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): October 25, 2021

EYENOVIA, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38365**	**47-1178401**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

295 Madison Avenue, Suite 2400 **New York, NY**	**10017**
(Address of principal executive offices)	(Zip Code)

(917) 289-1117
Registrant's telephone number, including area code

Not applicable
(Former name or former address, if changed since last report)

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(s)**	**Name of each exchange on which registered**
Common Stock	EYEN	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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

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

Item 2.02 Results of Operations and Financial Condition.

Eyenovia, Inc. (the "Company") expects to report that it had approximately $21.4 million in cash and cash equivalents as of September 30, 2021, although it has not finalized its full financial results for the quarter. The Company also expects the outstanding number of shares of its common stock as of September 30, 2021 to be 25,963,185. This estimate is unaudited and preliminary and does not present all information necessary for an understanding of the Company's financial condition as of September 30, 2021 and its results of operations for the three and nine months then ended. The Company also reported that management believes that, as of October 25, 2021, the Company's existing cash and cash equivalents and available credit will allow the Company to continue its operations into the first quarter of 2023. The review of the Company's financial statements for the three and nine months ended September 30, 2021 by management and by the Company's independent registered public accounting firm is ongoing and could result in changes to the information set forth above.

The information contained in this Current Report on Form 8-K 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 liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

Press Release

On October 25, 2021, the Company issued a press release announcing the reclassification of the Company's proprietary, first-in-class combination microdose formulation of tropicamide and phenylephrine for in-office pupil dilation, MydCombi, as a drug-device combination product by the U.S. Food and Drug Administration in a Complete Response Letter ("CRL") received on October 22, 2021. The press release also announces that the Company is preparing the necessary documents for expedited resubmission of the new drug application for MydCombi in response to the CRL. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Corporate Presentation

Attached hereto as Exhibit 99.2 and incorporated herein by reference is an updated corporate presentation the Company intends to use with various investors and analysts.

Forward-Looking Statements

Statements in this Current Report on Form 8-K regarding management's future expectations, beliefs, intentions, goals, strategies, plans or prospects are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited, to statements regarding Company's expected cash balance and projected cash needs, and intentions of the company with respect to resubmission of the new drug application for MydCombi. Forward-looking statements may be identified by words such as "anticipates," "believe," "continue," "expect," "intend," "may," "plan to," "potential," "projects," "will," and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors, including, without limitation, the risks referred to under the section "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and Quarterly Report on Form 10-Q for the period ended June 30, 2021, as such factors may be updated from time to time in the Company's other filings with the Securities and Exchange Commission ("SEC"), which filings are accessible on the SEC's website at www.sec.gov and the Company's website at https://ir.eyenovia.com/financial-information/sec-filings. All forward-looking statements speak only as of the date of this Current Report on Form 8-K and, except as required by applicable law, the Company has no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release of the Company, dated October 25, 2021.
99.2	Eyenovia, Inc. corporate presentation dated October 2021.
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: October 25, 2021

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Announces Reclassification of MydCombi(tm) as Drug-Device Combination Product by FDA

Genus Medical Technologies, LLC v. FDA legal case leads to agency-wide review and reclassification of eye cups, eye droppers, and ophthalmic dispensers

Company received Complete Response Letter with additional requests and is preparing necessary documents for expedited resubmission

NEW YORK—October 25, 2021—Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that MydCombi, the company's proprietary, first-in-class combination microdose formulation of tropicamide and phenylephrine for in-office pupil dilation, has been reclassified as a drug-device combination product by the U.S. Food and Drug Administration (FDA) in a Complete Response Letter (CRL) for the company's new drug application (NDA) received on October 22, 2021.

Eyenovia will provide additional information to the FDA, as requested in the CRL, as soon as possible, including information necessary to meet additional requirements under *Genus Medical Technologies, LLC v. FDA. Genus* refers to a recent decision by the U.S. Court of Appeals for the District of Columbia Circuit which has resulted in an agency-wide reclassification by FDA of certain drugs to devices or to drug-device combination products. There were no issues raised related to the phase III clinical program for MydCombi.

"While we were surprised by the FDA's position in the CRL, given our original FDA designation, we understand the unusual situation created by the impact of the Genus case, which compelled an Agency-wide reclassification," stated Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia. "Fortunately, we had taken actions throughout the development of MydCombi to minimize the impact of a potential reclassification by the FDA. We are preparing additional documentation requested by the FDA and look forward to resubmitting our NDA in early 2022 for the FDA's review. Since the device used for MydCombi has commonality with that used in the MicroLine and MicroPine programs, we believe that the information submitted in support of MydCombi will pave the way in advance of those regulatory submissions. In fact, we are on track to initiate our second Phase III MicroLine study for presbyopia in the coming days."

The Company's current total pro forma cash balance is approximately $30.7 million after the sale of approximately 1.8 million shares of common stock earlier this quarter through the Company's At The Market offering facility. The Company believes its total unrestricted and restricted cash balance will be sufficient for the resubmission of the NDA for MydCombi, completion of the MicroLine clinical program and other planned activities through the beginning of 2023.

Eyenovia announced FDA acceptance of the MydCombi NDA in March 2021. The NDA was based on the MIST-1 and MIST-2 studies. In these two Phase 3 studies, a fixed combination of micro-dosed tropicamide 1% and phenylephrine 2.5% ophthalmic solution met the studies' primary endpoints and was shown to be well-tolerated and effective for pharmacologic mydriasis. Approximately 94% of treated eyes achieved 6mm or greater dilation at 35 minutes post-instillation. Adverse events were infrequent, with fewer than 1% of patients reporting blurred vision, reduced acuity, photophobia or instillation site pain.

About Eyenovia, Inc.
Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for mydriasis, presbyopia and myopia progression. 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 our ability to re-use the information in our NDA for MydCombi for the NDAs for MicroLine and MicroPine, the impact of the delay in FDA approval of MydCombi, acceptance by the FDA of our NDA resubmission for MydCombi, our ability to initiate our second Phase III MicroLine study for presbyopia, the sufficiency of our unrestricted and restricted cash for the resubmission of the NDA for MydCombi, completion of the MicroLine clinical program and other planned activities through the beginning of 2023. 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 (which could still be adversely impacted by COVID-19 and resulting social distancing), timing, progress and results of such trials; the timing of, and our ability to submit or re-submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential impacts of COVID-19 on our supply chain; the potential advantages of our product candidates and platform technology; 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 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; 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 Contact:
Eyenovia, Inc.
John Gandolfo
Chief Financial Officer
jgandolfo@eyenovia.com

Eyenovia Investor Contact:
Eric Ribner
LifeSci Advisors, LLC
eric@lifesciadvisors.com
(646) 751-4363

Eyenovia Media Contact:
Sam Choinski
Pazanga Health Communications
schoinski@pazangahealth.com
(603) 489-5964

Exhibit 99.2

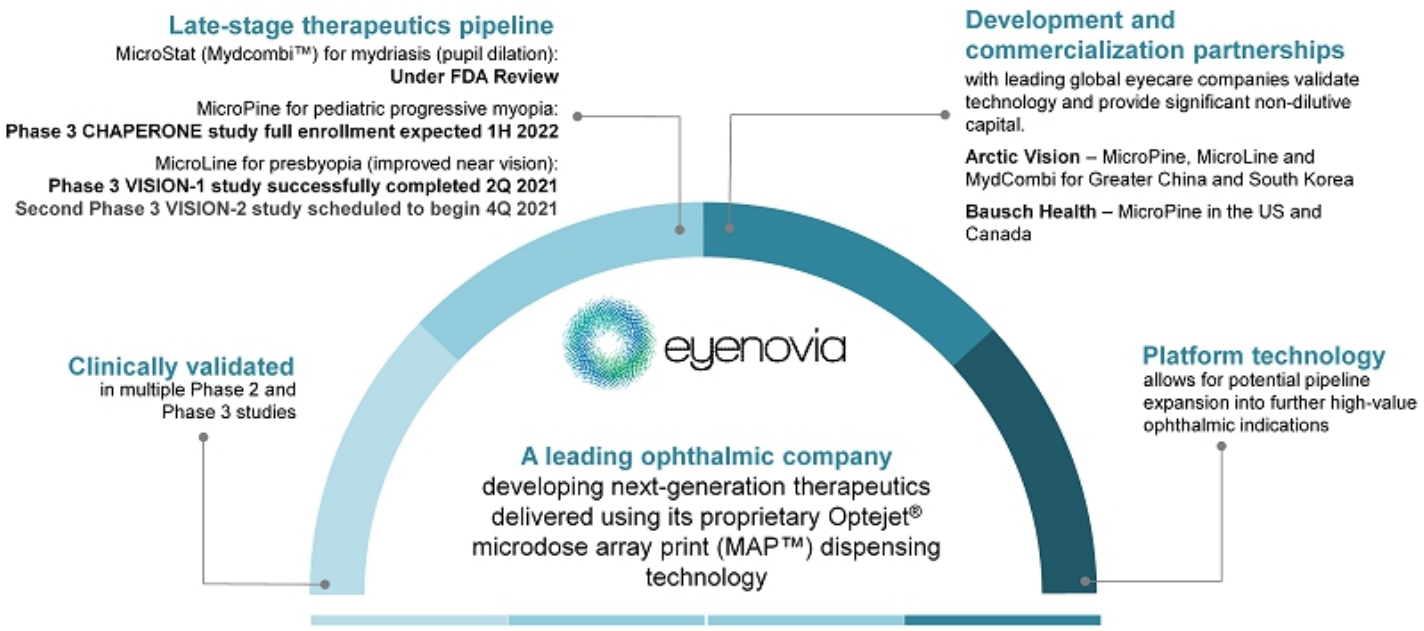
Forward-Looking Statements

Except for historical information, all of 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 (which could still be adversely impacted by COVID-19 and resulting social distancing), 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 COVID-19 and related economic disruptions on our supply chain, including the availability of sufficient components and materials used in our product candidates; the potential advantages of our product candidates and platform technology; 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 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; 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.

Investment Highlights



Leadership Team

Sean Ianchulev, MD, MPH
CEO, CMO and Co-Founder

John Gandolfo
CFO

Michael Rowe
COO

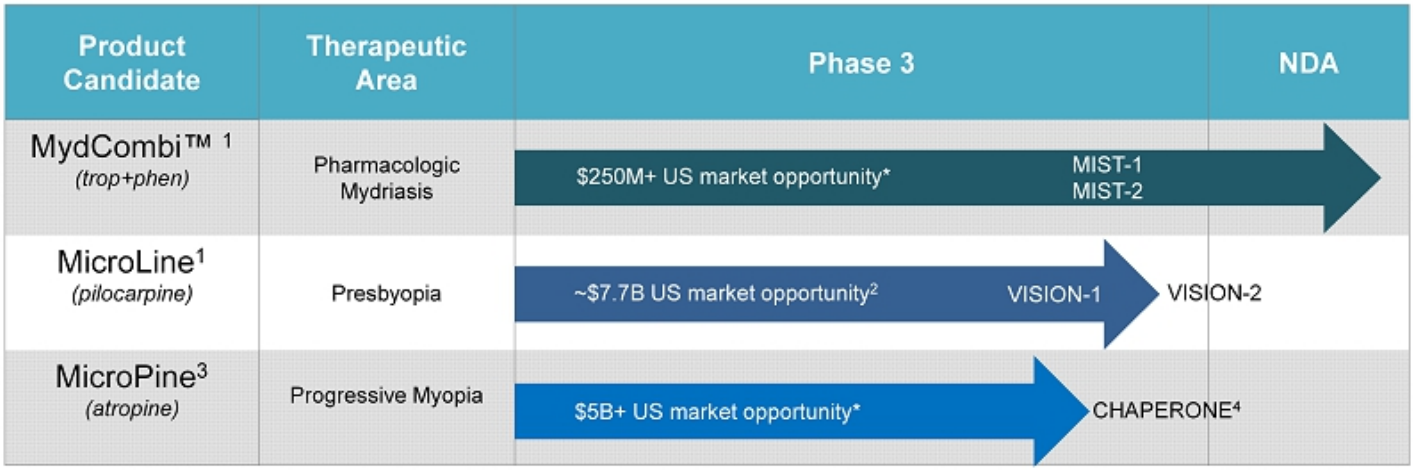
Jennifer Clasby
VP Regulatory, Clinical and Quality

Malini Batheja, PhD
VP, Pharmaceutical R&D

Beth Scott, OD
VP, Medical Affairs

Norbert Lowe
VP, Sales & Marketing

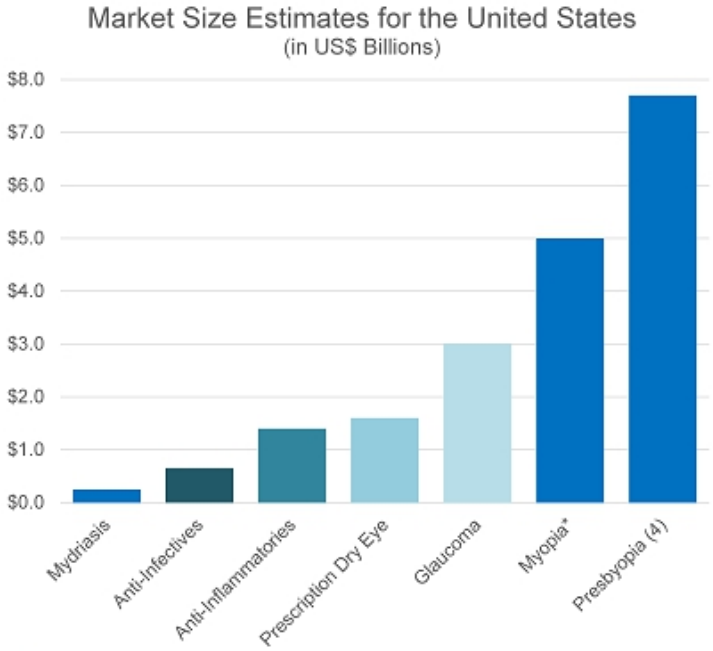
Late-Stage Ophthalmic Pipeline for US Registration in Markets Valued Over $12.7 Billion



* *Estimate only*
[1] *Out-licensed to Arctic Vision in Greater China and South Korea*
[2] *Estimate from DelveInsight Presbyopia report, December 2020*
[3] *Out-licensed to Bausch Health in the US and Canada, and Arctic Vision in Greater China and South Korea*
[4] *CHAPERONE oversight and costs assumed by Bausch Health*

Potential pipeline expansion activities leveraging Optejet® technology are ongoing

Potential Topical US Ophthalmic Market For Platform Technology*



Current Portfolio: ~$12.7 Billion*

Existing Eyenovia portfolio in mydriasis, presbyopia, and myopia, with late-stage, first-in-class therapeutics.

Anti-Infectives: ~$650 Million[1]

Eliminate contamination from poor usage of eyedropper bottles.

Anti-Inflammatories: ~$1.4 Billion[1]

Reduce IOP spikes due to high doses of steroids.

Prescription Dry Eye: ~$1.6 Billion[2]

Improve clinical probability of success. Enable patients, especially the elderly, to better instill medication for improved results. Multi-dose preservative free options.

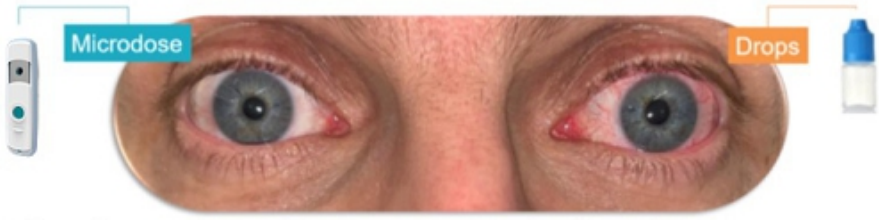
Glaucoma: ~$3 Billion[3]

Improve systemic safety profile and allow for development of PGA + BB fixed combinations. Improvement in topical (e.g., hyperemia) and systemic AE profile. Multi-dose preservative free options.

*All potential market opportunities are estimates only
[1] IMS, 2015
[2] Mixture of public information, IQVIA , Market Scope and estimates – Feb 2020
[3] IQVIA, 2019
[4] Estimate from Delveinsight Presbyopia Report, December 2020

Standard Eyedroppers Have Limited Therapeutic Approaches

- Potential overexposure to drug and preservatives
  - Conventional droppers can overdose the eye by as much as 300%+[1]
  - Known to cause ocular and systemic side effects[1]



- Protruding tip may create cross-contamination risk
  - More than 50% of administrations touch ocular surface[2]
- More difficult to use with poor compliance
  - Requires head tilting and aiming which may be compromised in pediatric and elderly populations
  - No dosage reminders or tracking which may lead to missed doses

[1] Abelson, M., 2020. The Hows And Whys Of Pharmacokinetics. ReviewofOphthalmology.com; accessed 11/3/20
[2] Brown MM, Brown GC, Spaeth GL. Improper topical self-administration of ocular medication among patients with glaucoma. Can J Ophthalmol. 1984 Feb;19(1):2-5. PMID: 6608974.

Optejet Microdose Array Print (MAP) Technology Designed for Optimal Drug Delivery

Precise, Physiological Dosing:

Directly coats the cornea with ~80% less exposure to drug and preservative toxicity (based on 8µL dose). [1]
Designed to eliminate drug overflow for a more comfortable patient experience.

Efficacy:

Demonstrated statistical and clinically significant efficacy in IOP reduction, pharmacological mydriasis and presbyopia (improvement in near vision)1.[2,5]

Safety:

Low systemic drug absorption and good ocular tolerability.[3,4]
Non-protruding nozzle for no-touch spray application, potentially minimizing risk of cross contamination seen with traditional eyedroppers.

Ease of Use:

Horizontal drug delivery means no need to tilt the head back.
Demonstrated first-time success with both medical professionals and patients.[2]

Compliance and Adherence:

Can be paired with smart devices to enable dosage reminders and tracking.

[1] Abelson, M., 2020. The Hows And Whys Of Pharmacokinetics. ReviewofOphthalmology.com; accessed 11/3/20
[2] Pasquale L. et al., Clinical Ophthalmology 2018
[3] Wirta D. et al, Presentation at 2019 ASCRS meeting
[4] Ianchulev T. et al, Therapeutic Delivery 2018
[5] Presented at Eyecelerator, July 2021

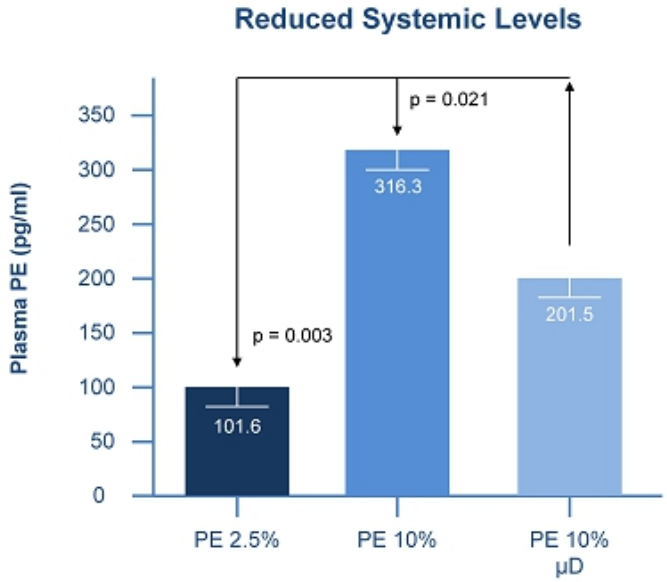
eyenovia

Optejet: Significant Clinical Experience and Validation

Five Phase 2 or Phase 3 clinical trials to date featured in dozens of publications and major meetings including ASCRS, AAO, AAOpt, OIS and EYEcelerator.

eyenovia

Optejet: Clinical Experience and Validation



Drugs in traditional eyedroppers can **enter systemic blood circulation** and may cause **significant side effects**.[1]

Microdose delivery of phenylephrine 10% (PE-µD) **was associated with significantly less systemic exposure** than traditional eye drops (PE 10%).[2]

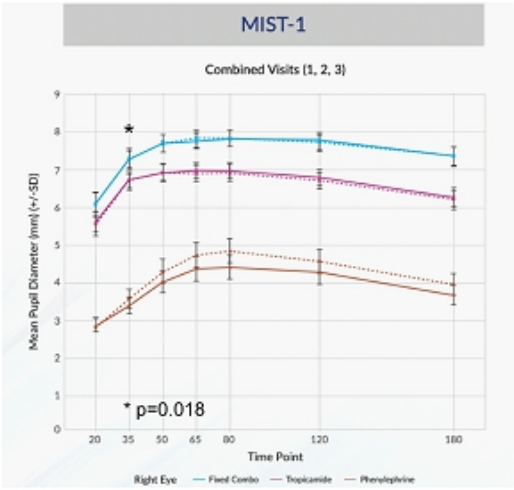
[1] Muller, M., van der Velpe, N., Jaap, W., van der Cammen, T.; Syncope and falls due to timolol eye drops. BMJ, 2006 April; 332:960-961
[2] Ianchulev, I. High-precision piezo-ejection ocular microdosing: Phase II study on local and systemic effects of topical phenylephrine. Ther Deliv, 2018 Jan;9(1):17-27

Optejet: Demonstrated Effectiveness in Multiple Phase 3 Studies

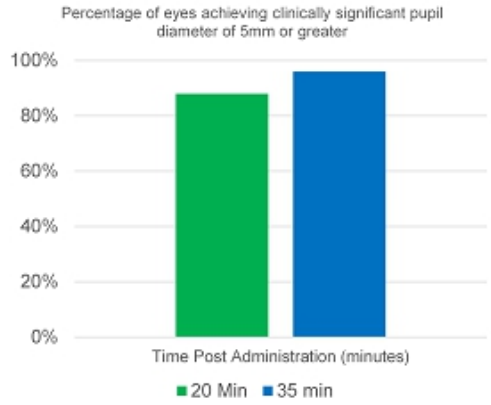
Microdosing a fixed combination of tropicamide-phenylephrine
had a superior mydriatic effect compared to either component formulation[1]

Microdose Efficacy

MIST-1



Combined MIST Studies[1,2]



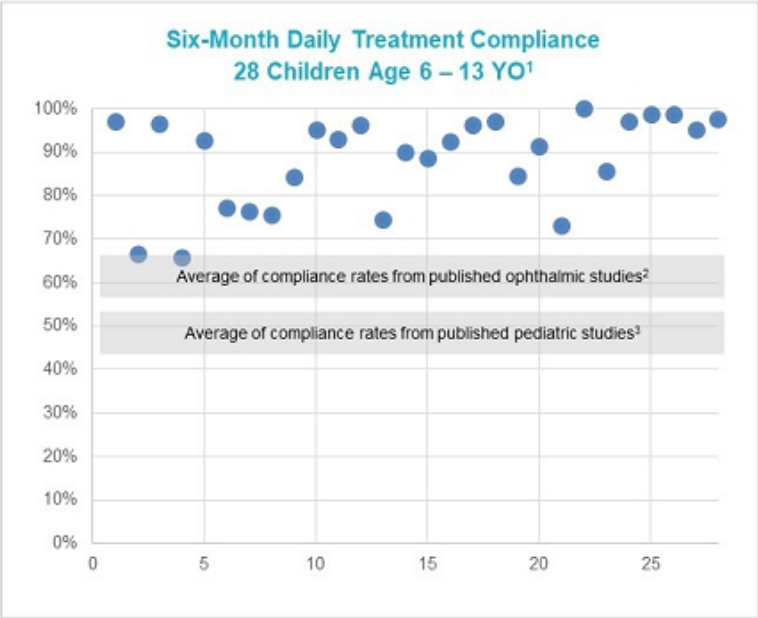
1. Wirta DL, Walters TR, Flynn WJ, Rathi S, Ianchulev T. Mydriasis with micro-array print touch-free tropicamide+phylephrine fixed combination MIST: pooled randomized phase III trials. Ther Deliv; 2021
2. Data on File, Eyenovia 2021

Optejet: Impressive Treatment Compliance

Real Improvement in Real World Use

In an ongoing late-stage trial, among the initial group of children using the Optejet once-daily, average compliance was nearly 90% during 6 consecutive months of Optejet use

This compares favorably to the approximately 50% compliance rate for pediatric medications as a whole, or the 59 – 69% range published for adult topical ophthalmic drug users



[1]Data on file with Eyenovia.
[2]Naito, 2018; Patel, 1995; Winfield, 1990
[3]Matsui, 1997

eyenovia

Optejet Platform: Potential High-Value Opportunities

Estimated Gross Margins Based on $100/Month Price[1]

82% - 94%

Next-Generation Ophthalmic Therapeutics

- Eyenovia's microdose therapeutics are regulated by CDER (Drug Division of the FDA) with additional requirements as a Drug/Device combination product

Eyenovia Products Aim to Provide Competitive Pharmaceutical Margins:

- All pipeline products are Eyenovia's own proprietary micro-formulations
- Eyenovia currently owns the pharma-economics of the entire prescription value chain
- MicroLine has strong potential as a cash-pay cosmeceutical

[1] Estimates for "at scale" (250,000 annual units minimum)

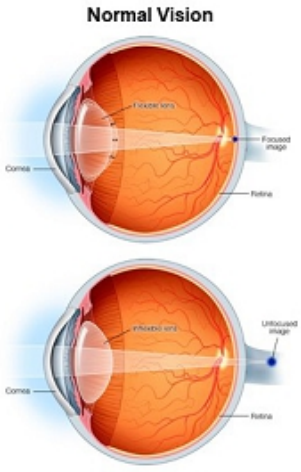
MicroLine for Presbyopia

Etiology

- The progressive loss of ability to focus on nearby objects
- Non-preventable, age-related hardening of the lens

Symptoms

- Tendency to hold reading material farther away to make the letters clearer
- Blurred vision at normal reading distance
- Eye strain, headaches after reading or doing close-up work



Risk Factors

- Age
- Medical conditions and co-morbidities such as cardiovascular conditions, multiple sclerosis, and type 2 diabetes
- Drugs associated with premature symptoms include antidepressants, anti-histamines and diuretics

Diagnosis

- Basic eye exam, with refraction assessment

Sources: Mayo Clinic Presbyopia Overview. Wolffsohn et al. Prog Retin Eye Res. Fernandez et al. J Ophthalm. Accessed December 2018

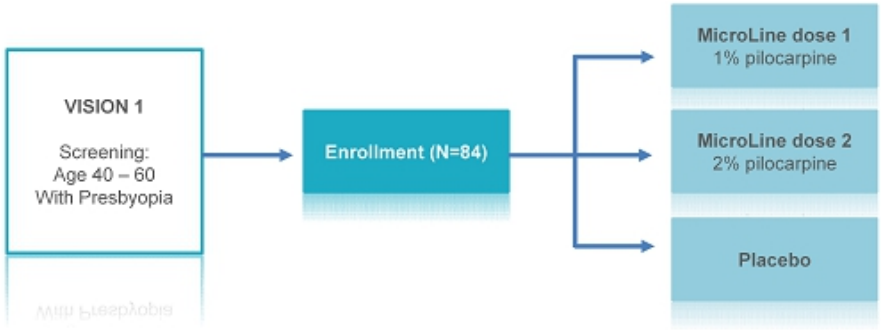
MicroLine Achieves Primary Endpoint in Phase 3

- [x] **May 2021: Phase 3 VISION-1 trial achieves primary endpoint**
  - *Statistically significant* proportion of subjects in treatment arm achieved three-line or more improvement in distance corrected near visual acuity
  - *Well tolerated* with only mild adverse events; less than 3% brow ache
  - *71% of study participants* reported strong interest in using MicroLine if approved

- [ ] **Registrational Phase 3 VISION-2 study planned for Q4 2021**
  - *Topline data* anticipated in H1 2022

VISION-1 Study Design

- Double-masked, placebo-controlled, cross-over superiority trial
  - Phase 3 (microdosed pilocarpine 1%, 2% and placebo)
- Primary endpoint: mesopic, high contrast binocular distance corrected near visual acuity



VISION-1 Met Primary Endpoint
Formulation is Well-Tolerated and Comfortable

1° Outcome
≥3-line gain

OR 7.7

p-value<0.05

Patients Report
seeing improvement

71%

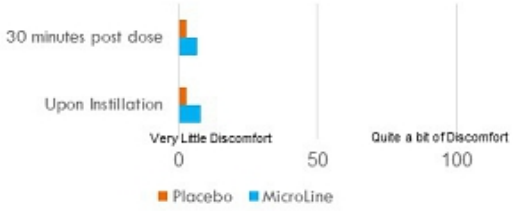
Exit survey: Percent reporting significant improvement in near vision

Key Safety Outcomes

All AEs were Mild and Transient in Nature

	MicroLine	Placebo
Moderate Hyperemia[1]	2%	0%
Instillation Discomfort	2%	0%
Brow ache	2%	0%

Patient Comfort Assessment

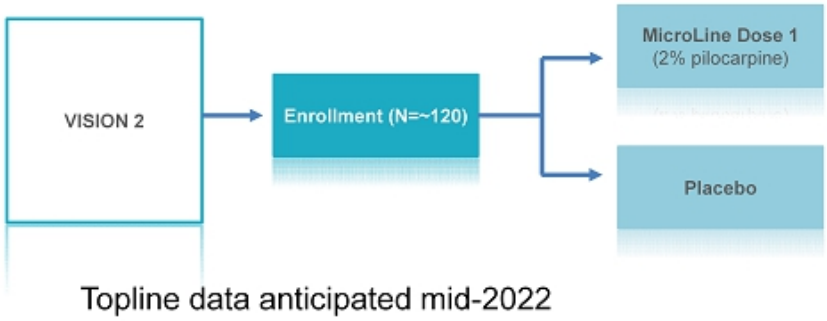


[1]Resolved by 3 hours post-dose

eyenovia

VISION-2 Study Design

- Double-masked, placebo-controlled, cross-over superiority trial
  - Phase 3 (microdosed pilocarpine 2% and placebo)
- Primary endpoint: mesopic, high contrast binocular distance corrected near visual acuity
- Enrollment to commence 2H 2021



Topline data anticipated mid-2022

There Exists a Significant Unmet Need in Presbyopia

- Majority of presbyopia patients have never had to wear glasses prior to having difficulty with near vision
- Having to wear glasses can be an inconvenience and an outward signal of aging
- A "no glasses" option may be valuable and more convenient to patients
- Eyenovia's MicroLine is intended to be a companion product to spectacles, not a replacement
  - Provides freedom to use the product *as needed*

18 million people 40-55 years of age who never previously needed glasses suffer from presbyopia in the US alone

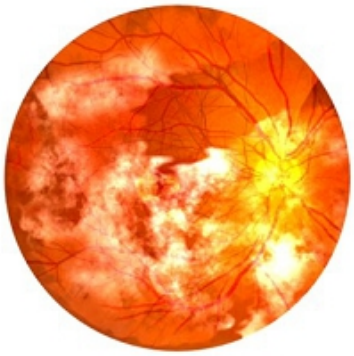
A 7.7 **billion dollar**[1] addressable market

[1] Estimate from DelveInsight Presbyopia report; December 2020

MicroLine Product Profile

- Effective at restoring functional vision, such as the ability to read a menu or cell phone
- Ability to use “as needed” without chronic dosing
- Rapid onset of action
- Easy to administer
- Comfortable instillation with low incidence of brow or headache to drive patient satisfaction and re-use

MicroPine for Progressive Myopia



Progressive of Myopic Maculopathy

Affects ~25M children in the US alone, with ~5M considered to be at high risk[4]

- Back-of-the-eye disease
- Mostly begins in early childhood, with a genetic link to myopic parents[1]
- Pathologic elongation of sclera/retina which can lead to significant morbidity and visual sequelae[2]
  - Retinal detachment
  - Myopic retinopathy
  - Vision loss
  - Quality of life
- Currently, no FDA-approved drug therapies to slow myopia progression
- Atropine may slow myopia progression by 60% or more[3]

[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.

Strategic Partnerships to Potentially Extend Commercial Reach

Arctic Vision

Validating partnership for the development and commercialization of **MicroPine, MicroLine and MydCombi**

Upfront payment: $4M

Potential milestone payments and reimbursed development costs: $45M

Commercial supply terms or royalties: mid-single digits

Territory: Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea

Impacted population estimated at approx. more than 8x the US[1]

Bausch Health

Strategic partnership for the development and commercialization of **MicroPine**

Upfront payment: $10M

Potential milestone payments and reimbursed development costs: $50M *(Reimbursed development costs associated with Phase 3 CHAPERONE trial to begin immediately)*

Royalties on gross profit: mid-single digit to mid-teen percentages

Territory: US and Canada

US impacted population with high myopia estimated at approx. 3M[2,3]

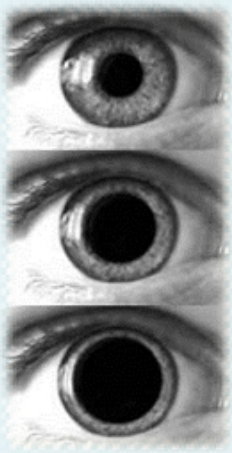
[1]Min Chen, 2018
[2] Theophanous C. Myopia Prevalence and Risk Factors in Children. Clinical Ophthalmology. December 2018.
[3] U.S. Census Bureau, Current Population Survey, Annual Social and Economic Supplement, 2019.

Future Licensing Opportunities

eyenovia

MydCombi for Mydriasis

- Pharmacologic mydriasis (pupil dilation) is part of the comprehensive eye exam
  - Estimated 100 million office-based comprehensive and diabetic eye exams and 4 million ophthalmic surgical dilations performed annually in the United States
  - Essential for diabetic retinopathy, glaucoma and retina disease screening
  - An estimated $250 million US market opportunity[1]
- Places technology at the initial point-of-care with prescribers (ophthalmologists and optometrists)
- No direct contact increases patient safety by reducing potential cross contamination associated with the use of shared dilating drops in OD/OPH offices
- No anticipated reimbursement hurdles; expect to sell directly to ophthalmology and optometry practices
- Able to commercialize efficiently with a small, targeted sales force
- Currently under FDA Review



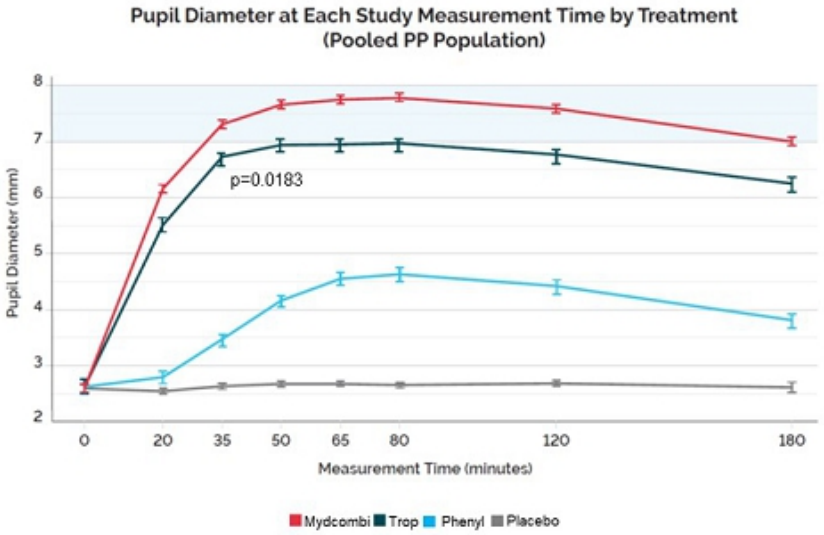
[1] $200M annual sales of pharmaceutical mydriatic products used during 100M office-based exams ($2 * 100M) + $50M of single bottle mydriatic agents used cataract replacement surgery ($12.5 x 4M)

MydCombi™
Mydriasis Made Modern

- If approved, the only fixed combination of the two leading mydriatic medications in the US
- Administered with the push of a button, saving up to ten minutes of technician time[1]
- Touch-free, comfortable application with fewer than 1% of patients experiencing stinging discomfort[2]
- Lower drug and preservative exposure, including systemic absorption of phenylephrine, which can be problematic in hypertensive patients[2,3]
- Reliable in numerous patient practices. More than 9 out of 10 patients achieved clinically significant mydriasis at 35 minutes post-dosage[2]

[1] Denion E. et al, A 5-Minute Interval between Two Dilating Eye Drops Increases Their Effect. Optom Vis Sci. 2017 Aug
[2] Wirta, D. Presented at ASCRS Annual Meeting, 2019, San Diego CA
[3] Abelson, M., 2020. The Hows And Whys Of Pharmacokinetics. ReviewofOphthalmology.com; accessed 11/3/20

MydCombi has a Superior Mydriatic Effect vs. Single Agents



Prompt Mydriasis

Mydriasis >5mm achieved in 88% of patients at 20 minutes, without the delay of instilling multiple drops

Superior Efficacy

MydCombi achieved superior efficacy over single-agent components

Office & Surgical Use

Mydriasis >6 mm achieved in >93% of patients at 35 minutes post-dosage which is clinically meaningful for both office retinal exam and surgical dilation

Presented by S. Rathi et al, American Academy of Optometry Annual Meeting, 2020

MydCombi Launch Expenses:
A Fraction of a Typical Ophthalmic Drug Launch

eyenovia		Big Eye Pharma
11 FTE for $2.2 million Calling on large group practices in largest population centers for 50% reach at launch	Salesforce 	100 FTE for $20.0 million Calling on 18,000 doctors across the US for 80% reach at launch
Not needed. Product is a diagnostic bought by the practice.	Managed Care Group 	8 FTE for $1.6 million Often delay of up to 1 year to obtain formulary access.
$2.0 million Glossy pieces and interactive programs are not needed. Key Account People will train and leave a sample for evaluation.	Promotion 	$10.0 million Dinner meetings, large convention booths, investigational grants, advertising, lunch and learns.
Total: ~$4.2 million		**Total: ~$31.6 million**

Note: All figures above are estimates

Intellectual Property

Technology that has Multiple Layers of IP, Clinical and Regulatory Protection

Worldwide patents are granted on the dispenser, the drop size, velocity of delivery and data capture from the base unit, and are in effect **until late 2031**

Provisional patents have been filed on the Gen 2 dispenser and if approved will bring protection **through 2040**

An **additional barrier** is the clinical and regulatory hurdles a competitor would have to meet to gain approval for an 8µ dose

Financial Snapshot

Nasdaq: EYEN	
Common Shares Outstanding	25.9M
Equity Grants Outstanding Under Stock Plans	4.4M
Warrants	1.2M
Fully Diluted Shares	31.6M
Cash	$27.2M
Debt	$7.5M

All figures as of June 30, 2021

Board of Directors

Dr. Fred Eshelman
Chairman

Founder and former CEO of PPDI, founding chairman of Furiex Pharmaceuticals, and founder of Eshelman Ventures

Dr. Ernest Mario
Board Member

Former Chairman and CEO of Reliant Pharmaceuticals, ALZA, and Glaxo Holdings

Dr. Curt LaBelle
Board Member

Managing Director of GHIF venture fund and Co-Founder of Eyenovia

Kenneth Lee Jr.
Board Member

General partner of Hatteras Venture Partners

Charles Mather IV
Board Member

Managing Director, Equity Capital Markets at Suntrust Robinson Humphrey

Dr. Anthony Sun
Board Member

CEO, Zentalis Pharmaceuticals, Inc.

Dr. Sean Ianchulev
Board Member

CEO, CMO and Co-Founder of Eyenovia

Dr. Julia Haller
Board Member

Ophthalmologist-in-Chief Wills Eye Hospital


eyenovia
Making it Possible
October 2021