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 15, 2024

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)

(833) 393-6684
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, par value $0.0001 per share	**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 2.05 Costs Associated with Exit or Disposal Activities.

The information required by this item is incorporated by reference from Item 8.01 below.

Item 8.01 Other Events.

On November 15, 2024, Eyenovia, Inc. (the "Company") issued a press release announcing the outcome of a review of the three-year efficacy and safety data from the MicroPine Phase 3 CHAPERONE study conducted by an independent Data Monitoring Committee. In light of the results of this review, the Company is considering a variety of steps to maximize value to all stakeholders, to reduce expenses and to evaluate its strategic options, which may include a business combination, reverse merger, asset sales or a combination of those alternatives. Further information will be made available once the evaluation of strategic options has been completed.

The Company is implementing a reduction in force affecting approximately 50% of its workforce. The remaining staff will be focused on Optejet® Gen-2 development, our dry eye collaborations and clobetasol commercialization. The estimated total cost of severance-related expenses relating to this reduction in force is $0.2 million. These estimated charges are subject to a number of assumptions and actual results may differ. The Company may also incur other charges not currently contemplated due to events that may occur as a result of, or associated with, the evaluation of its strategic options.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release dated November 15, 2024.
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.

Dated: November 15, 2024

By: /s/ Andrew Jones
Andrew Jones
Chief Financial Officer

Exhibit 99.1

Eyenovia Provides Update on Phase 3 CHAPERONE Study

A review of study data by an independent Data Review Committee found that CHAPERONE is not meeting its primary three-year efficacy endpoint

Company to discontinue study, review full data set, and evaluate next steps for the program

NEW YORK— November 15, 2024—Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company, today announced that a review of the CHAPERONE data by an independent Data Review Committee (DRC) found that the trial is not meeting its primary endpoint of a less than 0.5 diopter progression in visual acuity over three years. CHAPERONE is Eyenovia's Phase 3 study evaluating its proprietary drug-device combination of low-dose atropine in the Company's Optejet dispensing platform as a potential treatment for pediatric progressive myopia.

The DRC reviewed the safety and efficacy data from 252 evaluable patients. The DRC found that the rate of myopia progression was not significantly different between the two active treatment arms (0.01% and 0.1% atropine ophthalmic metered spray) and placebo. In the safety analysis, all dosages and placebo appeared to be well-tolerated, with a mild and infrequent adverse event profile. Full study data has not yet been released to Eyenovia.

"We are disappointed that the DRC determined that the CHAPERONE study does not appear to be meeting its primary efficacy endpoint," stated Michael Rowe, Chief Executive Officer of Eyenovia. "We plan to terminate the study, review the data more thoroughly, and evaluate next steps. On behalf of the entire company, I would like to express my sincere appreciation to the children, parents, caregivers and healthcare professionals who participated in this trial, as well as all the Eyenovia team members for their exceptional work on this program."

In light of the results of this review, the Company is considering a variety of steps to maximize value to all stakeholders, to reduce expenses and to evaluate its strategic options, which may include a business combination, reverse merger, asset sales or a combination of those alternatives. Further information will be made available once the evaluation of strategic options has been completed.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic technology company developing and commercializing products leveraging its proprietary Optejet topical ophthalmic medication dispensing platform. The Optejet is targeted at chronic front-of-the-eye diseases due to its ease of use, enhanced safety and tolerability, and potential for superior compliance. The company's current commercial portfolio includes clobetasol propionate ophthalmic suspension, 0.05%, for post-surgical pain and inflammation, and Mydcombi® for mydriasis. Eyenovia has also secured licensing and development agreements for additional multi-billion-dollar indications where the Optejet may be advantageous, including dry eye. For more information, visit Eyenovia.com.

Forward-Looking Statements

Except for historical information, all 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 regulatory submissions, estimated market opportunities for our product candidates and platform technology, the impact of the Gen-2 Optejet device, and the timing for availability and sales growth of our approved products. 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: the availability of sufficient financial resources to make payments on its debt obligations to Avenue Capital and to continue the clinical development and commercialization of our products, as to which no assurance can be given; risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment, timing, progress and results of such trials; the timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our products and product candidates; the potential advantages of our products, product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our products and product candidates; our estimates regarding the potential market opportunity for our products and product candidates; reliance on third parties to develop and commercialize our products and product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our products and product candidates; intellectual property risks; changes in legal, regulatory, legislative and geopolitical 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 product candidates; 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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