock Plans	5.3M
Warrants	6.1M
Fully Diluted Shares	49.6M
Cash	\$17.5M
Debt	\$15.8M

2

Experienced Leadership Team



Upcoming Potential Milestones



Investment Summary

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