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 20, 2022

EYENOVIA, INC.

(Exact Name of Registrant as Specified in its Charter)

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

295 Madison Avenue, Suite 2400, New York, NY 10017
(Address of Principal Executive Offices, 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 8.01. Other Events.

On October 20, 2022, Eyenovia, Inc. issued a press release announcing positive results from its VISION-2 Phase 3 study of MicroLine as a potential topical, on-demand treatment for presbyopia. A copy of the press release is filed hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Eyenovia, Inc. Press Release dated October 20, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

EYENOVIA, INC.

Date: October 20, 2022

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Announces Positive Results from VISION-2 Phase 3 Study of MicroLine as a Potential On-Demand Treatment for Presbyopia

NEW YORK—October 20, 2022—Eyenovia, Inc. (NASDAQ: EYEN), a pre-commercial ophthalmic technology company developing the Optejet® delivery system for use both in combination with its own drug-device therapeutic programs for mydriasis, presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced positive results from its VISION-2 Phase 3 study of MicroLine as a potential topical, on-demand treatment for presbyopia.

The VISION-2 study evaluated the safety and efficacy of Eyenovia's 2% pilocarpine micro-array print (MAP) formulation versus placebo, all administered via the company's proprietary Optejet device. VISION-2 is the fourth Phase 3 study demonstrating the utility of the company's MAP technology in improving the therapeutic index of topical ophthalmic drugs.

Key highlights from the study include:

- In a modified per-protocol analysis of evaluable patients, excluding a non-study related adverse event impacting pupil size and reactivity (new onset anisocoria), VISION-2 met its primary endpoint with a statistically significant proportion of subjects treated with MicroLine showing a 15-letter or more improvement in distance corrected near visual acuity (DCNVA) with less than a 5-letter loss in distance acuity versus placebo in low light conditions at two hours post-treatment.

- The study also achieved all secondary endpoints at a statistically significant level.

- MicroLine was very well tolerated. Adverse events were reported in fewer than 3% of patients, and all were mild and/or transient.

"We are very pleased with these Phase 3 study results which again demonstrate the benefits of our proprietary Optejet device that underpins MicroLine as a potential on-demand treatment for presbyopia," stated Michael Rowe, Chief Executive Officer of Eyenovia. "We look forward to meeting with the FDA within our planned commercialization timeline in preparation for a potential new drug application (NDA) submission. MicroLine, if approved, would be the only option that is designed to provide the ease-of-use, convenience, and reduced exposure to drug and preservatives that we believe are significant benefits of the Optejet device."

"Proprietary market research that we conducted in May of this year reveals that 80% of patients in our target market surveyed would prefer the Optejet device over traditional eyedrops. That market consists of presbyopes between the ages of 40 and 55 years who have otherwise never needed to wear glasses. We view Optejet as a significant advantage not only for MicroLine, but for our entire pipeline of development programs, including MydCombi for pharmacologic mydriasis, for which we are preparing to resubmit our New Drug Application (NDA), and MicroPine for progressive myopia," Mr. Rowe concluded.

"The positive results from this study confirm earlier findings that MicroLine may represent an exciting new on-demand treatment option for the millions of people who suffer from presbyopia who never had to wear reading glasses previously," stated April Jasper, OD, medical monitor and scientific advisor to the company. "Of note in this study is the very low incidence of side effects, such as headache and brow ache, that are often associated with topical pilocarpine treatments. This is due to the precision dispensing of the Optejet, which coats the corneal surface without exposing the eye to excess drug and preservative toxicity. I look forward to incorporating this novel technology into my own practice if and when approved."

The VISION-2 study was a double-masked, placebo-controlled, cross-over superiority trial in which 140 subjects with presbyopia were treated. During the study, subjects were randomly assigned to a treatment sequence for dosing with pilocarpine 2% as well as placebo, both administered via the Optejet dispenser. The primary endpoint was improvement in high contrast binocular distance corrected near visual acuity without loss of distance vision measured in low light conditions 2 hours after treatment.

About the VISION Trials

The VISION trials are Phase 3, double-masked, placebo-controlled, cross-over superiority trials that enroll participants with presbyopia. The primary endpoint is improvement in high-contrast binocular distance corrected near visual acuity without loss of distance vision in low light conditions. MicroLine is intended for the "on demand" improvement of near vision in people with presbyopia.

About MicroLine for Presbyopia

MicroLine (pilocarpine ophthalmic solution) is Eyenovia's investigational pharmacologic treatment for presbyopia. Presbyopia or farsightedness 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. 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. MicroLine has been licensed to Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

About MicroPine for Progressive Myopia

MicroPine (atropine ophthalmic spray) 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+Lomb, Inc. in the United States and Canada, and Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

About Mydcombi™ for Mydriasis

Mydcombi is Eyenovia's investigational, first-in-class fixed-dose-combination product (tropicamide 1% and phenylephrine 2.5% ophthalmic spray) 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 as a micro-formulation for use without anesthetic, Eyenovia believes Mydcombi will help improve the efficacy, tolerability, and efficiency of pharmacologic mydriasis. Mydcombi has been licensed to Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

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 on our supply chain; the potential advantages of our product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; intellectual property risks; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and our competitive position. Any forward-looking statements speak only as of the date on which they are made, and except as may be required under applicable securities laws, Eyenovia does not undertake any obligation to update any forward-looking statements.

Eyenovia Contact:
Eyenovia, Inc.
John Gandolfo
Chief Financial Officer
jgandolfo@eyenovia.com

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

Eyenovia Media Contact:
Eyenovia, Inc.
Norbert Lowe
Vice President, Commercial Operations
nlowe@eyenovia.com