UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) November 19, 2019

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.

On November 19, 2019, Eyenovia, Inc. presented a corporate update to analysts and investors. A copy of the corporate update is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Eyenovia, Inc. corporate update dated November 2019.

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: November 19, 2019

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 in the United States for our product candidates. 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 SEC.

In addition, such statements could be affected by risks and uncertainties related to, among other things: the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our ability to identify new product candidates; 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; the potential advantages of our product candidates; risks involved in clinical trials, including, but not limited to, the design, initiation, timing, progress and results of such trials; the timing and our ability to submit applications for, and obtain and maintain regulatory approvals for, our product candidates; our ability to timely develop and implement anticipated manufacturing, commercialization and marketing capabilities and strategies for existing product candidates; fluctuations in our financial results; our ability to raise money; 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, we do not undertake any obligation to update any forward-looking statements.

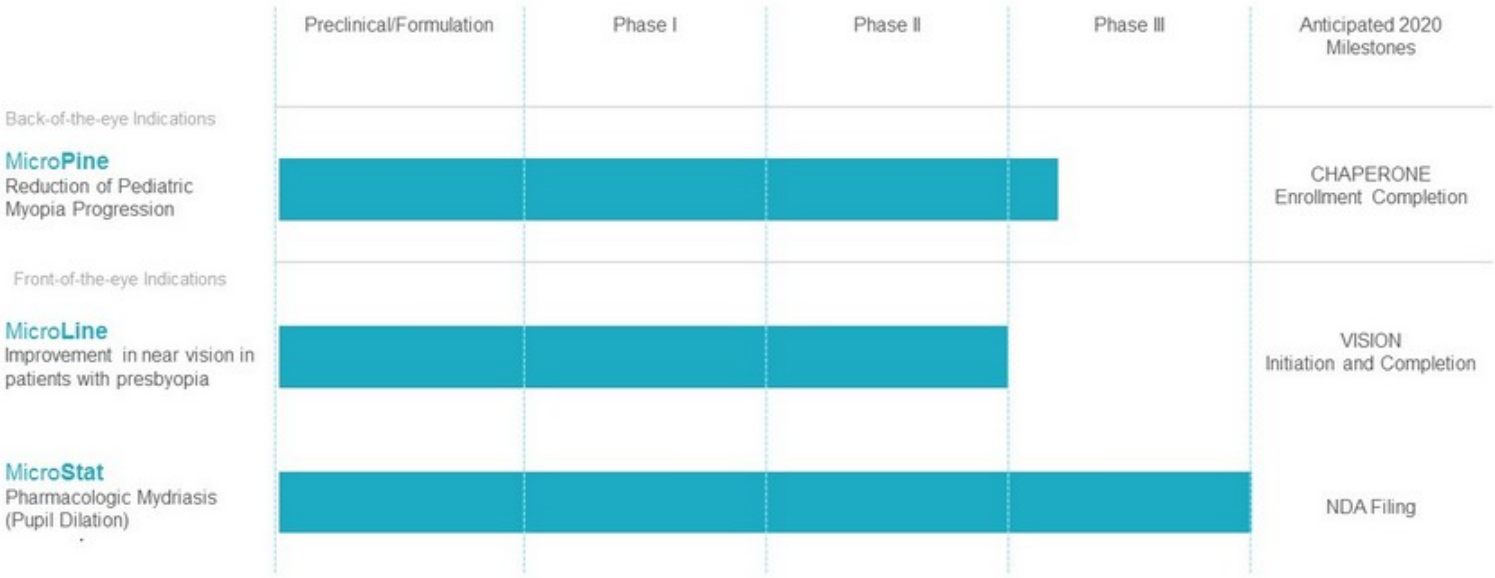
Eyenovia: Building the Smart Eye Care Company of the Future

- Specialty ophthalmic biopharmaceutical company developing a late stage pipeline of microdose therapeutics in areas of key front and back-of-the-eye indications
- Validated microdosing approach through multiple Phase II/III studies
- **Progressive Myopia**: Complete patient enrollment for Phase III CHAPERONE study in 2020
- **Presbyopia**: Initiate and complete Phase III VISION studies in 2020
- **Pharmacologic Mydriasis**: Phase III studies successful, New Drug Application to be submitted in 2020

* Estimate for U.S. market only

[1] In-office and cataract surgery uses

Multiple Late Stage Clinical Assets

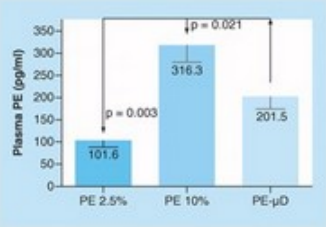


Significant Clinical Experience and Validation

Completed Clinical Trials

- Ph II — **MicroStat** — Pheneylephrine Mydriasis
- Ph II — **MicroStat** — Phen + Trop Mydriasis
- Ph II — **EYN PG21** — IOP Lowering, Safety & Usability
- Ph III — **MicroStat** — MIST-1 Mydriasis Program
- Ph III — **MicroStat** — MIST-2 Mydriasis Program

Reduced Systemic Levels



Microdose delivery of phenylephrine was associated with significantly less systemic exposure (Ianchulev, 2017)

Improved Ocular Tolerability

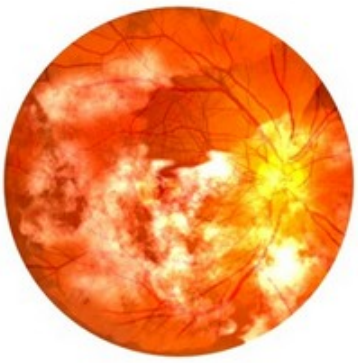
Microdosing May Reduce Side Effects[1]

MicroDose Efficacy

Mydriasis with microdose phen-trop fixed combination (Wirta, 2019)

[1] Wouldn't it be great if eyedrops didn't spill out of your eyes? Science Daily. 2017 Nov

Progressive Myopia: Back-of-the-eye disease affecting ~5M in the U.S.



Progressive of Myopic Maculopathy

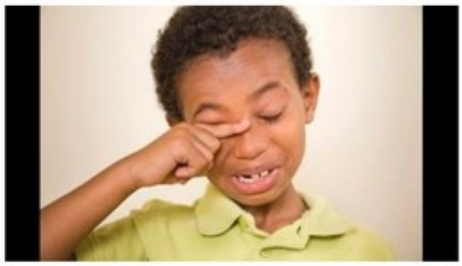
- Pathologic elongation of sclera/retina which can lead to significant morbidity and visual sequelae[1]
  - Retinal detachment
  - Myopic retinopathy
  - Vision loss
  - Quality of life
- Mostly occurs in young adults and children
  - ~9% of children in the United States[2]
  - ~10% of the world population by 2050[3]
- Currently, no FDA-approved drug therapies to slow myopia progression
- Atropine may slow myopia progression by 60% or more[4]

(1) Eye and Contact Lens. 2004; 30
(2) Arch Ophthalmol. 2003 Aug;121(8):1141-7).
(3) Ophthalmology. 2016;123:1036-1042
(4) Ophthalmology. 2016;123:391-399

There are no known FDA-approved Pharmaceutical Therapies for Myopia

- Significant unmet need as demonstrated by ATOM1, ATOM2 & LAMP studies
- Compounding of atropine in the absence of FDA-approved therapeutic driven by clinical need
- Mostly distributed by compounding pharmacies with limited central quality control

Not Shelf Stable[1]



Often Not Tolerable[2]

Not Currently Covered by 3rd Party Insurance

(1) Patient.info: Atropine eye drops. 2018 Mar
(2) AAO: How to Use Low-Dose Atropine to Slow Myopic Progression in Kids. 2016 Dec

MicroPine for Progressive Myopia

- MicroPine is Eyenovia's proprietary piezo-compatible microdose formulation of atropine
- One of the first topical therapeutic approaches to prevent a number of back-of-the-eye diseases
- Single Phase III CHAPERONE trial initiated in June 2019
  - Primary EP: Change in refractive error (myopia progression) from baseline through 36 months

Presbyopia: the Progressive Loss of Ability to Focus on Nearby Objects

Etiology

- Non-preventable, age-related hardening of the lens

Symptoms

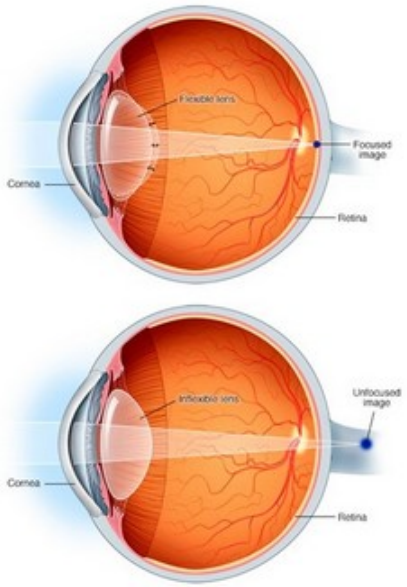
- Tendency to hold reading material farther away to make the letters clearer
- Blurred vision at normal reading distance
- Eye strain, headaches after reading or doing close-up work

Risk Factors

- Age
- Medical conditions and co-morbidities such as cardiovascular conditions, multiple sclerosis and type 2 diabetes can increase risk of premature presbyopia
- 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

Presbyopia is a Widely Prevalent Vision Correction Issue

~113 Million Americans with Presbyopia

~43 Million Americans between age 40-65 with Presbyopia and otherwise normal vision and adequate disposable income

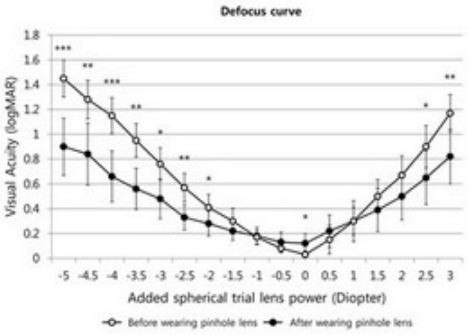
- Prevalence expected to increase and affect ~123 million Americans by 2020, representing over 1/3 of United States population; driven by aging population
- Nearly everyone experiences some degree of presbyopia after age 40
- Up to 1/3 of presbyopia sufferers are un-managed
- Presbyopia is a significant and emotional event in an adult's life – and often seen as the first sign of aging they cannot hide
- **Psychosocial impact is most important between onset (~40yo) and retirement age; this subset is also most likely to respond to Rx treatment, and willing to pay for it**

Sources: T, Fricke and N, Tahhan, 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.

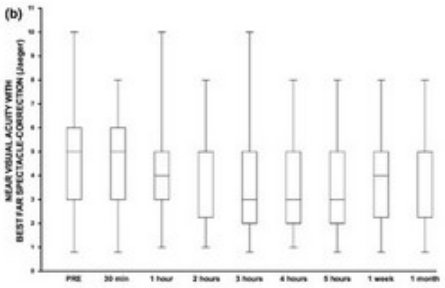
Pilocarpine: Dual Action Mechanism

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

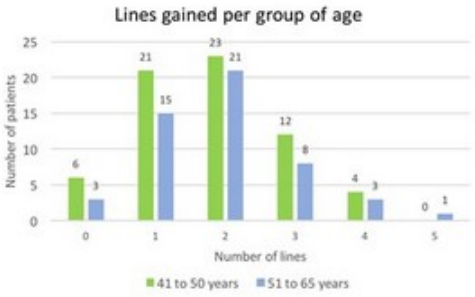
Pin-Hole Effect Improves Near Vision[1]



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

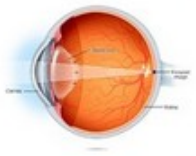
[1] Seminars in Ophthalmology, 2019; 34(2): 106–114
[2] Ophthalmol Ther (2016) 5:63–73
[3] Ophthalmol Ther (2019) 8:31–39

Micro**Line**: Targeted Corneal Horizontal Delivery with Gentle Microdose

Indication	• For the improvement in near vision in patients with presbyopia • Provides approximately 3-4 hours of near vision with a single microRx spray
Program Overview	• Two Phase III trials ready for initiation in 2020
Commercial	• Estimated addressable population: Adults between 40-65 years old with otherwise normal vision and adequate disposable income • Estimated addressable United States market: $2B+ • Anticipated reimbursement: Cash pay
Competition	• Anticipated among first to market, including Allergan's pilocarpine Phase III eyedrop program • Eyenovia is the only presbyopia product with piezo-print horizontal delivery and microdosing, designed to address potential pilocarpine side effects and improve user experience

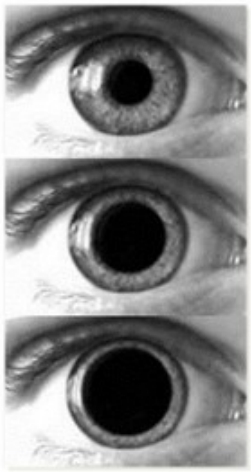
MicroLine: Phase III Program

- Two double-masked, placebo-controlled, cross-over superiority trials
  - Phase III (microdosed pilocarpine 1.0%, 2.0% and placebo)
- Primary endpoint: binocular distance corrected near visual acuity
- Expect both studies to be initiated and completed in 2020



Micro**Stat** for Mydriasis

- Pharmacologic mydriasis 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
- Reported positive results from Phase III MIST-1 and MIST-2 trials at the 2019 ASCRS annual meeting
- Places technology at the initial point-of-care with prescribers (ophthalmologists and optometrists)
- Differentiated best-in-class profile with improved simplicity, reliability and tolerability
- No anticipated reimbursement hurdles; expect to sell directly to ophthalmology and optometry practices
- Expected NDA filing in 2020



Micro**Stat** Phase III Key Take-Aways

1. Significant, prompt mydriasis achieved with microdose fixed-combination Phen-Trop
2. Micro**Stat** achieved superior efficacy over single-agent components
3. Mydriasis >6 mm achieved in >93% of patients at 35 minutes post-dose
   - Clinically meaningful for both office retinal exam and surgical dilation

Optejet™: Eyenovia's Unique Technology

- **Novel microdosing technology designed for optimal drug delivery**
  - Piezo-print microdosing to increase precision and reduce waste
  - Approximately 75% less drug and exposure to preservatives (based on 8µL dose)
  - Designed to eliminate drug overflow for a more comfortable patient experience
  - Non-protruding nozzle for no-touch spray application, potentially minimizing risk of cross contamination seen with traditional eye droppers
  - Smart Bluetooth technology to help monitor patient compliance
- **Efficient:** Demonstrated statistical and clinically significant efficacy in both IOP reduction and pharmacological mydriasis[1,2]
- **Safe:** Low systemic drug absorption and good ocular tolerability[2,3]
- **Easy of use:** Both in the hands of medical professionals and patients[1]

[1] Pasquale L. et al., Clinical Ophthalmology 2018
[2] Wirta D. et al, Presentation at 2019 ASCRS meeting
[3] Ianchulev T. et al, Therapeutic Delivery 2018

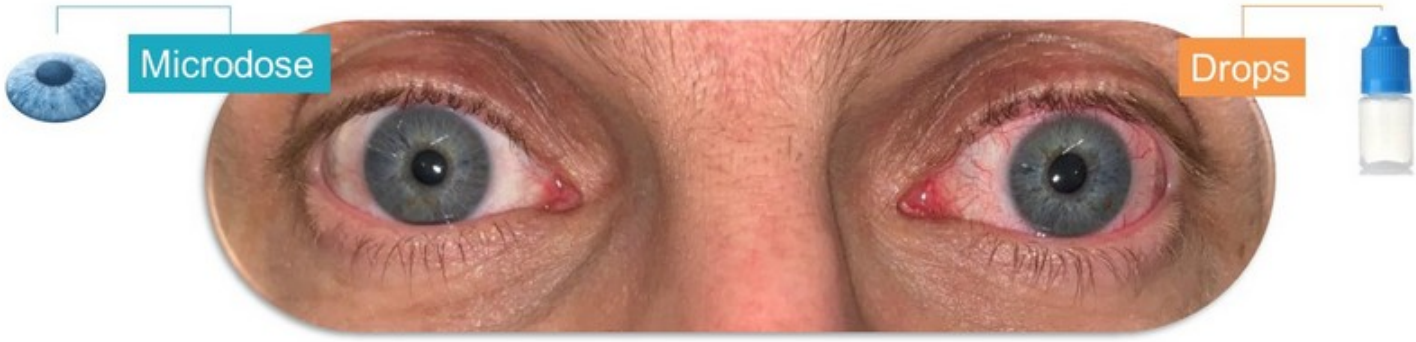
EYN PG21: Patients More Likely to Instill Medication with Optejet™

	Optejet™ Technician Administration	Optejet™ Self Administration	Standard of Care Eyedropper
Total Evaluable Administrations	150	53	
Successful Delivery on First Attempt	95%	88%	39-47%*
Touching Ocular Surface	0%	0%	50+%*

*Arch Ophthalmol 2009;127:6:732-6; Am J Ophthalmol. 2011 Dec;152(6):982-8. doi: 10.1016/j.ajo.2011.05.015. Epub 2011 Aug 6
Br J Ophthalmol 199579:4:376-9, J Cataract Refract Surg. 2014 Nov;40(11):1857-61. doi: 10.1016/j.jcrs.2014.02.037. Epub 2014 Sep 22

Microdosing May Reduce Side Effects

- Conventional eye drops may overdose the ocular surface by as much as 300%[1-3]
  - This potentially can cause significant ocular and systemic side effects[4]
- Microdosing has the potential to address these issues by reducing the amount of drug and exposure to preservatives



[1] Washington N, Washington C, Wilson CG. Ocular drug delivery. In: Physiological Pharmaceutics: Barriers to Drug Absorption. 2nd ed. Boca Raton, FL: CRC Press; 2001:249–270.
[2] Mishima S, Gasset A, Klyce SD, Baum JL. Determination of tear volume and tear flow. Invest Ophthalmol. 1966;5(3):264–276.
[3] Scherz W, Doane MG, Dohlman CH. Tear volume in normal eyes and keratoconjunctivitis sicca. Albrecht Von Graefes Arch Klin Exp Ophthalmol. 1974;192(2):141–150.
[4] Wouldn't it be great if eyedrops didn't spill out of your eyes? Science Daily. 2017 Nov

Eyenovia's Platform Unlocks Pharmaceutical Pipeline Opportunity

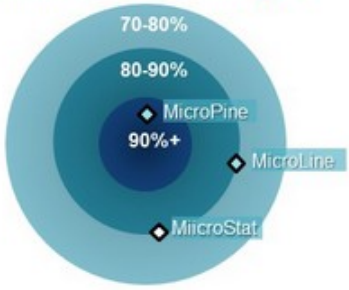
Next-Generation Ophthalmic Therapeutics

- Eyenovia's microdose therapeutics follow the 505(b)2 registration pathway and are **NOT** currently regulated as medical devices or drug-device combinations
- FDA considers the Optejet™ to be a container system

Eyenovia products aim to provide pharmaceutical margins

- All pipeline products are Eyenovia's own proprietary micro-formulations
- Eyenovia currently owns the pharma-economics of the entire prescription value chain
- Micro**Line** has strong potential as a cash-pay cosmeceutical
  - Certain other ophthalmic cosmeceuticals have been well-received into the market with quick penetration

Estimated Gross Margins



Experienced 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
Genentech
IanTech

John Gandolfo
CFO

BIOJECT
XTANT MEDICAL
Power Medical Interventions

Michael Rowe
VP Commercial

Allergan
Pfizer
aerie
BAYER

Jennifer Clasby
VP Clinical Operations

TRANSCEND MED CAL
AMO
PROMEDICA INTERNATIONAL

Dr. Lee Kramm
VP Regulatory Affairs

University of Colorado Denver
FDA

Luke Clauson
VP R&D, Manufacturing

TRANSCEND MED CAL
Carpisa
IanTech
INNOVATIVE DRIVE

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Managing Director, Co-Head Equity Capital Markets at BTIG

Dr. Anthony Sun
Board Member

Former partner at Aisling Capital

Dr. Sean Ianchulev
Board Member

CEO, CMO and Co-Founder of Eyenovia

Multiple Inflection Points in 2020

MicroPine: Progressive Myopia

2020 Enrollment completion

MicroLine: Presbyopia

2020 Phase III trial initiation and completion

MicroStat: Mydriasis

2020 NDA submission

Financials

Nasdaq:	EYEN
Share Price[1]	$2.83
Market Cap (fully diluted)	$56M
Common Shares Outstanding[2]	17.1M
Equity Grants Outstanding Under Stock Plans[2]	2.3M
Fully Diluted Shares	19.4M
Cash[3]	$18.3M
Debt	None

[1]As of 11/15/19
[2]As of 11/8/19
[3]As of 9/30/19


eyenovia
Making it Possible
November 2019