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): August 11, 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
(Address of Principal Executive Offices, and Zip Code)

(917) 289-1117
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, $0.0001 par value	**EYEN**	**The Nasdaq Stock Market (Nasdaq Capital Market)**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒

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

Item 2.02 Results of Operations and Financial Condition

On August 11, 2021, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal second quarter and six months ended June 30, 2021. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information contained in, or incorporated into, Item 2.02, including the press release attached as Exhibit 99.1, is being furnished and shall not be deemed "filed" for the 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 incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Item 8.01. Other Events.

Attached hereto as Exhibit 99.2 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. Press Release dated August 11, 2021
99.2	Eyenovia, Inc. corporate update presentation dated August 2021

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: August 11, 2021

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Reports Second Quarter 2021 Financial Results

Announced positive topline data from its Phase 3 VISION-1 study evaluating MicroLine for the treatment of presbyopia

Company on track to initiate second Phase 3 presbyopia trial, VISION-2, by year-end 2021

MydCombi PDUFA date confirmed for October 28, 2021

Company to host conference call and webcast today, August 11, at 4:30pm ET

NEW YORK—August 11, 2021—Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on its proprietary microdose array print (MAP™) platform technology, today announced its financial and operating results for the second quarter ended June 30, 2021.

Second Quarter 2021 and Recent Business Highlights

- Announced positive topline data from the company's Phase 3 VISION-1 clinical trial of its proprietary presbyopia therapy, MicroLine.

  Select data highlights include:

  - Subjects treated with MicroLine 2% were 7.7 times more likely to achieve the primary endpoint of 3-line or greater improvement in near vision as compared to placebo (Odds Ratio=7.7; statistically significant difference $p<0.05$).
  - 71% of patients reported a meaningful improvement in near vision according to an exit survey conducted by study investigators.
  - MicroLine had a favorable safety profile, with no serious adverse events and fewer than 3% of study participants reporting headache (including brow ache), instillation discomfort or moderate hyperemia.

- Based on the positive results from the VISION-1 trial, the company is advancing plans to initiate a second Phase 3 trial of MicroLine, VISION-2, by year end 2021.
- PDUFA date from the Company's pupil dilation agent, MydCombi™, confirmed for October 28, 2021.
- Participated in a panel discussion on presbyopia at Eyecelerator 2021
- Participated in the Ladenburg Thalmann 2021 Healthcare Conference and the William Blair Biotech Focus Conference 2021

Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia, commented, "We are pleased to report another productive quarter for Eyenovia. The recently announced positive topline data from our Phase 3 VISION-1 trial of MicroLine in presbyopia highlights the impressive potential of our ophthalmic and Optejet® platform. With compelling efficacy and tolerability in patients, MicroLine, if approved, could become a promising new alternative for patients who desire a temporary, on demand alternative to reading glasses, particularly in indoor or low light conditions, a clear differentiator versus many other presbyopia therapeutics in development. We continue to anticipate initiating a second Phase 3 trial, VISION-2, by the end of the year, and anticipate topline data in mid-2022.

“We are actively preparing for our MydCombi PDUFA date, which has been confirmed for October 28 of this year. We believe MydCombi, our mydriatic candidate, has the potential to become the new standard of care for the approximately 100 million comprehensive eye exams conducted every year in the U.S. alone.

“The MicroLine and MydCombi programs, together with MicroPine, which we have out-licensed to Bausch Health and Arctic Vision for up to $100 million in potential development milestones, compose our late-stage pipeline with three promising candidates and a potential approval as early as October. We look forward to providing updates on our progress during the remainder of the year,” Dr. Ianchulev concluded.

Second Quarter 2021 Financial Review

For the second quarter of 2021, net loss was approximately $4.8 million, or $(0.19) per share, compared to a net loss of approximately $5.0 million, or $(0.25) per share, for the second quarter of 2020.

For the second quarter of 2021, the Company reported license fee revenue from its Arctic Vision license agreement of $2.0 million and a corresponding cost of revenue representing payments to Senju of $800,000.

Research and development expenses for the three months ended June 30, 2021 totaled $3.6 million, an increase of 24%, as compared to $2.9 million recorded for the three months ended June 30, 2020.

For the second quarter of 2021, general and administrative expenses totaled $2.3 million, an increase of 12%, as compared to $2.1 million recorded for the three months ended June 30, 2020.

Total operating expenses for the second quarter of 2021 were approximately $6.0 million, compared to total operating expenses of approximately $5.0 million for the same period in 2020, an increase of approximately 19%.

As of June 30, 2021, the Company’s cash balance was approximately $27.2 million. This includes $7.5 million of net proceeds received from the previously announced credit facility of up to $25 million through Silicon Valley Bank (SVB). The remaining two tranches ($7.5 million and $10.0 million in gross proceeds) will be available to the Company subject to the satisfaction of certain milestones and covenants as outlined in the credit agreement.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30pm ET on Wednesday, August 11, 2021. Participants should dial 855-327-6837 (domestic) or 631-891-4304 (international) with the conference code 10015927. 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.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more information, visit www.eyenovia.com.

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

About MicroLine for Presbyopia

MicroLine is a pharmacologic treatment for presbyopia. Presbyopia is the non-preventable, age related hardening of the lens, which causes a gradual loss of the eye's ability to focus on nearby objects and is estimated to affect nearly 113 million Americans. Current treatment options are typically device-based, such as reading glasses and contact lenses. Pilocarpine ophthalmic solution is known to constrict the pupil and improve near-distance vision by creating an extended depth of focus through its small aperture effect. Eyenovia believes that its administration of pilocarpine using the Company's high precision microdosing technology could provide a meaningful improvement in near vision while enhancing tolerability and usability.

About MicroPine for Progressive Myopia

MicroPine (atropine ophthalmic solution) is Eyenovia's investigational, potentially first-in-class topical treatment for the reduction of pediatric myopia progression, also known as nearsightedness, in children ages 3-12. It has been developed for comfort and ease-of-use in children, and its microdose administration is designed to potentially result in low systemic and ocular drug exposure. MicroPine has been licensed to Bausch Health Companies, Inc. in the United States and Canada, and Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

About MicroStat (MydCombi™) for Mydriasis

MydCombi is Eyenovia's first-in-class fixed-combination micro-formulation product (tropicamide 1% - phenylephrine 2.5%) candidate for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 100 million office-based comprehensive eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. Developed for use without anesthetic, Eyenovia is developing MicroStat to help improve the efficacy and tolerability of pharmacologic mydriasis.

About Optejet® and Microdose Array Print (MAP™) Therapeutics

Eyenovia's Optejet microdose formulation and delivery platform for ocular therapeutics uses high-precision piezo-print technology to deliver 6-8 µL of drug, consistent with the capacity of the tear film of the eye. We believe the volume of ophthalmic solution administered with the Optejet is less than 75% of that delivered using conventional eyedroppers, thus reducing overdosing and exposure to drug and preservatives. Eyenovia's patented microfluidic ejection technology is designed for fast and gentle ocular surface delivery, where solution is dispensed to the ocular surface in approximately 80 milliseconds, beating the ocular blink reflex. Successful use of the Optejet has been demonstrated more than 85% of the time after basic training in a variety of clinical settings compared to 40 – 50% with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

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 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.

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EYENOVIA, INC.

Condensed Balance Sheets

	June 30, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 27,176,843	$ 28,371,828
Deferred license costs	-	1,600,000
License fee and expense reimbursements receivables	899,332	2,966,039
Prepaid expenses and other current assets	1,418,834	453,478
Total Current Assets	29,495,009	33,391,345
Property and equipment, net	968,881	396,380
Security deposit	119,035	119,035
Total Assets	$ 30,582,925	$ 33,906,760
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,667,634	$ 1,461,665
Accrued compensation	870,666	1,150,672
Accrued expenses and other current liabilities	1,054,923	1,480,692
Deferred rent - current portion	6,857	7,809
Deferred license fee	10,000,000	14,000,000
Notes payable - current portion	959,763	97,539
Total Current Liabilities	14,559,843	18,198,377
Deferred rent - non-current portion	37,632	38,684
Notes payable - non-current portion	6,994,893	365,814
Total Liabilities	21,592,368	18,602,875
Commitments and contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized;0 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 25,946,646 and 24,978,585 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	2,595	2,498
Additional paid-in capital	96,621,948	92,742,306
Accumulated deficit	(87,633,986)	(77,440,919)
Total Stockholders' Equity	8,990,557	15,303,885
Total Liabilities and Stockholders' Equity	$ 30,582,925	$ 33,906,760

EYENOVIA, INC.

Condensed Statements of Operations

(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating Income				
Revenue	$ 2,000,000	$ -	$ 4,000,000	$ -
Cost of revenue	(800,000)	-	(1,600,000)	-
Gross Profit	1,200,000	-	2,400,000	-
Operating Expenses:				
Research and development	3,616,382	2,915,250	7,864,108	6,549,537
General and administrative	2,347,191	2,104,163	4,647,518	3,940,945
Total Operating Expenses	5,963,573	5,019,413	12,511,626	10,490,482
Loss From Operations	(4,763,573)	(5,019,413)	(10,111,626)	(10,490,482)
Other Income (Expense):				
Small Business Administration Economic Injury Disaster Grant	-	10,000	-	10,000
Interest expense	(78,047)	(6,351)	(83,195)	(10,032)
Interest income	220	199	1,754	24,039
		-		
Net Loss	$ (4,841,400)	$ (5,015,565)	$ (10,193,067)	$ (10,466,475)
Net Loss Per Share				
- Basic and Diluted	$ (0.19)	$ (0.25)	$ (0.40)	$ (0.56)
Weighted Average Number of Common Shares Outstanding				
- Basic and Diluted	25,927,303	19,821,215	25,630,572	18,563,864

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

Late-stage therapeutics pipeline

MicroStat (Mydcombi™) for mydriasis (pupil dilation):
NDA PDUFA date expected October 28, 2021

MicroPine for pediatric progressive myopia:
Phase 3 CHAPERONE study full enrollment expected 1H 2022

MicroLine for presbyopia (improved near vision):
Phase 3 VISION-1 study successfully completed 2Q 2021
Second Phase 3 VISION-2 study scheduled to begin 2H 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

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

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

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
COO

Allergan · Bayer · Pfizer · aerie

Jennifer Clasby
VP Regulatory, Clinical and Quality

TRANSCEND MEDICAL · AMO

Luke Clauson
VP R&D, Manufacturing

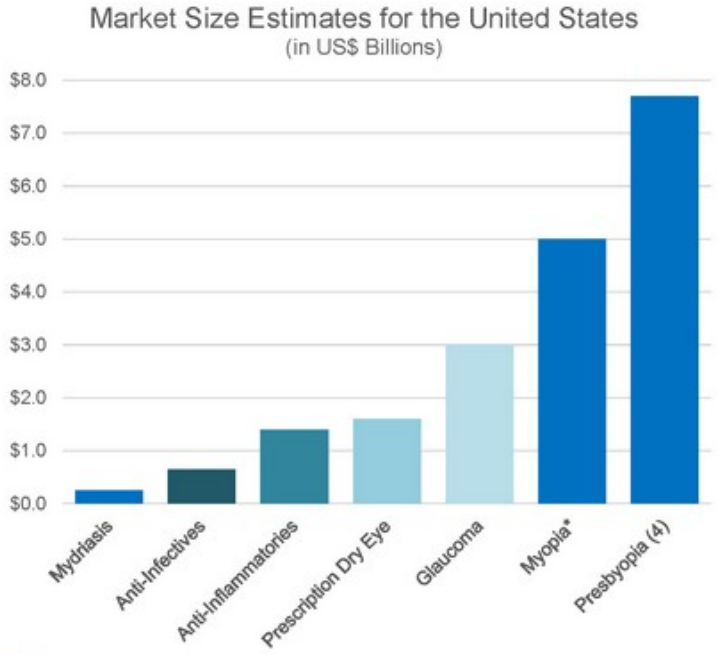
TRANSCEND MEDICAL · INNOVATIVE DRIVE · IanTech

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: ~$12.7 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.

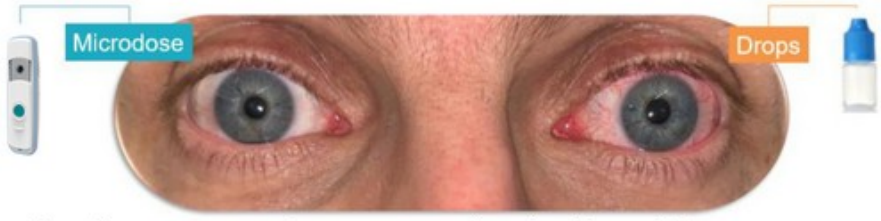
Glaucoma: ~$3 Billion[3]

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.

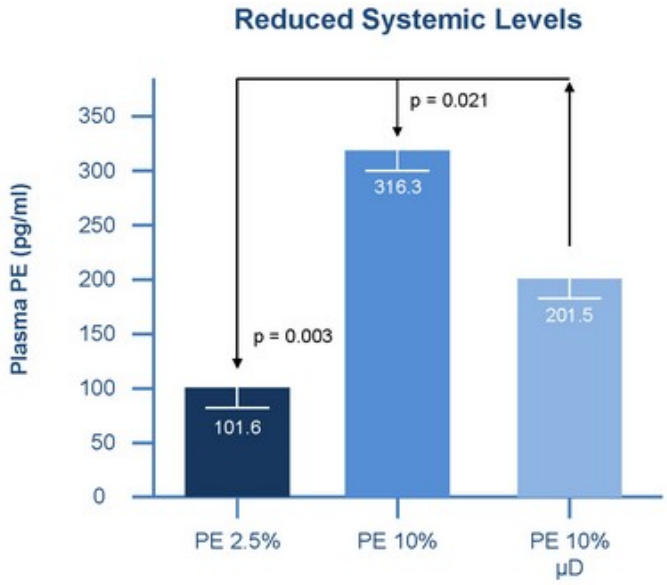
[1] Abelson, M., 2020. The Hows And Whys Of Pharmacokinetics. ReviewofOphthalmology.com; accessed 11/3/20
[2] Pasquale L. et al., Clinical Ophthalmology 2018
[3] Wirta D. et al, Presentation at 2019 ASCRS meeting
[4] Ianchulev T. et al, Therapeutic Delivery 2018
[5] Presented at Eyecelerator, July 2021

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]

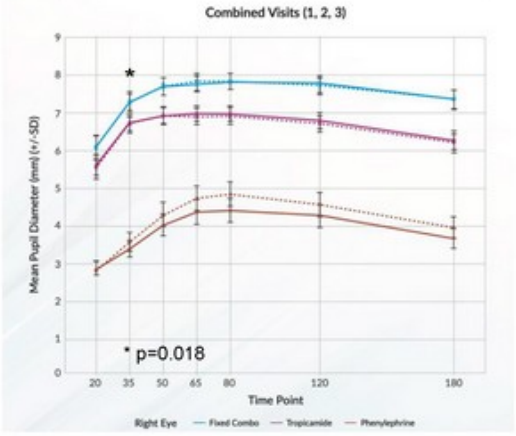
[1] Muller, M., van der Velpe, N., Jaap, W., van der Cammen, T.; Syncope and falls due to timolol eye drops. BMJ, 2006 April; 332:960-961
[2] Ianchulev, I. High-precision piezo-ejection ocular microdosing: Phase II study on local and systemic effects of topical phenylephrine. Ther Deliv, 2018 Jan;9(1):17-27

Optejet: Demonstrated Effectiveness in Multiple Phase 3 Studies

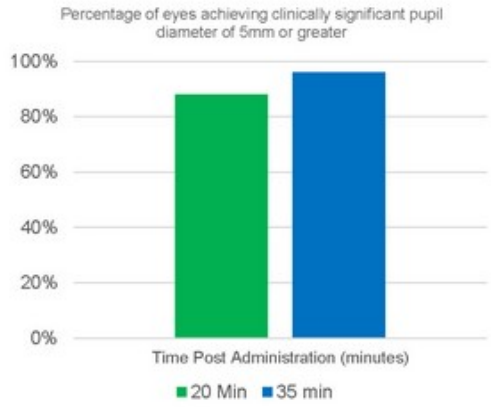
Microdosing a fixed combination of tropicamide-phenylephrine
had a superior mydriatic effect compared to either component formulation[1]

Microdose Efficacy

MIST-1



Combined MIST Studies[1,2]



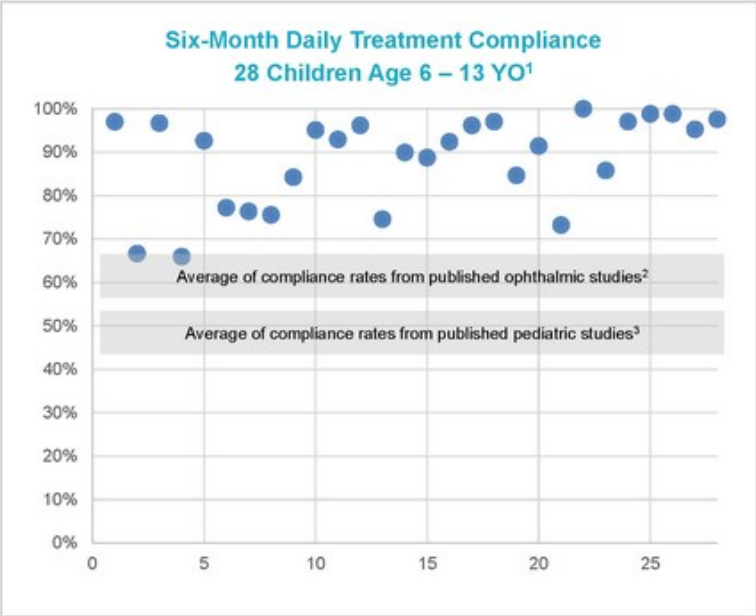
1. Wirta DL, Walters TR, Flynn WJ, Rathi S, Ianchulev T. Mydriasis with micro-array print touch-free tropicamide+phylephrine fixed combination MIST: pooled randomized phase III trials. Ther Deliv; 2021
2. Data on File, Eyenovia 2021

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

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)

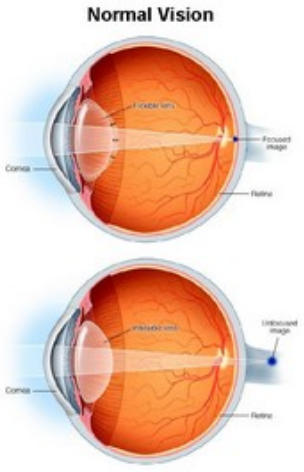
MicroLine for Presbyopia

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

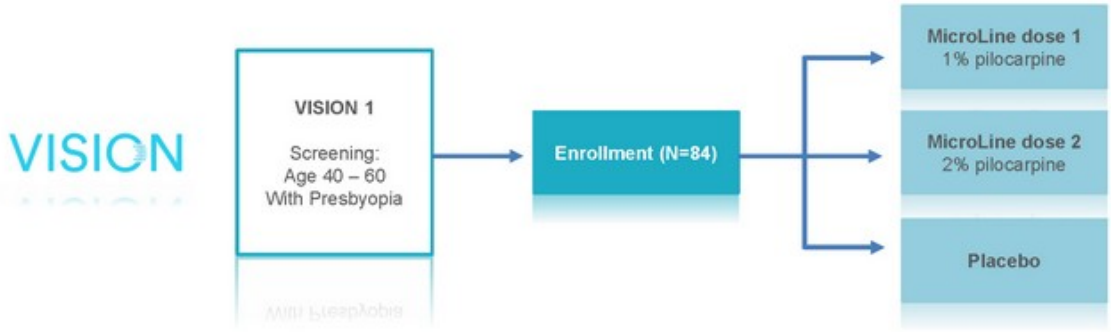
MicroLine Achieves Primary Endpoint in Phase 3

- [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 H2 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%

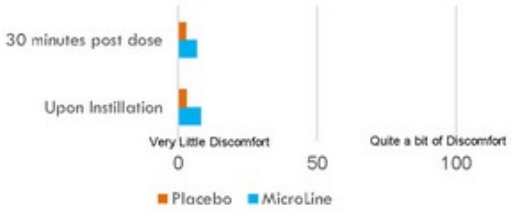
Exit survey: Percent reporting significant improvement in near vision

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

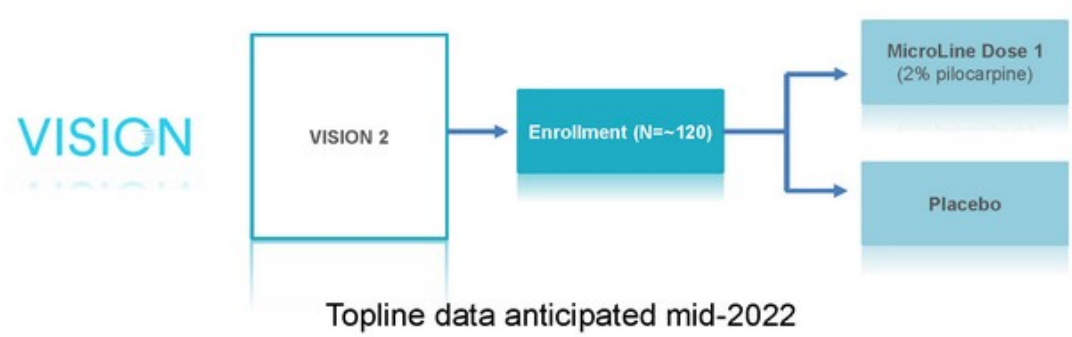


[1]Resolved by 3 hours post-dose

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

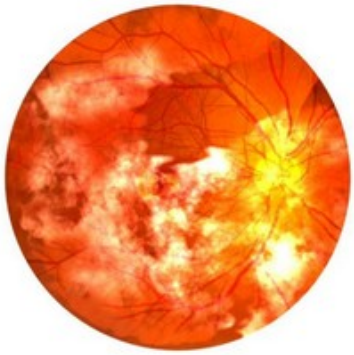
- Effective at restoring functional vision, such as the ability to read a menu or cell phone
- Ability to use “as needed” without chronic dosing
- Rapid onset of action
- Easy to administer
- Comfortable instillation with low incidence of brow or headache to drive patient satisfaction and re-use

Late-Stage Presbyopia Competitive Landscape

Company	API	Trial	Primary EP	Outcome	Status
eyenovia	Pilocarpine 2%	VISION-1 (40-60 YO)	Gain of 3 lines or more in mesopic, high contrast, binocular (DCNVA) at Hour 2 vs. placebo (vehicle)	Met primary EP	Completed; planning for VISION-2
Allergan	Pilocarpine 1.25%	Gemini I, II (40-55 YO)	Gain of 3 lines or more in mesopic, high contrast, binocular (DCNVA) at Day 30, Hour 3 vs. placebo (vehicle)	Met primary EP	PDUFA mid-December 2021
Ocuphire	Nyxol (phentolamine 0.75%) and pilocarpine	VEGA-1 (phase II)	Gain of 3 lines or more in photopic, binocular (DCNVA) over 6 hours vs. placebo (vehicle) under photopic (non-FDA endpoint) conditions	Met Primary EP	Preparing for Phase 3
VISUS THERAPEUTICS	Brimochol (carbachol and brimonidine)	NCT04774237 (phase II)	Change from baseline in near VA	Not Yet Completed	Actively Recruiting; Topline expected mid 2021
ORASIS PHARMACEUTICALS	Pilocarpine 0.2% and NSAID	NEAR-1 NEAR-2 (45-64 YO)	Gain of 3 lines or more at 40cm and no loss in BDCVA greater or equal to 5 letters at 4 meters on Day 8	Not Yet Completed	Actively Recruiting
LENZ THERAPEUTICS	Aceclidine 2.0%	NCT03201562 (phase IIb) (48-64 YO)	Gain of 3 lines (15 letters) or more at 45cm in DCNVA at one hour vs. placebo	Met primary EP	Preparing to move into Phase 3

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

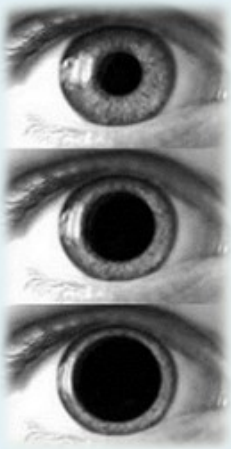
US impacted population with high myopia estimated at approx. 3M[2,3]

[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

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
- PDUFA date October 28, 2021



[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

MydCombi

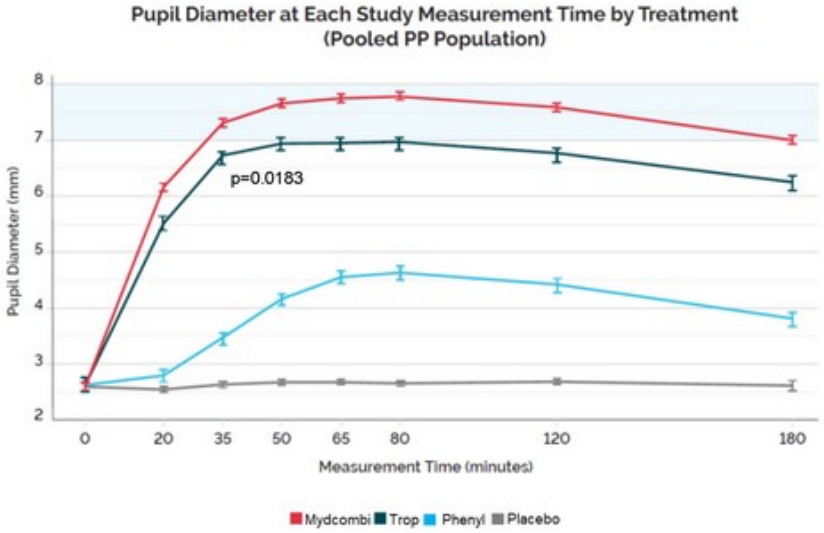
Tropicamide 1%/Phenylephrine 2.5%

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

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

eyenovia

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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Making it Possible
August 2021