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) March 15, 2021

EYENOVIA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-38365	47-1178401
(Commission File Number)	(IRS Employer Identification No.)

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

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

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, $0.0001 Par Value	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 8.01. Other Events.

Attached hereto as Exhibit 99.1 and incorporated herein by reference is a corporate update presentation Eyenovia, Inc. intends to use with various investors and analysts.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Eyenovia, Inc. corporate update presentation dated March 2021.

SIGNATURE

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: March 15, 2021

By: /s/ John Gandolfo
Name: John Gandolfo
Title: Chief Financial Officer

Exhibit 99.1

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 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: volatility and uncertainty in the global economy and financial markets in light of the COVID-19 pandemic and uncertainties arising from the U.S. elections; fluctuations in our financial results; the timing and our ability or the ability of our licensees to submit applications for, obtain and maintain regulatory approvals for our product candidates; 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; the potential impacts of COVID-19 on our supply chain; the potential advantages of our product candidates and platform technology and potential revenues from licensing transactions; 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 certain of our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for certain of our product candidates; risks of our ongoing 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; our ability to raise additional capital; intellectual property risks; 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

Late-stage therapeutics pipeline

MicroStat (Mydcombi™) for mydriasis (pupil dilation):
NDA PDUFA date expected 4Q 2021
MicroPine for pediatric progressive myopia:
Phase 3 CHAPERONE study full enrollment expected 4Q 2021
MicroLine for presbyopia (improved near vision):
Phase 3 VISION-1 study results expected 2Q 2021

Development and commercialization partnerships

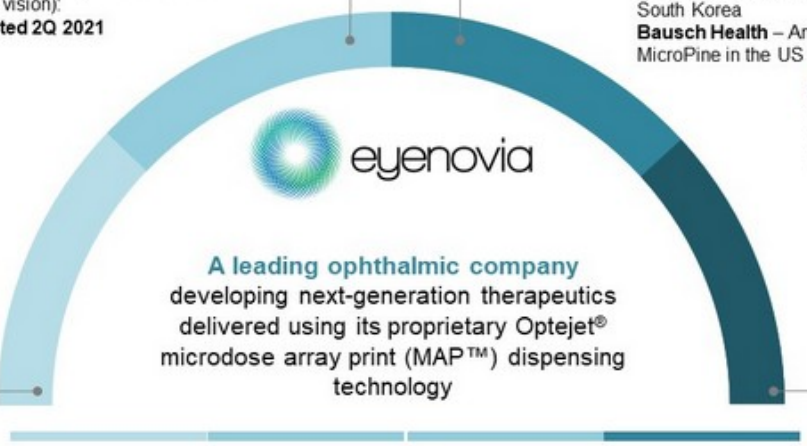
with leading global eyecare companies validate technology and provide significant non-dilutive capital.
Arctic Vision – Announced August 2020 with MicroPine and MicroLine for Greater China and South Korea
Bausch Health – Announced October 2020 for MicroPine in the US and Canada

Clinically validated

in multiple Phase 2 and Phase 3 studies

Platform technology

allows for potential pipeline expansion into further high-value ophthalmic indications



A leading ophthalmic company

developing next-generation therapeutics delivered using its proprietary Optejet® microdose array print (MAP™) dispensing technology

Leadership Team

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

- Head of ophthalmology research and directed development and FDA approval of Lucentis, most successful ophthalmic drug for Genentech
- IanTech founder for cataract device approved by FDA in 2016 and inventor of Intra-operative Aberrometry at Wavetec-Alcon/Novartis
- CMO of Transcend Medical (acquired by Alcon/Novartis)

TRANSCEND MEDICAL · WaveTec Vision · IanTech · Genentech

John Gandolfo
CFO

XTANT MEDICAL · BIOJECT · Power Medical Interventions

Michael Rowe
CCO

Allergan · Bayer · Pfizer · aerie

Jennifer Clasby
VP Regulatory and Clinical

TRANSCEND MEDICAL · ASMO

Luke Clauson
VP R&D, Manufacturing

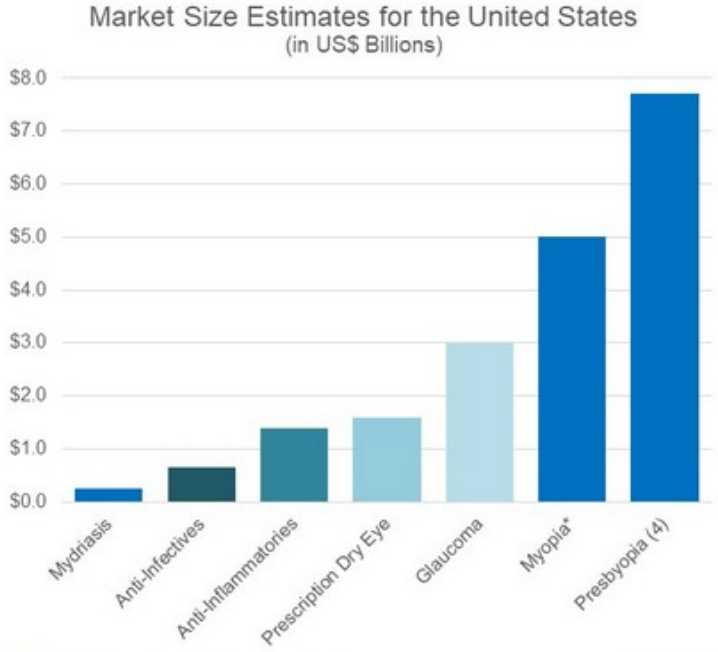
TRANSCEND MEDICAL · INNOVATIVE DRIVE · IanTech

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: ~$12.9 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.

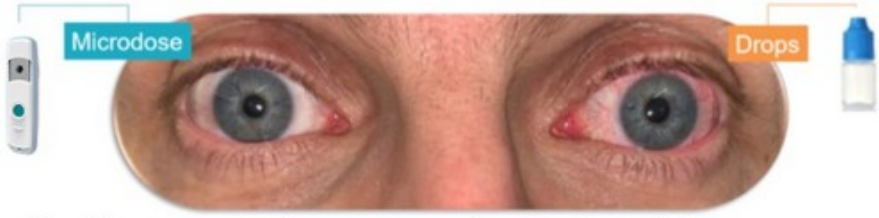
Glaucoma: ~$3 Billion[3]

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 both IOP reduction and pharmacological mydriasis.[2,3]

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:

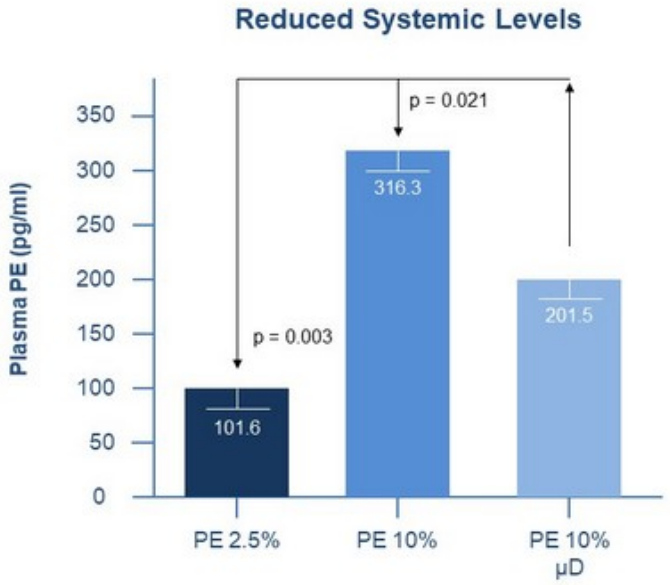
Can be paired with smart devices to enable dosage reminders and tracking.

[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

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.

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]

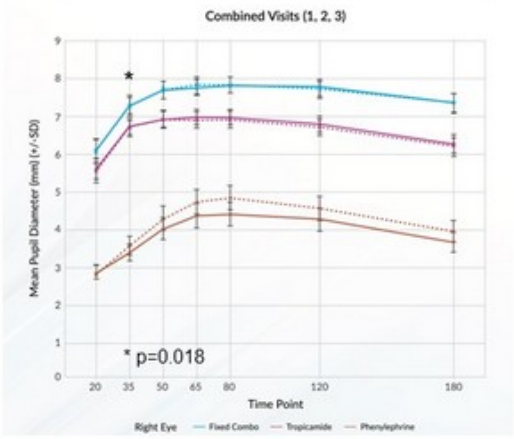
[1] Muller, M., van der Velpe, N., Jaap, W., van der Cammen, T.; Syncope and falls due to timolol eye drops. BMJ, 2006 April; 332:960-961
[2] Ianchulev, I. High-precision piezo-ejection ocular microdosing: Phase II study on local and systemic effects of topical phenylephrine. Ther Deliv, 2018 Jan;9(1):17-27

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

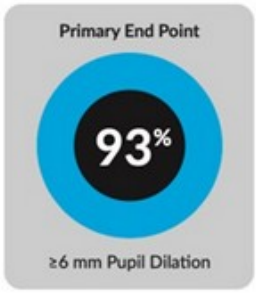
MIST-1



MIST-2

Percent of Patients Attaining 6 mm or Greater Pupil Dilation (exploratory analysis)

35 Minutes Post-Administration vs Baseline



[1] Wirta, D. Presented at ASCRS Annual Meeting, 2019, San Diego CA

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 follow the 505(b)(2) registration pathway and are not currently regulated as medical devices or drug-device combinations
- The FDA categorizes the Optejet as a container closure system

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)

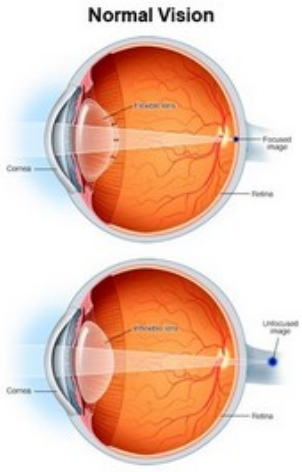
MicroLine for Presbyopia

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

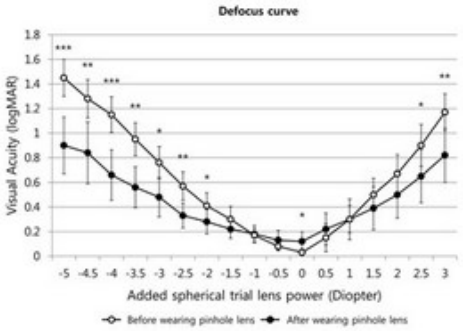
- Basic eye exam, with refraction assessment

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

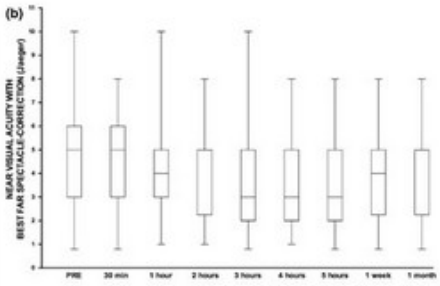
Pilocarpine: Dual Action Mechanism Improves Near Vision

- Pilocarpine is a Miotic (cholinergic) and has a clinically established dual action mechanism
- Accommodation and extended-depth of focus
- Optimized profile through microdose

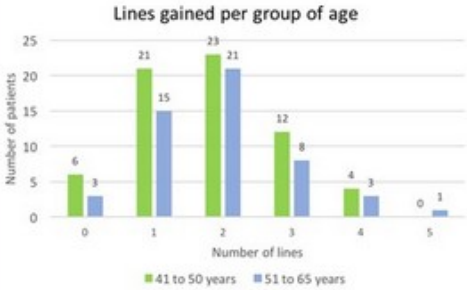
Pin-Hole Effect Improves Near Vision[1]



Pilocarpine Topical Near Vision Effect[2]



Pilocarpine Topical Near Vision Effect[3]



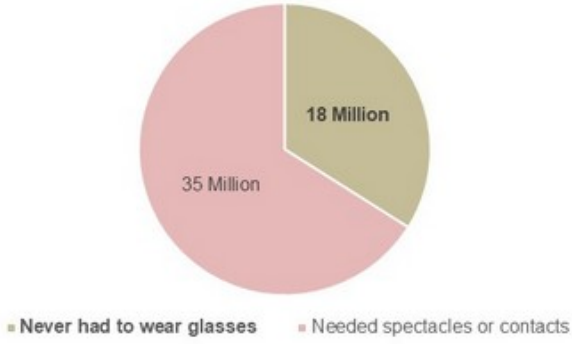
Number of lines gained in near vision 2h after instillation of one eye drop to each eye according to age group

[1] Seminars in Ophthalmology, 2019; 34(2): 106–114
[2] Ophthalmol Ther (2016) 5:63–73
[3] Ophthalmol Ther (2019) 8:31–39

Pharmacologic Treatment of Presbyopia: Targeting Millions of Patients Who "Never Wore Glasses"

~113 million people in the US are presbyopic

Of the ~53 million adults between 40 and 55 years of age, ~18 million previously never had to wear glasses



- 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

Sources; US Census; http://cureresearch.com/a/astigmatism/stats-country_printer.htm (accessed 9-28-20)
Fricke, T and Tahhan, N. Global Prevalence of Presbyopia and Vision Impairment from Uncorrected Presbyopia. 2018 Global Presbyopia Market Scope Research Report. Cataract & Refractive Surgery Today Europe. Accessed December 2018. Population estimates from U.S. Census (census.gov); presbyopia incidence from AAO.

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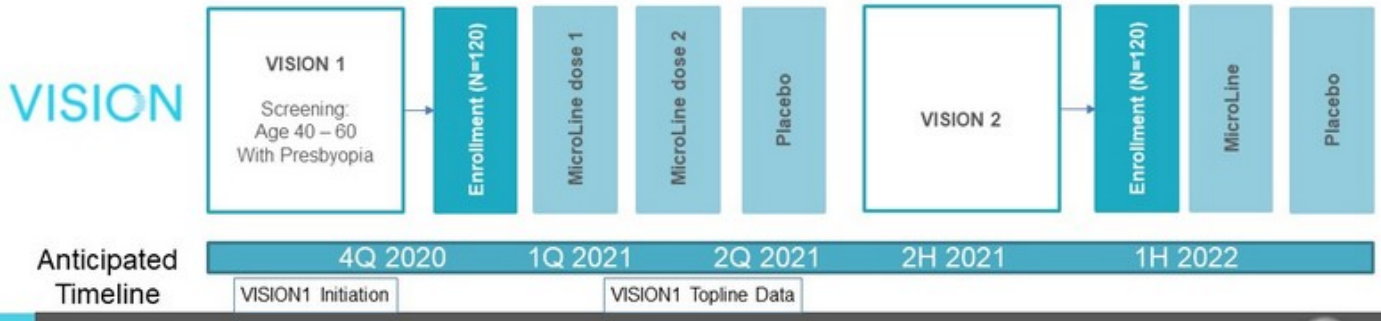
MicroLine: Phase 3 Program

- Two double-masked, placebo-controlled, cross-over superiority trials
  - Phase 3 (microdosed pilocarpine dose 1, dose 2 and placebo)
- Primary endpoint: binocular distance corrected near visual acuity
- First patient enrolled in VISION 1: December 2020



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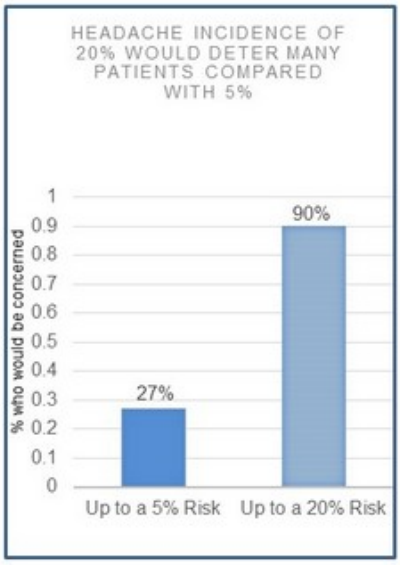
Eyenovia Offers Value Beyond Other Late-Stage Pilocarpine Therapies

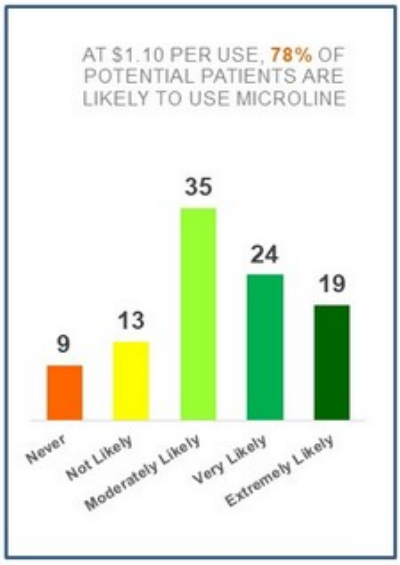
MicroLine Compared with the Standard Presbyopia Drop



OPTEJET VS. DROPPER

3 : 1

PREFER THE OPTEJET



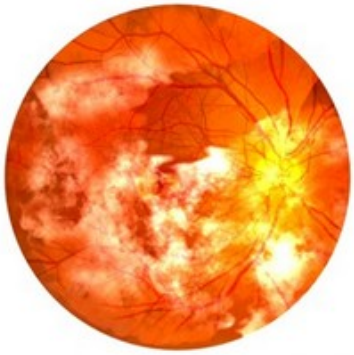
Source: Reckner and Associates, 2021 (data on file)

Late Stage Presbyopia Competitive Landscape

Trial	Compound	Company	3-line gain	2-line gain	Safety	Completion date	NDA Status
GEMINI-1 PIII	Pilo 1.25%	ALLERGAN/ ABBVIE	MET (40 – 55 YO)		Headache No serious AEs	Q3 2020	Filed 2/2021
GEMINI-2 PIII	Pilo 1.25%	ALLERGAN/ ABBVIE	MET (40 – 55 YO)		Headache No serious AEs	Q3 2020	
NEAR 1 PIII	Pilo+	ORASIS				Recruiting 45 – 64 YO Q2 2021	
NEAR 2 PIII	Pilo+	ORASIS				Recruiting 45 – 64 YO Q2 2021	
VISION 1 PIII	Pilo 1%, 2%	EYEN				Recruiting 40 – 60 YO Study results expected Q2 2021	

Source: Company press releases and clinicaltrials.gov

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** and **MicroLine**

Upfront payment: $4M

Potential milestone payments and reimbursed development costs: $41.75M

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

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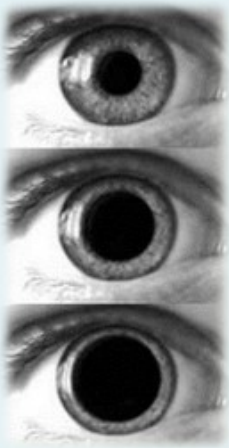
MydCombi for Mydriasis

- Pharmacologic mydriasis (pupil dilation) is part of the comprehensive eye exam
  - Estimated 80 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
- NDA accepted March 2021



[1] $160M annual sales of pharmaceutical mydriatic products used during 80M office-based exams ($2 * 80M) + $80M of single bottle mydriatic agents used cataract replacement surgery ($20 x 4M)

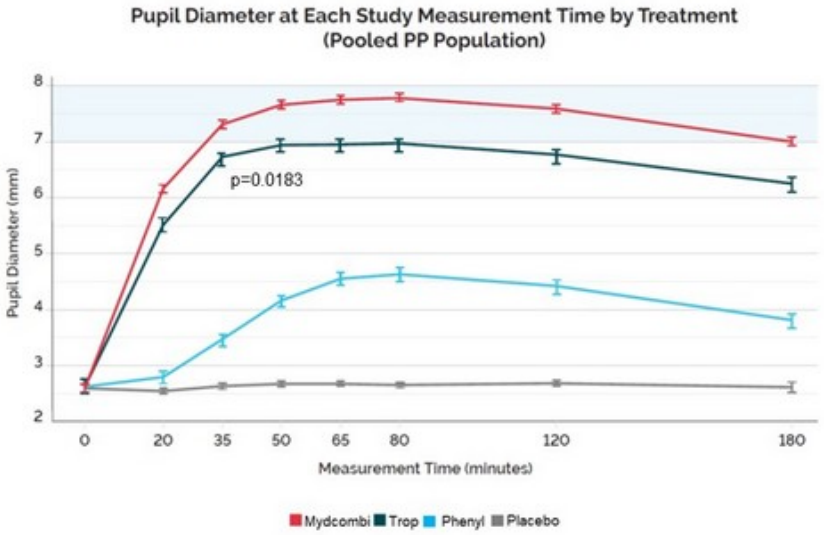
MydCombi
Does So Much with So Little

MydCombi
Tropicamide 1%/Phenylephrine 2.5%
Ophthalmic Spray

- 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

Significant, prompt mydriasis achieved with microdose fixed-combination Phen-Trop

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

Expense	Typical Launch	MydCombi Launch	Rationale
Sales Force	100 FTE @ $150K = $15M	11 FTE @ $150K = $1.7M	Only need to call on group practices; no need for ongoing visits
Managed Care Department	8 FTE @ $150K = $1.2M	0	No third-party payer; no formulary (cash to office)
Rebates and Logistics	8 – 12% of sales plus 2 FTE	9% of sales	Single specialty pharmacy partner
Promotion	$25M	$2M	Very little "noise" to break through; no direct-to-patient element; targeted education for technicians
Total	~$50M	~$5M	

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 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	24.9M
Equity Grants Outstanding Under Stock Plans	3.5M
Warrants	2.3M
Fully Diluted Shares	30.7M
Cash	$22.9M
Debt	None

Appendix

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


eyenovia
Making it Possible
March 2021