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): May 12, 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 May 12, 2022, Eyenovia, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 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 May 12, 2022
104	Cover Page Interactive Data File (embedded within the iXBRL (Inline eXtensible Business Reporting Language) 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: May 12, 2022

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Eyenovia Reports First Quarter 2022 Financial Results

Mydcombi™ NDA resubmission on track for Q3 2022

Phase 3 VISION-2 study evaluating MicroLine as an on-demand treatment for improving near vision (presbyopia) progressing as planned; topline data expected mid-year

Ended Q1 with sufficient cash and cash equivalents for the potential launch of Mydcombi and completion of the VISION program

Company to host conference call and webcast today, May 12, at 4:30pm ET

NEW YORK—May 12, 2022—Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on its proprietary microdose array print (MAP™) platform technology, today announced its financial and operating results for the first quarter ended March 31, 2022.

First Quarter 2022 and Recent Business Developments

- Completed substantially all of the Optejet device validation testing required by FDA upon Mydcombi's reclassification as a drug-device combination. No additional clinical data required. On track to resubmit New Drug Application during the third quarter.
- Ended the first quarter of 2022 with approximately $34.6 million in cash and cash equivalents, including $7.9 million of restricted cash.
- VISION-2 Phase 3 trial evaluating MicroLine as a potential, on-demand treatment for presbyopia progressing as planned, with topline data anticipated mid-year. If successful, the Company plans to start production of registration batches as a requirement towards filing a new drug/device combination application to the U.S. FDA.
- With Tufts Medical Center, successfully completed several ophthalmic preservative studies, demonstrating the value of the Optejet® technology for reducing the ocular stress caused by preservatives in medications to a level comparable with non-preserved drugs.

Dr. Sean Ianchulev, Chairman, Chief Executive Officer and Chief Medical Officer of Eyenovia, commented, "During the first quarter, we made excellent progress on the additional Optejet device validation testing requested by FDA as part of our Mydcombi NDA, and we remain on track for resubmission during the third quarter of this year. In parallel, our VISION-2 trial for our MicroLine presbyopia program continues to progress as planned, and we anticipate topline data mid-year."

"The recent commercial launch of a presbyopia eye drop product by a competitor, supported by a robust direct-to-consumer advertising and awareness campaign, will help create a market that we estimate to be worth multiple billions of dollars. However, MicroLine, if and when commercially available, will be the only product that will leverage our proprietary Optejet dispensing technology, which has been shown in the VISION-1 study to cause a very low rate of headache, and is both easier and neater to administer than an eye drop."

“We remain on track to achieve very significant milestones in 2022 that give us potential line of sight to two commercially approved products. We are off to a strong start, and I am excited about all that we can achieve this year.”

First Quarter 2022 Financial Review

For the first quarter of 2022, net loss was approximately $(7.3) million, or $(0.24) per share compared to a net loss of approximately $(5.4) million, or $(0.21) per share, for the first quarter of 2021.

Total license revenue was $0.00 for the first quarter of 2022 as compared to $2.0 million for the first quarter of 2021.

Research and development expenses totaled approximately $3.7 million for the first quarter of 2022 as compared to $4.3 million for the first quarter of 2021.

For the first quarter of 2022, general and administrative expenses were approximately $3.5 million, compared to $2.2 million for the first quarter of 2021.

Total operating expenses for the first quarter of 2022 were approximately $7.2 million compared to $6.6 million for the first quarter of 2021.

As of March 31, 2022, the Company’s cash and cash equivalents were approximately $34.6 million, including $7.9 million of restricted cash, as compared to $27.3 million as of December 31, 2021. As of March 31, 2022, cash included $15 million raised through the securities purchase agreement with Armistice Capital in March.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30pm ET today, May 12. Participants should dial 877-207-9876 (domestic) or 212-231-2932 (international) with the conference code 22018217. 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. 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 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 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 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. 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 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.

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

EYENOVIA, INC.

Condensed Balance Sheets

	March 31, 2022 (unaudited)	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 26,716,269	$ 19,461,850
License fee and expense reimbursements receivable	1,364,309	1,805,065
Prepaid expenses and other current assets	2,318,047	734,942
Total Current Assets	30,398,625	22,001,857
Restricted cash	7,875,000	7,875,000
Property and equipment, net	1,370,359	1,271,225
Security deposits	119,035	119,035
Equipment deposits	425,036	391,941
Total Assets	$ 40,188,055	$ 31,659,058
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,534,764	$ 1,614,104
Accrued compensation	675,394	1,543,618
Accrued expenses and other current liabilities	404,707	845,719
Deferred rent - current portion	23,780	18,685
Notes payable - current portion, net	7,740,120	7,150,368
Total Current Liabilities	10,378,765	11,172,494
Deferred rent - non-current portion	15,080	19,949
Total Liabilities	10,393,845	11,192,443
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2022 and December 31, 2021	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 31,698,424 and 28,426,616 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	3,171	2,844
Additional paid-in capital	127,350,010	110,683,077
Accumulated deficit	(97,558,971)	(90,219,306)
Total Stockholders' Equity	29,794,210	20,466,615
Total Liabilities and Stockholders' Equity	$ 40,188,055	$ 31,659,058

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended March 31,	
	2022	**2021**
Operating Income		
Revenue	$ -	$ 2,000,000
Cost of revenue	-	(800,000)
Gross Profit	-	1,200,000
Operating Expenses:		
Research and development	3,712,584	4,322,648
General and administrative	3,474,965	2,243,990
Total Operating Expenses	7,187,549	6,566,638
Loss From Operations	(7,187,549)	(5,366,638)
Other Income (Expense):		
Other (expense) income, net	(7,073)	18,585
Interest expense	(145,237)	(5,148)
Interest income	194	1,534
Net Loss	$ (7,339,665)	$ (5,351,667)
Net Loss Per Share - Basic and Diluted	$ (0.24)	$ (0.21)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	30,008,194	25,330,563