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) December 16, 2020

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 December 16, 2020, Eyenovia, Inc. (the "Company") issued a press release announcing that the first set of patients has been enrolled in the Company's Phase 3 VISION-1 study of MicroLine, its proprietary pilocarpine formulation for the improvement in near vision in patients with presbyopia. 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 No.	Description
99.1	Press release dated December 16, 2020.

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: December 16, 2020

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

Exhibit 99.1

Eyenovia Announces First Patients Enrolled in Phase 3 Study of MicroLine for Presbyopia

Topline Results Expected First Half of 2021

NEW YORK—December 16, 2020—Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that the first set of patients has been enrolled in the Company's Phase 3 VISION-1 study of MicroLine, its proprietary pilocarpine formulation delivered via its Optejet® dispenser, for the improvement in near vision in patients with presbyopia.

Presbyopia, the age-related hardening of the lens causing blurred near vision, affects approximately 113 million Americans. Vision impairment typically begins after age 40 and is often corrected with eyeglasses or "readers," contact lenses or surgery.

"Eyenovia's VISION studies are designed to demonstrate improvement in near visual acuity in patients with presbyopia. Along with mydriasis and myopia, this is our third Phase 3 program using our smart Optejet system, which is the first technology of which we are aware to demonstrate the benefits in Phase 3 trials of topical ophthalmic therapies using high precision, targeted microdosing," said Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia. "With our first set of patients now enrolled in the Phase 3 VISION-1 study, we expect to complete enrollment relatively quickly and have topline data in the first half of 2021, subject to any impacts of COVID-19."

The VISION trials are Phase 3, double-masked, placebo-controlled, cross-over superiority trials that will each enroll approximately 100 participants between the ages of 40 and 60 who suffer with visual impairment from presbyopia. The primary endpoint is same-day improvement of binocular distance corrected near visual acuity. MicroLine is designed for use "on demand" for symptomatic improvement of near vision impairment secondary to presbyopia.

"For the large percentage of my patients who have no prior vision impairment, developing presbyopia can be a life-altering event as they come to terms with one of the first outward signs of aging," said Dr. David Wirta of the Eye Research Foundation in Newport Beach, California, a VISION-1 study investigator. "MicroLine has the potential to remove my patients' dependance on reading glasses by providing an easy-to-use pharmaceutical treatment that could add to our options in treating this condition."

Dr. William Flynn, Director of Eye Associates Research Center of San Antonio, Texas and a VISION-1 study investigator added, "Many patients find transitioning from no glasses to reading glasses has a significant impact on their quality of life. By providing a way to minimize this impact so that glasses are not needed in all situations, we have the potential to help improve our patients' treatment satisfaction."

About MicroLine

Eyenovia's MicroLine is a proprietary microdosed formulation of pilocarpine for presbyopia that is delivered via the Company's Optejet dispenser. Providing high precision microdosing at approximately 1/5th the drug volume of a traditional eyedropper, the Optejet is designed to deliver targeted, consistent doses more conveniently than typical eyedroppers.

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.

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 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 and our ability to submit applications for, obtain and maintain 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.

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