

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported) October 29, 2019

EYENOVIA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-38365

(Commission File Number)

47-1178401

(IRS Employer Identification No.)

295 Madison Avenue, Suite 2400, New York, 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 ☒ x

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

Item 8.01. Other Events.

On October 29, 2019, Eyenovia, Inc. (the “Company”) issued a press release announcing that it is advancing the development of its MicroLine program for the improvement in near vision in patients with presbyopia towards Phase III development. The Company also is prioritizing its MicroPine (progressive myopia) and MicroStat (mydriasis) programs while deferring development activities for its MicroProst (glaucoma and ocular hypertension) and MicroTears (red eye and itch relieve/lubrication) programs. The Company will host a conference call at 5:00 p.m. ET on October 29, 2019 to discuss its reprioritized pipeline. A copy of the press release and the slides that the Company will use in connection with the conference call are attached as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press release dated October 29, 2019.</u>
<u>99.2</u>	<u>Reprioritized pipeline presentation.</u>

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: October 29, 2019

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



Eyenovia Advances MicroLine for the Treatment of Presbyopia Towards Phase III Development and Reprioritizes Late-Stage Ophthalmology Pipeline

Defers development activities of MicroProst and MicroTears

Company to host conference call on Tuesday, October 29, 2019 at 5:00 pm ET

New York, NY – October 29, 2019 – Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose therapeutics utilizing its patented piezo-print delivery technology, today announced that the Company is advancing the development of its MicroLine program for the improvement in near vision in patients with presbyopia towards Phase III development. As a result of prioritizing MicroLine in tandem with its MicroPine (progressive myopia) and MicroStat (mydriasis) programs, the Company is deferring development activities for its MicroProst (glaucoma and ocular hypertension) and MicroTears (red eye and itch relief/lubrication) programs.

Presbyopia is a non-preventable, age-related hardening of the lens, which causes the gradual loss of the eye's ability to focus on nearby objects, commonly known as farsightedness. There are currently no known FDA-approved drugs for the improvement in near vision in patients with presbyopia and existing modalities are typically device-based, such as reading glasses or contact lenses. In the United States, presbyopia affects an estimated 113 million people, of which Eyenovia estimates that approximately 43 million people between the ages of 40 and 65 who have otherwise normal vision could benefit from a pharmacologic treatment option like MicroLine.

"The MicroLine program, based on our proprietary piezo-formulation of the well-known drug pilocarpine, could potentially be one of the first pharmacologic treatment options for presbyopia. Combined with our novel platform technology, we believe that Eyenovia can provide people interested in enhancing their lifestyle with pharmacotherapy similar to other aesthetic-focused products. MicroLine is designed to replace reading glasses for approximately 3-4 hours, while addressing the tolerability and instillation issues associated with traditional eye drop approaches," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "We anticipate initiating and completing the Phase III VISION trials for MicroLine in 2020."

Dr. Fred Eshelman, Eyenovia's Chairman of the Board added, "After conducting a strategic review of Eyenovia's pipeline with the goal of maximizing the value of its portfolio, we believe that MicroLine, MicroPine and MicroStat represent the highest value opportunities for Eyenovia, with potential product launches from 2022 to 2024. We believe these three programs focus on areas with significant unmet needs or where the patient experience could be greatly improved. MicroLine, in particular, represents an exciting part of our pipeline, potentially enabling millions of people in the United States to forgo their reading glasses for approximately 3-4 hours of improved vision."

The Company expects the reprioritization of its programs to yield overall cost savings to Eyenovia of approximately \$1.5 to \$1.9 million in 2020.



Program	Indication	2020 Milestones	Estimated U.S. Market Opportunity
MicroLine	Presbyopia	Initiate and Complete Phase III VISION Study	\$2B+
MicroPine	Progressive Myopia	Complete Phase III CHAPERONE Enrollment	\$5B+
MicroStat	Mydriasis	File NDA	\$300M+

Conference Call and Webcast

The conference call is scheduled to begin at 5:00 pm ET on Tuesday, October 29, 2019. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 3192808. 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. In addition, a telephonic replay of the call will be available until November 5, 2019. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 3192808.

About Eyenovia

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

About MicroLine for Presbyopia

MicroLine is Eyenovia's 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. Eyenovia believes that its high precision microdosing technology combined with the well-known drug pilocarpine could provide short-term improvement in vision in patients, lasting approximately 3-4 hours while addressing tolerability and instillation issues associated with macrodose pilocarpine.

Upcoming Milestone: Initiate and Complete MicroLine Phase III Trial in 2020

About MicroPine for Progressive Myopia

MicroPine is Eyenovia's first-in-class topical treatment for progressive myopia, a back-of-the-eye condition commonly known as nearsightedness. Progressive myopia is estimated to affect close to 5 million people in the United States who suffer from uncontrolled axial elongation of the sclera leading to increasing levels of myopia and in some cases major pathologic changes such as retinal atrophy, macular staphylomas, retinal detachment and visual impairment. Early dose finding studies by collaborative academic groups have demonstrated high therapeutic potential with low dose atropine which can reduce myopia progression by 60 – 70% with a sustained effect through three years. A recent therapeutic evidence assessment and review by the American Academy of Ophthalmology indicates Level 1 (highest) evidence of efficacy for the role of low dose atropine for progressive myopia ([Ophthalmology 2017;124:1857-1866](#); [Ophthalmology 2016; 123\(2\) 391:399](#)).



Feasibility Dose-finding Atropine Studies: [ATOM 1](#); [ATOM 2](#); LAMP (Independent Collaborative Group Trials)
Upcoming Milestone: Complete Enrollment of the Phase III CHAPERONE Study in 2020

About MicroStat for Mydriasis

MicroStat is Eyenovia's first-in-class fixed-combination micro-formulation product (phenylephrine 2.5% -tropicamide 1%) candidate for pharmacologic mydriasis (eye dilation), which is targeted to address the growing needs of the estimated 80 million office-based comprehensive and diabetic eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. We are developing MicroStat to improve the efficacy and tolerability of pharmacologic mydriasis.

Upcoming Milestone: File NDA in 2020

About Optejet™ and MicroRx Ocular 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 with minimal training in 85% of topical medication administrations 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 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 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.

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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; our ability to identify new product candidates; the rate and degree of the 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 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 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

- Eyenovia is building a robust late-stage pipeline in ophthalmology ...with next generation, intelligent μ -therapeutics
- Initiated 2 Phase III programs in last 12 months
 - MICROPINE: First-in class back-of-the-eye therapeutic program for myopic progression (CHAPERONE Phase III trial)
 - MICROSTAT: First fixed combination Phenylephrine-Tropicamide for office-based and surgical mydriasis
- Additional programs: MicroProst (Glaucoma) - Submitted IND and planned FPI in Q4 2019 | MicroTears OTC
- Recent development: Advancing MicroLine (Presbyopia Rx) towards Phase III



Eyenovia Updated Pipeline: Prioritize Presbyopia Phase III Program

- **PRESBYOPIA:** Prioritize MicroLine for the pharmacologic treatment of presbyopia
 - Initiate and complete MicroLine Phase III VISION study in 2020
- **MYOPIC PROGRESSION:** Continue CHAPERONE Ph III trial with complete enrollment in 2020
- **MYDRIASIS:** Phase III studies successful, NDA on track for 2020 filing
- **DEFERRED PROGRAMS:** MicroProst and MicroTears

MicroLine

Ph III VISION



MicroPine

Ph III CHAPERONE

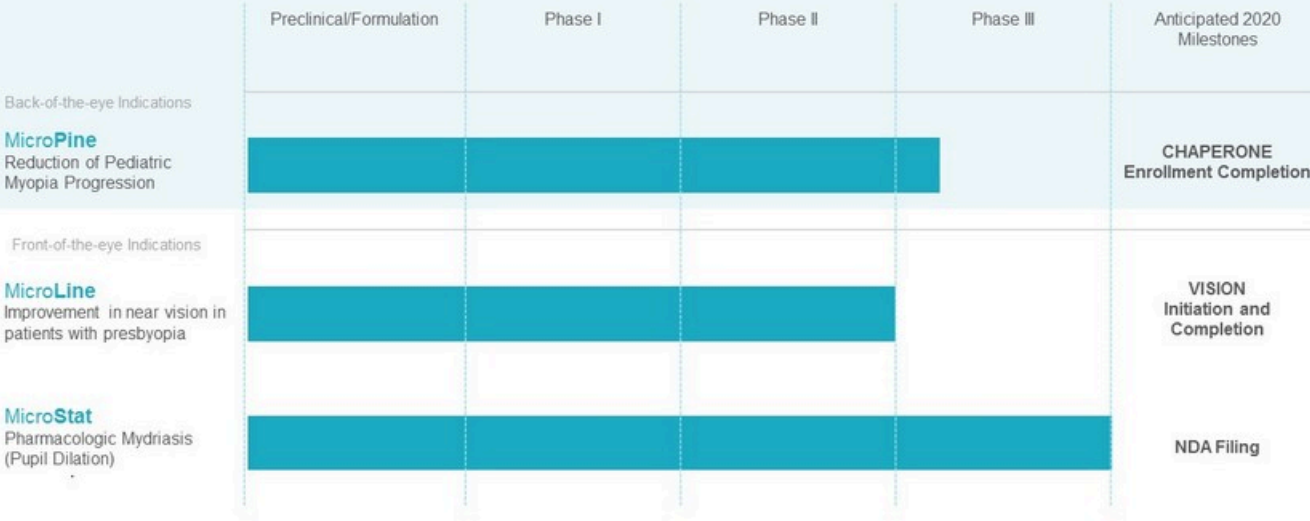


MicroStat

Ph III MIST-1 MIST-2



Multiple Late Stage Clinical Assets



Why MicroLine?

MicroProst for Glaucoma (CACG+OAG+OHT)		MicroLine for Presbyopia
\$1.5B+	Estimated U.S. Market Opportunity	\$2.0B+
Ease of use; potentially superior tolerability profile; compliance and adherence aid with Optejet™	Value Proposition	Among first-in-class; aesthetic benefits, potentially superior tolerability profile and easier, neater application with Optejet
High	Prob. of Success	High
Moderate	Prescriber Receptivity	High
High Payer Rebates and Co-pays	Patient Access	Cash
12 months	Time to Phase III Completion Post-IND	12 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



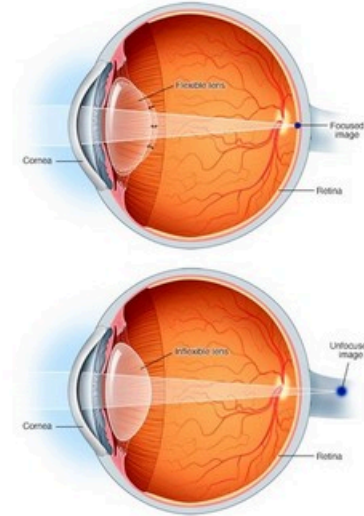
Risk Factors

- Age
- Medical conditions and co-morbidities such as cardiovascular conditions, Multiple sclerosis, Type 2 diabetes can increase risk of premature presbyopia
- Drugs associated with premature symptoms: antidepressants, anti-histamines, diuretics



Diagnosis

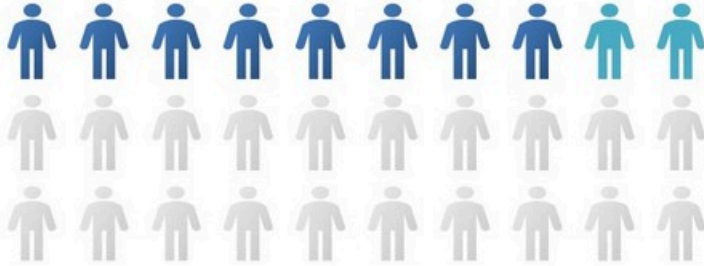
- Basic eye exam, with refraction assessment



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 U.S. 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**

MicroLine: Pharmacologic Treatment of Presbyopia

Phase III ready program for the Improvement in near vision in patients with presbyopia

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

- 2 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 U.S. market: \$2B+
- Anticipated reimbursement: Cash pay

Competition

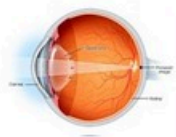
- Anticipated among first to market, including Allergan's pilocarpine Phase III eyedrop program
- Eyenovia is the only presbyopia product with piezo-print horizontal delivery and microdosing, designed to address potential pilocarpine side effects and improve user experience









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



Eyenovia Can Lead the Way in Presbyopia ...



Company	Compound	Active	Stage
 eyenovia	MicroLine	Pilocarpine piezo-formulation	Phase III
 Allergan	Pilocarpine	Pilocarpine formulation	Phase III
Presbyopia Therapies	PRX-100	Aceclidine + Tropicamide	Phase IIb
 ORASIS PHARMACEUTICALS	Presbi-Drops	Pilocarpine + NSAID	Phase II
 NOVARTIS	UNR844	Lipoic acid choline ester 1.5%	Phase II

