# 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 10, 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 2.02. Results of Operations and Financial Condition.**

On November 10, 2022, Eyenovia, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information contained in, or incorporated into, Item 2.02, including the press release attached as Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

## Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Eyenovia, Inc. Press Release dated November 10, 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: November 10, 2022

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

**Exhibit 99.1**

**Eyenovia Reports Third Quarter 2022 Financial Results and Provides Business Update**

Announced positive results from the second Phase 3 study of MicroLine in presbyopia, VISION-2; Company planning to meet with the FDA to gain alignment on regulatory path forward as a drug/device combination product

Company to host conference call and webcast today, November 10, at 4:30 pm ET

NEW YORK—November 10, 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 its financial and operating results for the third quarter ended September 30, 2022.

**Third Quarter 2022 and Recent Business Developments**

- Announced that in a modified per-protocol analysis of evaluable patients, VISION-2 met its primary endpoint with a statistically significant proportion of MicroLine-treated subjects showing a ≥15-letter 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 and the Company is planning to meet with the FDA as soon as practicable.

- Development partner Arctic Vision continues to enroll patients in its Phase 3 study of MicroLine (ARVN003) as a potential treatment for presbyopia in China. Arctic Vision anticipates completing the study in late 2023.

- Announced data at the 40th Congress of the European Society Of Cataract and Refractive Surgeons (ESCRS) in September 2022 demonstrating that preserved drugs delivered with the Optejet act more like unpreserved drugs, reducing ocular stress and potentially avoiding long-term adverse events.

- Announced the appointment of Eyenovia's former Chief Operating Officer, Michael Rowe, as the Company's new Chief Executive Officer. Mr. Rowe was also appointed to Eyenovia's Board of Directors.

- Announced that the Company's new manufacturing facility in Redwood City, CA is now operational, and also announced the appointment of Bren Kern as Senior Vice President of Operations.

- Ended the third quarter of 2022 with approximately $25.3 million in total cash and cash equivalents, including $7.9 million of restricted cash.

Michael Rowe, Chief Executive Officer, commented, “Since our last quarterly update, we achieved a significant milestone with positive results from VISION-2, our second Phase 3 trial of MicroLine, a potential topical, on-demand therapeutic that we are developing as a temporary treatment for presbyopia. We are planning to meet with the FDA early next year followed by the manufacture of registration batches at our new, state-of-the-art facility in Redwood City, CA.”

“Our collaboration and license agreements with Bausch+Lomb and Arctic Vision are progressing nicely, and Arctic Vision continues to enroll patients in its own Phase 3 trial of MicroLine in China. This study, when complete in late 2023, is expected to add to the growing body of evidence demonstrating the safety and efficacy of MicroLine and Optejet. We continue to evaluate additional opportunities to partner or collaborate in other high value ophthalmic indications where the Optejet technology can be used to improve medical care.”

“We believe we have set the stage for achievement of multiple key milestones in 2023, and we will work tirelessly to sustain the momentum that we currently enjoy.”

**Third Quarter 2022 Financial Review**

For the third quarter of 2022, net loss was approximately $(7.3) million, or $(0.21) per share compared to a net loss of approximately $(5.6) million, or $(0.21) per share, for the third quarter of 2021.

Research and development expenses totaled approximately $3.9 million for the third quarter of 2022 as compared to $3.6 million for the third quarter of 2021, an increase of approximately 9.1%.

For the third quarter of 2022, general and administrative expenses were approximately $3.4 million, compared to $2.4 million for the third quarter of 2021, an increase of approximately 41.3%.

Total operating expenses for the third quarter of 2022 were approximately $7.2 million compared to $5.9 million for the third quarter of 2021. This represents an increase of approximately 22.0 %.

As of September 30, 2022, the Company’s cash and cash equivalents were approximately $25.3 million, including $7.9 million of restricted cash, as compared to $27.3 million as of December 31, 2021.

**Conference Call and Webcast**

The conference call is scheduled to begin at 4:30 pm ET today, November 10. Participants should dial 1-866-575-6539 (domestic) or 1-929-477-0448 (international) with the conference code 1600616. 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.

**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 spray) 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. 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.

**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 pre-commercial ophthalmic 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. 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), 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 and related economic disruptions on our supply chain, including the availability of sufficient components and materials used in our product candidates; 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; our competitive position; and other risks described from time to time in the “Risk Factors” section of our filings with the U.S. Securities and Exchange Commission, including those described in our Annual Report on Form 10-K as well as our Quarterly Reports on Form 10-Q, and supplemented from time to time by our Current Reports on Form 8-K. 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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**EYENOVIA, INC.**
**Condensed Balance Sheets**

| | September 30, 2022 (unaudited) | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 17,398,605 | $ 19,461,850 |
| Restricted cash | 7,875,000 | 7,875,000 |
| Deferred clinical supply costs | 1,871,096 | - |
| License fee and expense reimbursements receivable | 809,430 | 1,805,065 |
| Prepaid expenses and other current assets | 1,463,020 | 721,438 |
| Total Current Assets | 29,417,151 | 29,863,353 |
| | | |
| Property and equipment, net | 1,342,657 | 1,271,225 |
| Security deposits | 200,153 | 132,539 |
| Equipment deposits | 445,530 | 391,941 |
| Total Assets | $ 31,405,491 | $ 31,659,058 |
| | | |
| **Liabilities and Stockholders' Equity** | | |
| Current Liabilities: | | |
| Accounts payable | $ 1,104,959 | $ 1,614,104 |
| Accrued compensation | 1,268,009 | 1,543,618 |
| Accrued expenses and other current liabilities | 1,384,803 | 845,719 |
| Deferred rent - current portion | 28,999 | 18,685 |
| Notes payable | 7,229,013 | 7,150,368 |
| Total Current Liabilities | 11,015,783 | 11,172,494 |
| Deferred rent - non-current portion | 60,540 | 19,949 |
| Total Liabilities | 11,076,323 | 11,192,443 |
| | | |
| Stockholders' Equity: | | |
| Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2022 and December 31, 2021 | - | - |
| Common stock, $0.0001 par value, 90,000,000 shares authorized; 35,525,689 and 28,426,616 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively | 3,553 | 2,844 |
| Additional paid-in capital | 132,432,682 | 110,683,077 |
| Accumulated deficit | (112,107,067) | (90,219,306) |
| Total Stockholders' Equity | 20,329,168 | 20,466,615 |
| Total Liabilities and Stockholders' Equity | $ 31,405,491 | $ 31,659,058 |

**EYENOVIA, INC.**
**Condensed Statements of Operations**
**(unaudited)**

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2022** | **2021** | **2022** | **2021** |
| **Operating Income** | | | | |
| Revenue | $ - | $ - | $ - | $ 4,000,000 |
| Cost of revenue | - | - | - | (1,600,000) |
| Gross Profit | - | - | - | 2,400,000 |
| | | | | |
| **Operating Expenses:** | | | | |
| Research and development | 3,876,876 | 3,552,068 | 11,176,326 | 11,559,364 |
| General and administrative | 3,353,352 | 2,372,999 | 10,362,907 | 6,914,481 |
| Total Operating Expenses | 7,230,228 | 5,925,067 | 21,539,233 | 18,473,845 |
| | | | | |
| Loss From Operations | (7,230,228) | (5,925,067) | (21,539,233) | (16,073,845) |
| | | | | |
| **Other Income (Expense):** | | | | |
| Extinguishment of PPP 7(a) loan | - | 463,353 | - | 463,353 |
| Other income, net | 70,277 | 11,728 | 96,580 | 48,880 |
| Interest expense | (177,138) | (119,212) | (475,811) | (202,407) |
| Interest income | 28,093 | 600 | 30,703 | 2,354 |
| | | - | | |
| **Net Loss** | $ (7,308,996) | $ (5,568,598) | $ (21,887,761) | $ (15,761,665) |
| | | | | |
| Net Loss Per Share - Basic and Diluted | $ (0.21) | $ (0.21) | $ (0.67) | $ (0.61) |
| | | | | |
| Weighted Average Number of Common Shares Outstanding - Basic and Diluted | 34,631,774 | 26,053,532 | 32,778,551 | 25,773,098 |