
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): November 10, 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 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 ☒ x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 13, 2023, Eyenovia, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended September 30, 2023. A copy of the press release 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 2.02, 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 2.02, 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On November 10, 2023, the Board of Directors (the “Board”) of the Company appointed Michael Geltzeiler to serve on the Board and as the Chair of the Audit Committee of the Board (the “Audit Committee”), in each case, effective November 14, 2023. Mr. Geltzeiler will serve as a director until the Company’s 2024 annual meeting of stockholders and thereafter until his successor has been elected and qualified or until his earlier death, resignation or removal.

There is no arrangement or understanding between Mr. Geltzeiler and any other person pursuant to which he was selected as a director of the Company. There are no related party transactions with regard to Mr. Geltzeiler that are reportable under Item 404(a) of Regulation S-K.

In accordance with the Company’s Non-Employee Director Compensation Policy (the “Policy”), Mr. Geltzeiler will receive an initial equity award valued at \$49,534 issued half in options (with an exercise price equal to the closing price of the Company’s common stock on November 14, 2023, valued under the Black-Scholes model), and half in restricted stock units (“RSUs”). The options and RSUs will each vest in full on the date of the Company’s 2024 annual meeting of stockholders; provided, however, that the settlement of the RSUs will be deferred until Mr. Geltzeiler ceases to be a director. Mr. Geltzeiler will also be entitled to (1) annual cash retainers of \$40,000 for service on the Board and \$20,000 for service as the Chair of the Audit Committee, in each case, paid quarterly and prorated to reflect Mr. Geltzeiler’s tenure; and (2) indemnification pursuant to the standard indemnification agreement between the Company and each of its directors.

Item 7.01. Regulation FD Disclosure.

On November 13, 2023, the Company began using an updated corporate presentation with various investors and analysts. A copy of the presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 7.01, including Exhibit 99.2, 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 99.2, 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>Press Release, dated November 13, 2023.</u>
<u>99.2</u>	<u>Eyenovia, Inc. Updated Investor Presentation, dated November 2023.</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

EYENOVIA, INC.

Date: November 13, 2023

/s/ John Gandolfo

John Gandolfo

Chief Financial Officer



Eyenovia Reports Third Quarter 2023 Financial Results and Provides Business Update

Acquired U.S. commercial rights to APP13007, currently under FDA review for post-surgical ocular pain and inflammation, from Formosa Pharmaceuticals

Announced FDA approval of Coastline International as contract manufacturer for Mydcombi cartridge subassemblies and preparations for national launch

Company to host conference call and webcast today, November 13th, at 4:30 pm ET

NEW YORK—November 13, 2023—Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage, topical ophthalmic company leveraging its Optejet® dispensing technology for both internally developed and acquired programs as well as out-licensing for additional indications, today announced its financial and operating results for the third quarter ended September 30, 2023.

Third Quarter 2023 and Recent Business Developments

- Acquired the U.S. commercial rights to APP13007 for post-surgical ocular pain and inflammation from Formosa Pharmaceuticals. If approved, APP13007 would complement Eyenovia's commercially approved mydriasis product, Mydcombi, and allow for the generation of additional near-term revenue. A New Drug Application (NDA) for APP13007 is currently under review by the FDA, which has assigned a PDUFA action date of March 4, 2024.
 - Announced the appointment of senior finance executive Mr. Michael Geltzeiler to Eyenovia's Board as an independent director and Chair of the Audit Committee.
 - Announced FDA approval of Coastline International as contract manufacturer for Mydcombi cartridge subassemblies, enabling a national launch in early 2024.
 - Initiated training of ophthalmic technicians in the use of Mydcombi through sponsorship of a course at the International Joint Commission on Allied Health Personnel in Ophthalmology (IJCAHPO) 51st Annual Continuing Education (ACE) program.
 - Advanced its Gen-2 Optejet device and anticipates shipping to MicroPine partners Bausch and Lomb and Arctic Vision by year-end 2023.
 - Continued to validate its manufacturing facilities in Redwood City, CA and Reno, NV, the former having a PDUFA date in February 2024 for use as a commercial facility.
 - Presented data from a study of the preservative-free microbial integrity of the Optejet® at the American Academy of Optometry's "Academy 2023 New Orleans" Annual Meeting in October. The study successfully demonstrated the Optejet's ability to maintain product sterility even when exposed to a microbial load that exceeds typical environmental conditions.
-



Michael Rowe, Chief Executive Officer, commented, "During the third quarter, we expanded our near-term commercial product portfolio with our acquisition of the commercial rights to APP13007 from Formosa Pharmaceuticals. This unique, twice-a-day steroid will compete against products that are typically used four times a day, with a desirable efficacy and safety profile. Together with Mydcombi, we expect the two products to increase the capability of our planned ten-person sales force to generate near-term revenue for our company which in turn will help fund the completion of our internal development programs. APP13007 has the additional benefit of potential use in the Optejet for the treatment of dry eye disease, and after recent positive discussions with the FDA, we are evaluating the timing and value of this potential program.

"We were also pleased to announce recently that Coastline International was approved by the FDA as a contract manufacturer for certain elements of Mydcombi in the Optejet. With Coastline, we expect to initiate manufacturing imminently in preparation for a broader launch in early 2024.

"We have made the strategic decision to prioritize our current Gen-2 Optejet manufacturing capabilities to ensure that our partners, Bausch and Lomb and Arctic Vision, have this advanced product for their pediatric myopia studies by the end of this year. This will shift the manufacture of registration batches of our pre-NDA presbyopia candidate, Apersure, to the first quarter of 2024. We see no downside to this change as the nascent presbyopia market continues to evolve and mature, as evidenced by the disappointing performance of the only available eye drop product for this indication. As new entrants come into the presbyopia market and revitalize it, we look forward to introducing Apersure in the highly differentiated and desirable Optejet dispenser.

"We are also excited to announce today the appointment of Mr. Michael Geltzeiler to our Board as an independent director and Chair of our Audit Committee. Mike has a strong track record of successful value creation for shareholders, including over 17 years of CFO experience at companies including ADT Corporation, Euronext and Readers Digest. We are fortunate to have Mike with his extensive finance background join us at this time, and I know that he is as excited as I am about the potential that Eyenovia represents.

"With three distinct sources of potential growth – internally developed programs, complementary product acquisitions that can be further developed in the Optejet, and strategic partnerships that license the Optejet for additional indications – I believe we have firmly established ourselves as a leader in topical ophthalmic medication delivery, and I am excited about the many opportunities that are in front of us," Mr. Rowe concluded.

Third Quarter 2023 Financial Review

For the third quarter of 2023, net loss was approximately \$(7.3) million, or \$(0.18) per share compared to a net loss of approximately \$(7.3) million, or \$(0.21) per share, for the third quarter of 2022.



Research and development expenses totaled approximately \$3.6 million for the third quarter of 2023 as compared to \$3.9 million for the third quarter of 2022.

For the third quarter of 2023, general and administrative expenses were approximately \$2.9 million, compared to \$3.4 million for the third quarter of 2022.

Total operating expenses for the third quarter of 2023 were approximately \$6.5 million compared to \$7.2 million for the third quarter of 2022.

As of September 30, 2023, the Company's cash and cash equivalents were approximately \$20.7 million compared to \$22.9 million as of December 31, 2022.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, November 13th. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international), and reference conference ID 13741898.

To access the Call me™ feature, which avoids having to wait for an operator, click [here](#).

A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.eyenovia.com. After the live webcast, the event will be archived on Eyenovia's website for one year.

IMPORTANT SAFETY INFORMATION for MYDCOMBI™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

INDICATIONS

MYDCOMBI is indicated to induce mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired

CONTRAINDICATIONS: In patients with 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 1-833-393-6684 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch)

Please go to www.mydcombi.com for **FULL PRESCRIBING INFORMATION**

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its Optejet platform. Eyenovia is currently focused on the commercialization of Mydcombi (tropicamide+phenylephrine ophthalmic spray) for mydriasis.

In addition to commercializing Mydcombi, in August 2023, Eyenovia acquired the U.S. commercial rights to APP13007 (clobetasol propionate ophthalmic nanosuspension, 0.05%) from Formosa Pharmaceuticals. APP13007, which is currently under review by the FDA, is a potent steroid being developed to reduce pain and inflammation following ocular surgery. The agency has assigned a Prescription Drug User Fee Act (PDUFA) action date for APP13007 of March 4, 2024.

Eyenovia is also advancing late-stage development of medications in the Optejet device for presbyopia and myopia progression (partnered with Bausch+Lomb in the U.S. and Canada and Arctic Vision in China and South Korea).

For more information, visit www.eyenovia.com.

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



Forward-Looking Statements

Except for historical information, all of the statements, expectations and assumptions contained in this press release are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions, including estimated market opportunities for our products, product candidates and platform technology. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may, and in some cases are likely to, differ materially from what is expressed or forecasted in the forward-looking statements. 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 impacts of any disruptions on our supply chain, including the availability of sufficient components and materials used in our products and product candidates; the potential advantages of our products, product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our products and product candidates; our estimates regarding the potential market opportunity for our products and product candidates; reliance on third parties to develop and commercialize our products and product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our products and product candidates; the risk of defects in, or returns of, our products; intellectual property risks; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; our competitive position; and other risks described from time to time in the “Risk Factors” section of our filings with the U.S. Securities and Exchange Commission, including those described in our Annual Report on Form 10-K as well as our Quarterly Reports on Form 10-Q, and supplemented from time to time by our Current Reports on Form 8-K. 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 Contact:

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Eyenovia Media Contact:

Eyenovia, Inc.
Norbert Lowe
Vice President, Commercial Operations
nlowe@eyenovia.com



EYENOVIA, INC.
Condensed Balance Sheets

	September 30, 2023 (unaudited)	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	\$ 20,702,212	\$ 22,863,520
Inventories	50,296	-
Deferred clinical supply costs	3,622,687	2,284,931
License fee and expense reimbursements receivable	397,014	1,183,786
Security deposits, current	-	119,550
Prepaid expenses and other current assets	1,760,824	1,190,719
Total Current Assets	26,533,033	27,642,506
Property and equipment, net	3,531,365	1,295,115
Security deposits, non-current	198,674	80,874
Intangible assets	2,122,945	-
Operating lease right-of-use asset	1,792,667	1,291,592
Equipment deposits	686,753	726,326
Total Assets	\$ 34,865,437	\$ 31,036,413
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,426,028	\$ 1,428,283
Accrued compensation	1,375,832	1,747,191
Accrued expenses and other current liabilities	295,703	503,076
Operating lease liabilities - current portion	444,616	484,882
Notes payable - current portion, net of debt discount of \$327,217 and \$33,885 as of September 30, 2023 and December 31, 2022, respectively	3,006,116	174,448
Convertible notes payable - current portion, net of debt discount of \$0 and \$33,885 as of September 30, 2023 and December 31, 2022, respectively	-	174,448
Total Current Liabilities	6,548,295	4,512,328
Operating lease liabilities - non-current portion	1,441,081	907,644
Notes payable - non-current portion, net of debt discount of \$754,919 and \$813,229 as of September 30, 2023 and December 31, 2022, respectively	6,549,248	4,190,938
Convertible notes payable - non-current portion, net of debt discount of \$452,920 and \$813,229 as of September 30, 2023 and December 31, 2022, respectively	4,547,080	4,190,938
Total Liabilities	19,085,704	13,801,848
Stockholders' Equity:		
Preferred stock, \$0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 42,898,246 and 36,668,980 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	4,290	3,667
Additional paid-in capital	153,299,865	135,461,361
Accumulated deficit	(137,524,422)	(118,230,463)
Total Stockholders' Equity	15,779,733	17,234,565
Total Liabilities and Stockholders' Equity	\$ 34,865,437	\$ 31,036,413



EYENOVIA, INC.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating Income				
Revenue	\$ 1,198	\$ -	\$ 1,198	\$ -
Cost of revenue	(1,198)	-	(1,198)	-
Gross Profit	-	-	-	-
Operating Expenses:				
Research and development	3,578,113	3,876,876	8,911,124	11,176,326
General and administrative	2,942,073	3,353,352	9,028,768	10,362,907
Total Operating Expenses	6,520,186	7,230,228	17,939,892	21,539,233
Loss From Operations	(6,520,186)	(7,230,228)	(17,939,892)	(21,539,233)
Other Income (Expense):				
Other income (expense), net	(348,226)	70,277	(157,783)	96,580
Interest expense	(679,222)	(177,138)	(1,691,228)	(475,811)
Interest income	208,901	28,093	494,944	30,703
Total Other Income (Expense)	(818,547)	(78,768)	(1,354,067)	(348,528)
Net Loss	<u>\$ (7,338,733)</u>	<u>\$ (7,308,996)</u>	<u>\$ (19,293,959)</u>	<u>\$ (21,887,761)</u>
Net Loss Per Share - Basic and Diluted	<u>\$ (0.18)</u>	<u>\$ (0.21)</u>	<u>\$ (0.50)</u>	<u>\$ (0.67)</u>
Shares Outstanding				
- Basic and Diluted	<u>40,139,697</u>	<u>34,631,774</u>	<u>38,563,074</u>	<u>32,778,551</u>



November 2023

FOCUS: INCREASING VALUE NOW AND IN THE FUTURE



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 at a Glance

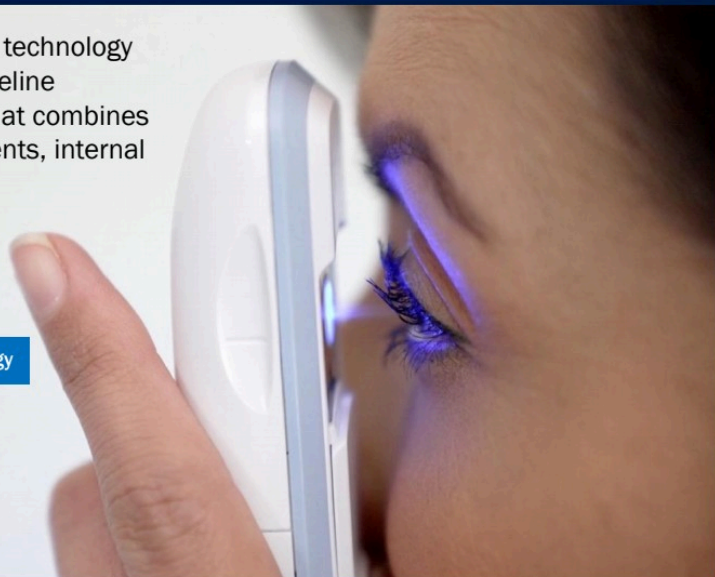
Eyenovia (NASDAQ | EYEN) is a US based medical device and ocular therapeutics company



- Patented digital device platform technology
- Exciting and diverse product pipeline
- Multi-faceted business model that combines partnerships, licensing agreements, internal product development and sales

Optejet® with microdose array print technology

- Horizontal delivery
- Precision dose
- Digital compliance capabilities



Today's Eyedropper Bottle

Designed for manufacturing ease, not patient ease

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



1800's
Glass Pipette



1900's
Glass Pipette with Bulb
and Separate Vial



Today
Integrated Bottle with Dropper Tip

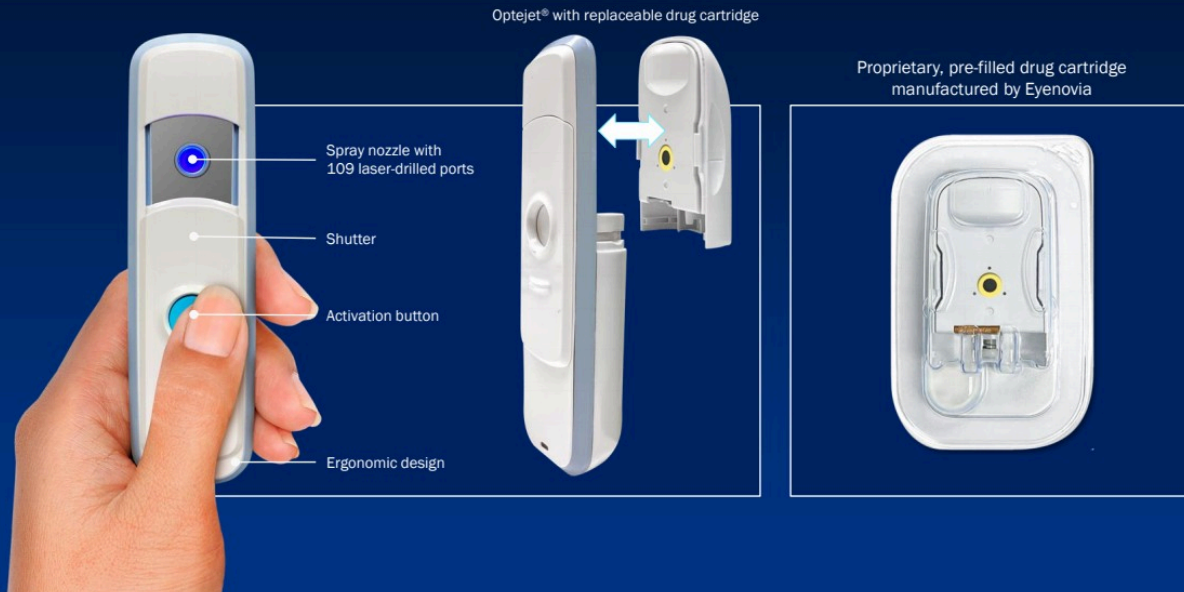
In a recent survey conducted by J. Reckner and Associates, consumers reported that taking eye drops was among the most difficult ways to self-administer medication¹



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

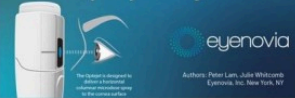


MydCombi Utilizes the Optejet® Technology



The Optejet® Cartridge Has Been Through Extensive Sterility Testing

Demonstration of Microbial Integrity for a Multi-Dose Ophthalmic Spray Drug Device



Authors: Peter Lam, Julie Whitcomb
Eyenovia, Inc., New York, NY

Introduction

Multidose eyedropper bottles have a higher risk for contamination with frequent use, especially when users have poor techniques like touching the tip with their fingers or touching the ocular surface of the eye. Surfactant preservatives added to these multidose eye drops help maintain the sterility after opening the cap. Preservatives can cause ocular irritation, punctate keratitis, toxicity to the corneal epithelial cells, and allergic reactions^{1,2,3}. The Optejet[®] is a novel ophthalmic dispenser designed to prevent bacterial penetration into the vial containing the ophthalmic medications.

Problem

Bacterial ingress in multidose eyedropper bottles

To fingertip touching the mouth of the vial significantly increases the risk of contaminating the contents of the vial⁴. Non-sterile containers are at risk of contamination in a daily point-of-use use setting, especially in patients with a poor administration technique, which is associated with adverse eye⁵.

Solution

Optejet is designed to prevent bacterial ingress



Seals within the vial are enough to prevent external bacterial touch. The Optejet device is designed to prevent bacterial ingress by creating a barrier between the external environment and the internal fluid path.

References

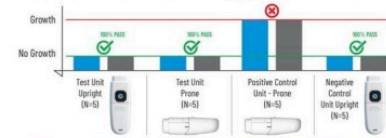
Objective of the Study

Evaluate the effectiveness of the Optejet[®] to prevent microbial ingress for multi-dose usage of topical ophthalmic medications.

Methodology

- 20 Test units were filled with Tryptic Soy Broth (TSB)
- Devices were exposed to high concentration of spore micro-organisms in a chamber
- Test units were tested for microbial growth
- Positive and Negative Control Unit Test Samples

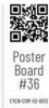
Results of the Study



The test sample, positive, and negative control sample results for the microbial aerosol challenge study using the ISO microbial challenge protocol met the passing criteria: all positive controls showed growth, all negative control did not show growth, and all test units did not show growth as indicated by the testing results for the 28-day simulated use.

Discussion

- Ingress testing simulates the highest contamination levels, while a typical optometric office has a much less bio-burden of approximately 100 CFU/L^{-1}
- This study demonstrates Optejet's design effectively blocks microbial entry into drug containers and fluid paths.
- The Optejet may reduce the contamination risk and may be potentially useful with the administration of preservative-free ophthalmic medications.
- Microbial ingress prevention becomes more critical with the shift towards preservative-free products since preservatives may adversely affect the ocular surface.



Poster Board #36

15/04/2019 10:00 AM

Ergonomic Design to Improve Usability

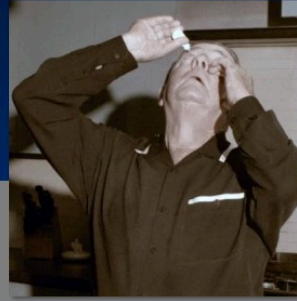
Horizontal delivery, push button dosing and no protruding tip



Eye Dropper Bottle tips can touch the eye surface



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

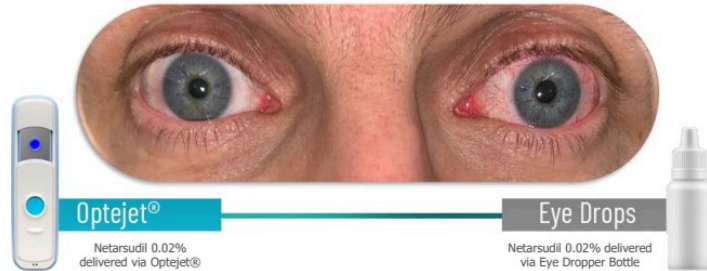
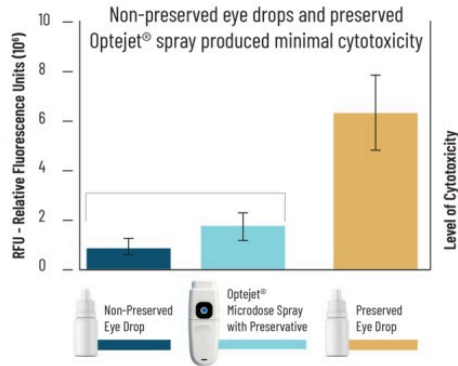
Minimal Sufficient Dosing May Improve Therapeutic Index

With 80% less dose volume, reduces excessive exposure to both drugs and preservatives ^{1,2}

Minimizes Excessive Drug Exposure to Ocular Tissues

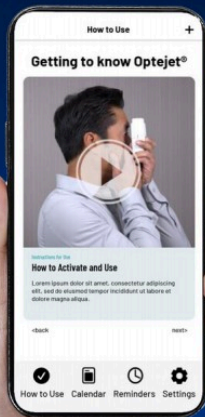


Minimizes Impact of Preservatives on Ocular Tissues



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, 5 Arias A. et al. Patient persistence with first-line antiglaucomatous monotherapy. Clin Ophthalmol. 2010

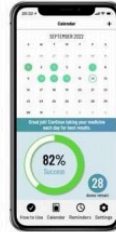
Optejet Digital Technology to Improve Delivery of Care



The Optejet® is capable of automatically tracking usage



Bluetooth



Remote Patient Monitoring: More Data May Benefit All Parties

- Reminders to take medicine
- Ability to track compliance progress
- Opportunity for brand-specific encouragement

PHYSICIAN

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

Pipeline US and China Markets

	Target Market	Optejet Targeted Differentiation	United States Addressable Population	United States Market \$USD*	China Addressable Population	US Status	Licensee
PROPRIETARY	Pupil dilation (Mydriasis)	Ease of use, well tolerated, less systemic absorption, fast recovery time	Procedures: 108M ¹	\$250M	650M ⁸	MydCombi Eyenovia Commercializing	USA eyenovia China 
	Ocular Surgery Pain and Inflammation	Eyedrop: 2X day dosing, low AE incidence ¹⁰	Procedures: 7M ²	\$200M	N/A	PDUFA March 2024	USA eyenovia
	Alternative to glasses for early presbyopia	Ease of use, convenience, low side effect incidence	7M ³	\$850M	12M ⁹	Manufacturing registration batches 1Q 2024	USA eyenovia China 
	Eye Hydration	High technology delivery system	117M ⁴	\$3.1B	N/A	FDA device registration discussions	USA eyenovia
PARTNERED	Treatment of childhood progressive Myopia	Ease of use, digital monitoring technology, pediatrics self-dosing	3M ⁵	\$4.5B	50M ^{9A}	USA Ph3 study enrollment may be completed in 2024	USA BAUSCH + LOMB China 
POTENTIAL	Glaucoma	Digital monitoring technology, ease of use, low side effect incidence	3M ⁶	\$3B	20M ⁹	Biocompatibility testing of potential partner's drug product	--
	Dry Eye	New drug class, ease of use, fast onset	31M ⁷	\$3.6B	235M ⁹	Positive feedback from FDA received; exploring partnership options	--



1. <https://doi.org/10.1001/jamaophth.139.10.1400> | 2. 2022 Delta Insights, Acute Ocular Pain Report | 3. Population of 40.55M in the US - 60.8M A. 35% of this population has never needed corrected vision. Assumes product works in 35% of patients BA. Published by Eric Duffin, B. Sc. S. (2022), September 30. Population of the U.S. by sex and age 2022. Statista. Retrieved February 3, 2023, from <https://bit.ly/45du3d8>. What is 20/20 vision? University of Iowa Hospitals & Clinics. (n.d.). Retrieved February 3, 2023, from <https://bit.ly/482g2t1> | 4. <https://doi.org/10.1016/j.jamaophth.2018.08.001> | 5. Theophanous C, Modjtahedi RS, Batach M, Martin DS, Luong TS, Fong DS. Myopia prevalence and risk factors in children. *Clin Ophthalmol*. 2018 Aug;20(2):282-297. doi: 10.2147/OPTH.S164641. PMID: 30234242; PMCID: PMC620334. U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2021 | 6. Burdette B, Wang JH, Come GC. High Myopia Prevalence across Racial Groups in the United States: A Systematic Scoping Review. *J Clin Med*. 2022 Apr 23;11(8):2445. doi: 10.3390/jcm11082445 | 7. Frost & Sullivan, Prospective, World Bank 370M Adjusted to fit patient criteria | 8. <https://doi.org/10.1016/j.jamaophth.2018.08.001> | 9. Frost & Sullivan, Prospective, World Bank 150M adjusted for the highest at risk patients, 1/3rd of children | 10. Kornfeldt M, Walters T, Martel J, Nunez D, Wang L. A Phase 3 Study of APP13007 (Clobetasol Propionate Ophthalmic Emulsion 0.05%) to Treat Inflammation and Pain after Cataract Surgery. ASCRS presentation. San Diego. May 3 - 8 2023.

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
 - o - Estimated 108 million dilations in US annually
 - o - Estimated \$250 million US market opportunity¹
- Eyedrops are the current standard of care and ripe for innovation
 - o - Multiple eyedrops usually needed
 - o - Patient discomfort and avoidance
 - o - Time consuming administration and slow recovery to “normal”
 - o - 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™ Speed and simplicity with each spray



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: 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.

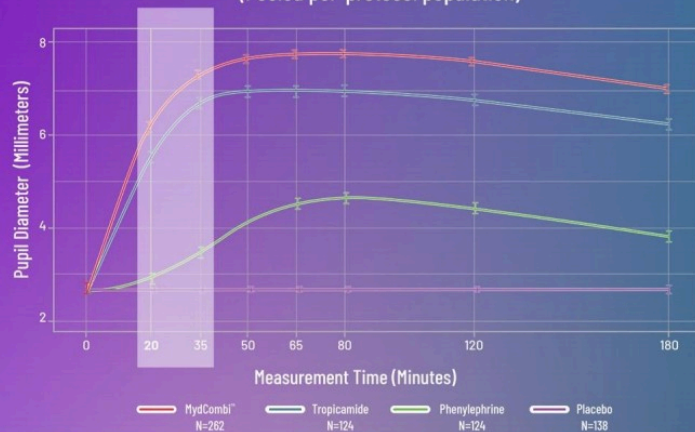


1. Wirta DL, Walters TR, Flynn WJ, Rath S, Ianchulev T. Mydriasis with micro-array print touch-free tropicamide-phenylephrine fixed combination MIST: pooled randomized Phase III trials. Ther Deliv. 2021 Mar;12(3):201-214.

- 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.

EFFICACY

Pupil diameter at each study measurement time by treatment
(Pooled per-protocol population)



Worle, D. L., Walters, T. R., Flynn, W. J., Rath, S., & Ianchulev, T. (2021). Mydriasis with micro-array print touch-free tropicamide-phenylephrine fixed combination MIST: pooled randomized Phase III trials. *In Therapeutic Delivery* (Vol. 12, Issue 3, pp. 201-214). Future Science Ltd. <https://doi.org/10.4155/tde-2021-0001>

APP13007

(Clobetasol Propionate Nanosuspension 0.05%, BID)

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

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

▶ 2024

Post-ocular surgery treatment

- Short and mid-term revenue opportunity (\$1.3B market)
- Synergistic commercialization with MydCombi

▶ 2027

Dry eye treatment

- Potential dry eye product in the Optejet (\$3.6B market)

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

There is an unmet medical and market need for an effective, twice-a-day therapy

Top 3 Attributes 1 = most important; 4 = least important	Ranking
<i>Efficacy</i>	1.6
<i>BID dosing</i>	2.2
<i>Low IOP spikes</i>	2.4



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?

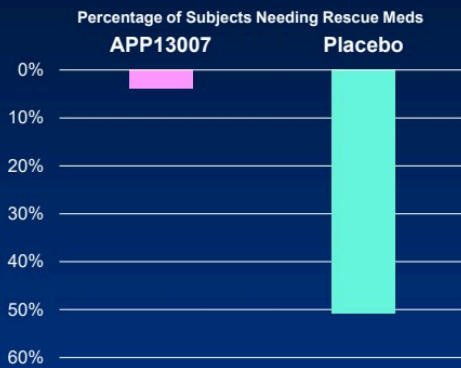
Technology Enables This Profile

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

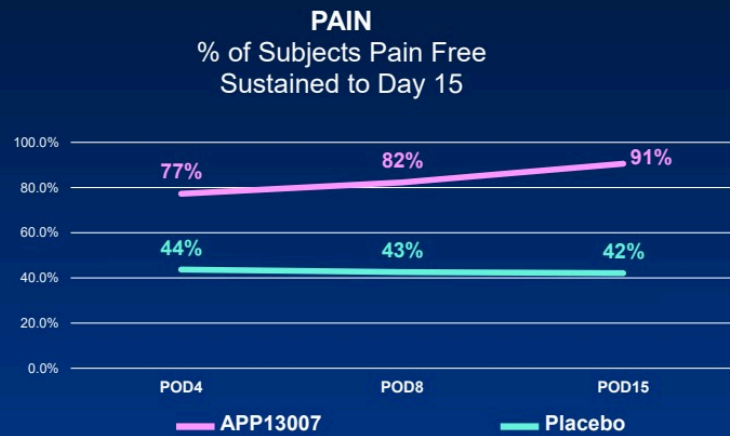
- High uniformity and purity in particle size
- Improved stability
- Improved dispersion properties
- Improved bioavailability



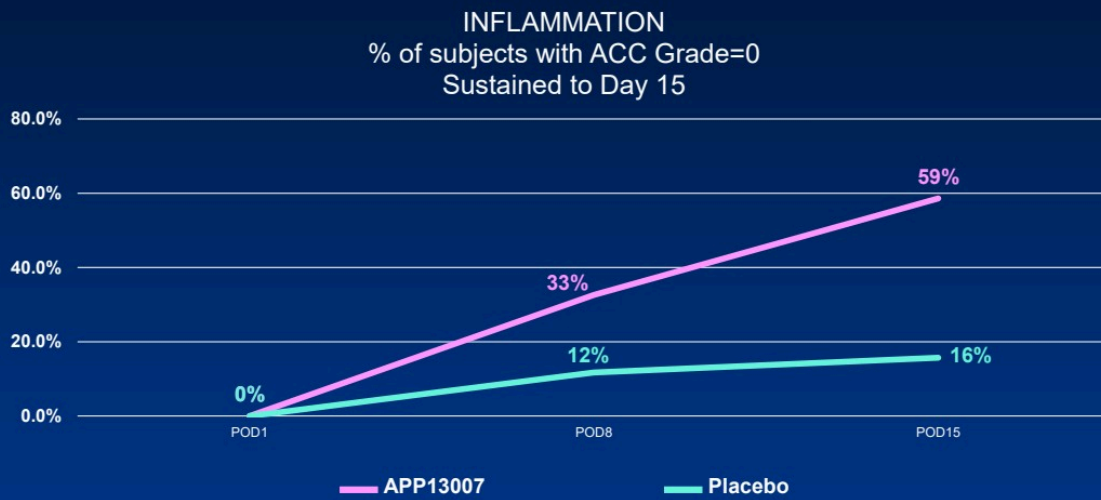
APP13007 Demonstrates Rapid and Sustained Ocular Pain Relief*



Subjects in the clinical study experienced significant pain, with over half requiring rescue from placebo.



APP13007 Demonstrates Rapid Clearance of Inflammation*



*Korenfeld ASCRS Presentation 2023 | CPN-301 A Phase 3 Study of APP13007 (Clobetasol Propionate Ophthalmic Nanosuspension 0.05%) to Treat Inflammation and Pain after Cataract Surgery (Phase 3 study CPN-302 resulted in similar safety and efficacy result but is not displayed here)

Twice-A-Day Dosing Matters

Doctors look to simplify the two week post surgical therapy to improve outcomes



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

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/PackageInserts/Pharma/Rx-Generics/Dexamethasone-Sodium-Phosphate-A-9100202-9100302.pdf>
https://www.accessdata.fda.gov/drugsatfda_docs/label/2008/022212b1.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/016851s063b1.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/202872b1.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/017011s047b1.pdf

Well Tolerated with Low Incidence of IOP Spikes No Need to Taper Dosing

Post-surgical patients need to avoid elevated IOP

In the clinical trial CPN-301, one patient in the treatment group experienced an incident of elevated IOP > 21mmHg (1/181)*

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

Eyenovia Will Focus on Eyecare Professional-Centric Distribution

- ✓ E-prescribing to a specialty pharmacy
- ✓ Ensures all patients receive the product for \$50 to \$60
- ✓ No substitutions
- ✓ No insurance issues
- ✓ **No call-backs to physicians**

E-Prescription sent from doctor to specialty pharmacy and delivered overnight to patient



APP13007 – 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 ≥ 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



Apersure delivered
via Optejet

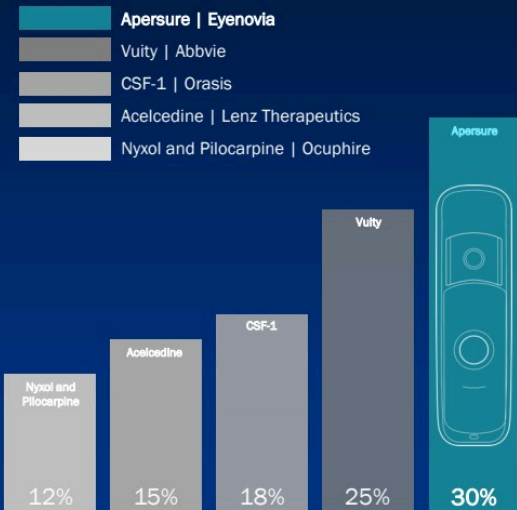


Apersure™

The invisible second set 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

Market Share of Products Predicted by Optometrists



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

Apersure™

The only presbyopia treatment with the Optejet that may enhance office economics



Market Receptivity

High among optometrists who are intrigued by the ability to sell the device through their offices; high among patients who are attracted to the benefits of the device

Potential Market Size

3.5 million people¹ @ \$250 per year = \$877M

Pricing

Approximately \$100 per cartridge (similar to Vuity on a per-use basis); market research indicates patients would use 2.5 cartridges/year on average

Reimbursement Status

Cash-pay cosmeceutical; can be purchased with HSA/FSA funds



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

Apersure™ NDA Timeline

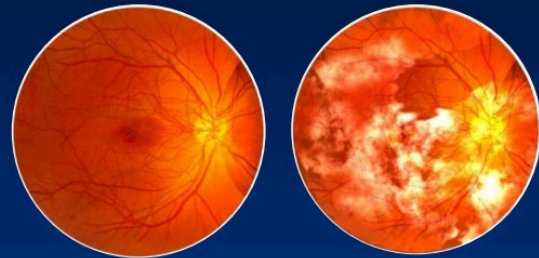
NDA Filing Targeted for 1Q 2025



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 therapies to slow myopia progression
- Atropine may slow myopia progression by at least 60%³

Progression of Myopic Maculopathy



Normal Macula

Myopic Maculopathy

Affects ~25M children in the US alone, with ~5M considered to have high myopia risk⁴



¹ Jones LA, Sinnott LT, Mutti DO, Mitchell GL, Moeschberger ML, Zadnik K. Parental history of myopia, sports and outdoor activities, and future myopia. Invest Ophthalmol Vis Sci. 2007 Aug;48(8):3524-32.

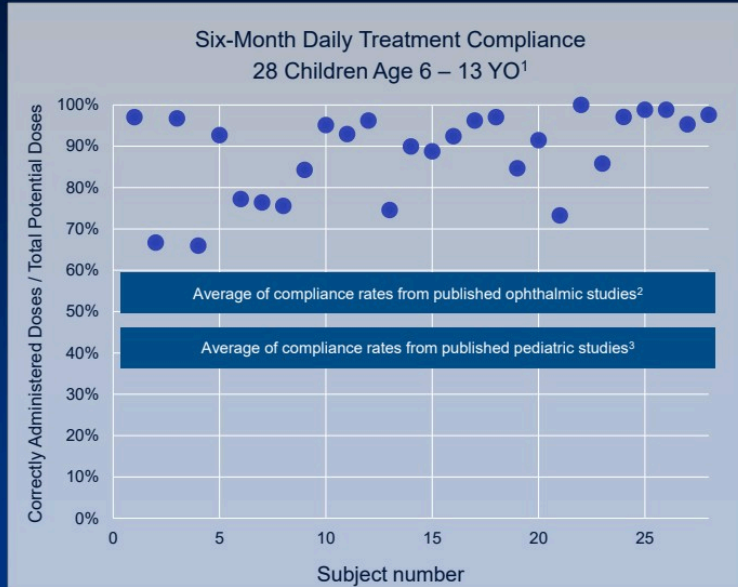
² Eye and Contact Lens. 2004; 30

³ Chia A, Chua WH, Cheung YB, et al. Atropine for the treatment of childhood Myopia: Safety and efficacy of 0.5%, 0.1%, and 0.01% doses (Atropine for the Treatment of Myopia 2). Ophthalmology 2012;119:347-354

⁴ Theophanous C. Myopia Prevalence and Risk Factors in Children. Clinical Ophthalmology. December 2018. U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2019.

MicroPine for Delaying Progression of Myopia in Children

- 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

A Pediatric Therapy Designed with Children in Mind



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

Multiple Commercialization Partners

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



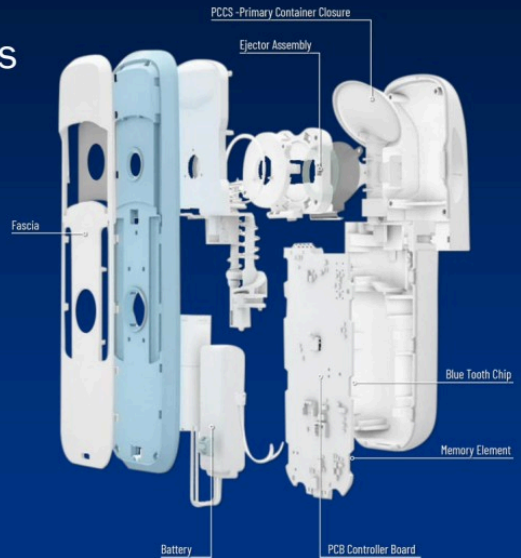
Arctic Vision – A China-based ophthalmic biotech focusing on breakthrough therapies, with a leading portfolio covering pre-clinical stage to commercial stage products

Licenses – MicroPine, MicroLine and MydCombi 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

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



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

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