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): March 28, 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 March 28, 2022, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal year ended December 31, 2021. 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 March 28, 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: March 28, 2022

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Reports Fourth Quarter and Full Year 2021 Financial Results

Successfully completed Type A meeting with FDA and anticipates MydCombi(tm) NDA resubmission in Q3 2022

Enrolled first patient in the Phase 3 VISION-2 study evaluating MicroLine as an on-demand treatment for improving near vision (presbyopia)

Entered into a $15 million Securities Purchase Agreement with Armistice Capital to support the Company's clinical and manufacturing operations

Company to host conference call and webcast today, March 28, at 4:30pm ET

NEW YORK—March 28, 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 results for the fourth quarter ended December 31, 2021.

Fourth Quarter 2021 and Recent Business Developments

- Concluded a successful Type A meeting with FDA regarding the Complete Response Letter (CRL) that the company received in October related to its MydCombi New Drug Application (NDA). Eyenovia and the agency reached full alignment on the path forward toward NDA resubmission. Specifically:
    - FDA has requested that additional non-clinical device testing be conducted on the OpteJet dispenser as required for a drug/device combination product;
    - No additional clinical work related to MydCombi is required;
    - The additional testing that the company is conducting now may be referenced in future regulatory applications for its other late-stage assets, MicroLine and MicroPine, potentially streamlining the review processes for those programs;
    - Eyenovia anticipates resubmitting the MydCombi NDA in the third quarter of this year.
- Announced first patient enrolled in VISION-2, the company's Phase 3 trial to evaluate MicroLine as a potential temporary, on-demand treatment for Presbyopia. If successful, the company plans to start production of registration batches as a requirement towards filing a new drug/device combination application to the US FDA.
- Successfully completed its SPEED and Ophthalmic Preservative studies, demonstrating the value of the Optejet® technology for delivering single-dose efficacy without the negative impact of ocular preservatives.
- Entered into a $15 million Securities Purchase Agreement in March 2022 with Armistice Capital to support the Company's clinical and manufacturing operations.

- Announced that Dr. Sean Ianchulev participated in a myopia panel discussion, *Myopia Control: Corrective Lenses, Drugs and Diagnostics*, at the Eyecelerator@AAO 2021 Meeting, which was held on Thursday, November 11, 2021 at the Ernest N. Morial Convention Center in New Orleans, LA.

Dr. Sean Ianchulev, Chairman, Chief Executive Officer and Chief Medical Officer of Eyenovia, commented, "During the fourth quarter and subsequent period, we took meaningful steps to advance our key programs: MydCombi for pharmacologic mydriasis and MicroLine for presbyopia. Beginning with MydCombi, we completed a very productive Type A meeting with FDA and, we believe, gained full alignment on the path forward. We are in the process of completing the additional non-clinical validation of the Optejet dispenser that has been requested by the agency and remain confident that we will resubmit an NDA during the third quarter of this year. Importantly, the additional testing that we are conducting on the Optejet now can be referenced in regulatory filings for our other programs – MicroLine and MicroPine – eliminating the need to repeat these tests on behalf of those programs.

"At the same time, we enrolled the first patient in VISION-2, which is the second Phase 3 study to evaluate MicroLine as a potential temporary, on-demand treatment for presbyopia, or blurred near vision. Recall that the results from our first Phase 3 study, VISION-1, were positive. If these results are consistent, we will be well positioned to file for regulatory approval in this indication as well, giving us potential line of sight to two approved, commercially available products. We anticipate topline data from VISION-2 mid-year.

"With the additional capital provided through Armistice Capital, we believe we are sufficiently capitalized to fund our Microline phase 3 Vision 2 study; the resubmission of the Mydcombi NDA as well as our Redwood City manufacturing expenditures. We look forward to delivering several potentially value creating milestones in 2022, and potentially our first product approval early next year," Dr. Ianchulev concluded.

Fourth Quarter 2021 Financial Review

For the fourth quarter of 2021, net income was approximately $3.0 million, or $0.11 per share ($0.10 per share on a diluted basis), compared to a net loss of approximately $(4.2) million, or $(0.17) per share, fourth quarter of 2020. For the full year ended December 31, 2021, net loss was approximately $(12.8) million, or $(0.49) per share. This compares to a net loss of approximately $(19.8) million, or $(0.94) per share for the full year 2020

Total license revenue was approximately $10.0 million for the fourth quarter and approximately $14.0 million for the full year 2021 as compared to $2.0 million for the fourth quarter and full year 2020.

Research and development expenses totaled approximately $3.2 million for the fourth quarter of 2021 as compared to $3.4 million for the fourth quarter of 2020. For the full year 2021, research and development expenses were $14.5 million as compared to $13.4 million for the full year 2020.

For the fourth quarter of 2021, general and administrative expenses were approximately $3.7 million, compared to $2.0 million for the fourth quarter of 2020. For the full year 2021, general and administrative expenses were $10.8 million versus approximately $7.6 million for the full year of 2020.

Total operating expenses for the fourth quarter of 2021 were approximately $6.9 million compared to $5.4 million for the comparable period in 2020. For the full year 2021, total operating expenses were $25.3 million compared to $21 million for the full year 2020.

As of December 31, 2021, the Company's cash and cash equivalents were approximately $27.3 million, including $7.9 million of restricted cash, compared to $28.4 million as of December 31, 2020.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30pm ET today, March 28. Participants should dial 877-407-9039 (domestic) or 201-689-8470 (international) with the conference code 13727374. 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 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 MyCombi™ 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.

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EYENOVIA, INC.
Balance Sheets

	December 31, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 19,461,850	$ 28,371,828
Deferred license costs	-	1,600,000
License fee and expense reimbursements receivable	1,805,065	2,966,039
Prepaid expenses and other current assets	734,942	453,478
Total Current Assets	22,001,857	33,391,345
Restricted cash	7,875,000	-
Property and equipment, net	1,271,225	396,380
Security and equipment deposits	510,976	119,035
Total Assets	$ 31,659,058	$ 33,906,760
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,614,104	$ 1,461,665
Accrued compensation	1,543,618	1,150,672
Accrued expenses and other current liabilities	845,719	1,480,692
Deferred rent - current portion	18,685	7,809
Deferred license fee	-	14,000,000
Notes payable - current portion, net	7,150,368	97,539
Total Current Liabilities	11,172,494	18,198,377
Deferred rent - non-current portion	19,949	38,684
Notes payable - non-current portion, net	-	365,814
Total Liabilities	11,192,443	18,602,875
Commitments and contingencies		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2021 and 2020, respectively	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 28,426,616 and 24,978,585 shares issued and outstanding as of December 31, 2021 and 2020, respectively	2,844	2,498
Additional paid-in capital	110,683,077	92,742,306
Accumulated deficit	(90,219,306)	(77,440,919)
Total Stockholders' Equity	20,466,615	15,303,885
Total Liabilities and Stockholders' Equity	$ 31,659,058	$ 33,906,760

EYENOVIA, INC.
Statements of Operations

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2021 (unaudited)	**2020 (unaudited)**	**2021 (unaudited)**	**2020**
Operating Income				
Revenue	$ 10,000,000	$ 2,000,000	$ 14,000,000	$ 2,000,000
Cost of revenue	-	(800,000)	(1,600,000)	(800,000)
Gross Profit	10,000,000	1,200,000	12,400,000	1,200,000
Operating Expenses:				
Research and development	3,175,229	3,397,506	14,509,525	13,363,251
General and administrative	3,711,499	2,009,112	10,794,158	7,625,974
Total Operating Expenses	6,886,728	5,406,618	25,303,683	20,989,225
Income (Loss) From Operations	3,113,272	(4,206,618)	(12,903,683)	(19,789,225)
Other Income (Expense):				
Small Business Administration Economic Injury Disaster Grant	-	-	-	10,000
Extinguishment of PPP 7(a) loan	-	-	463,353	-
Other income, net	55,193	-	47,183	-
Interest expense	(185,349)	(2,065)	(387,756)	(17,042)
Interest income	162	1,821	2,516	26,400
		-		
Net Income (Loss)	$ 2,983,278	$ (4,206,862)	$ (12,778,387)	$ (19,769,867)
Net Income (Loss) Per Share:				
Basic	$ 0.11	$ (0.17)	$ (0.49)	$ (0.94)
Diluted	$ 0.10	$ (0.17)	$ (0.49)	$ (0.94)
Weighted Average Number of Common Shares Outstanding:				
Basic	27,959,123	24,891,184	26,324,081	21,054,706
Diluted	30,019,966	24,891,184	26,324,081	21,054,706