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 4, 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**	**10017**
(Address of principal executive offices)	(Zip Code)

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

Not applicable
(Former name or former address, if changed since last report)

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	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 November 4, 2021, the Company issued a press release reporting the Company's announcement today that the first patient has been enrolled in the Company's second Phase 3 clinical trial of MicroLine, its proprietary pilocarpine formulation for temporary improvement in near vision (presbyopia), known as VISION-2. The press release described the VISION-2 study as a double-masked, placebo-controlled, cross-over superiority trial in which approximately 140 subjects with presbyopia will be treated, described the way in which the trial will be administered, and reported that the primary endpoint of the study is the improvement in high contrast binocular distance corrected near visual acuity measured in low light conditions two hours after treatment. The press release reported that topline data is expected in mid-2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release of the Company, dated November 4, 2021.
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: November 5, 2021

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

EYENOVIA ANNOUNCES FIRST PATIENT ENROLLED IN PHASE 3 VISION-2 TRIAL OF MICROLINE FOR PRESBYOPIA

Vision-2 follows successful Vision-1 trial with expected top-line results in Q2 2022

Presbyopia represents a multi-billion-dollar market opportunity in the U.S. alone

NEW YORK, Nov. 04, 2021 (GLOBE NEWSWIRE) -- Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that the first patient has been enrolled in the Company's second Phase 3 clinical trial of MicroLine, its proprietary pilocarpine formulation for temporary improvement in near vision (presbyopia), known as VISION-2.

"Following the completion of VISION-1 study, we are pleased to initiate this second Phase 3 trial that, if successful, will contribute to the clinical evidence supporting a new drug/device combination application to the US FDA," stated Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia. "By leveraging the numerous benefits of our microdose array print (MAP™) technology, we believe MicroLine has the potential to be among the first drug treatments to improve blurred near vision that can adversely impact quality of life in patients with presbyopia."

"Additionally, with 18 million people between the ages of 40 and 55 in the US afflicted with presbyopia, this is a significant market opportunity for our company – in excess of several billion dollars according to very recent third-party market research. We look forward to continuing to advance this promising and differentiated therapeutic through late-stage development for the potential benefit of patients, eye care practitioners and shareholders alike."

The VISION-2 study is a double-masked, placebo-controlled, cross-over superiority trial in which approximately 140 subjects with presbyopia will be treated. During the study, subjects will be randomly assigned to a treatment sequence for dosing with pilocarpine 2% as well as placebo, both administered via the Optejet™ dispenser. The primary endpoint is improvement in high contrast binocular distance corrected near visual acuity measured in low light conditions 2 hours after treatment. Topline data is expected in mid-2022.

VISION-1 recap

In May 2021, Eyenovia announced positive results from the first Phase 3 MicroLine study, VISION-1. In that trial, the primary endpoint was achieved with MicroLine 2% statistically superior to placebo, determined by improvement in high contrast binocular distance corrected near visual acuity measured in low light conditions 2 hours after treatment. Further, MicroLine was very well tolerated; adverse events reported were all mild and transient in nature including fewer than 3% of patients reporting brow/headache. In a post-study survey, 70% of study participants reported strong interest in using MicroLine for near vision improvement should it be approved. These patients said they would expect to use the product three to four times per week on average.

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 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 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 MydCombi™ for Mydriasis

MydCombi is Eyenovia's investigational, first-in-class fixed-dose-combination product (tropicamide 1% and phenylephrine 2.5% ophthalmic solution) 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.

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 estimate the volume of ophthalmic solution administered with the Optejet is less than 20% 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% historically seen with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

About Eyenovia, Inc.

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

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

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:
Sam Choinski
Pazanga Health Communications
schoinski@pazangahealth.com
(603) 489-5964