

**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 15, 2024

EYENOVIA, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38365
(Commission
File Number)

47-1178401
(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 2.02. Results of Operations and Financial Condition.

On May 15, 2024, Eyenovia, Inc. (the “Company”) issued a press release announcing its financial results for the fiscal quarter ended March 31, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02, including Exhibit 99.1, is being “furnished” and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that Section or Sections 11 and 12(a) (2) of the Securities Act of 1933, as amended (the “Securities Act”). The information contained in this Item 2.02, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Eyenovia, Inc. Press Release, dated May 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.

Date: May 15, 2024

/s/ John Gandolfo

John Gandolfo
Chief Financial Officer



Eyenovia Reports First Quarter 2024 Financial Results and Provides Updates on its Myopia Phase III Program and its Two FDA Approved Commercial Products, Mydcombi and Clobetasol

Remains on track towards accelerating development of its late-stage product candidate in the multi-billion-dollar pediatric progressive myopia market, MicroPine

Preparing for a 3Q 2024 launch of the first new ophthalmic steroid in 15 years, clobetasol propionate ophthalmic suspension 0.05%, for the treatment of inflammation and pain following ocular surgery

Company to host conference call and webcast today, May 15th, at 4:30 pm ET

NEW YORK—May 15, 2024—Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage ophthalmic company with two FDA-approved products and a late-stage asset in pediatric progressive myopia, today announced its financial and operating results for the first quarter ended March 31, 2024.

First Quarter 2024 and Recent Business Developments

- Announced updated plans to accelerate development of its late-stage product candidate for pediatric progressive myopia, MicroPine. These plans include a protocol amendment to allow for a Data Monitoring Committee to review the Phase 3 CHAPERONE study data early in the fourth quarter. External sources have valued the pediatric progressive myopia market at over \$3.0 billion annually in the U.S. and China.
- Announced FDA approval of clobetasol propionate ophthalmic suspension 0.05% for the treatment of inflammation and pain following ocular surgery. Eyenovia is planning a launch of this product in the third quarter of 2024. Clobetasol has a desirable clinical profile as compared to other topical ocular steroids with twice-a-day dosing, a high level of efficacy and with adverse events occurring in fewer than 2% of patients.
- Reported training and shipping product to 50 new Mydcombi-using offices by its initial five Key Account Managers since sales promotion started in April 2024. Additionally, formulary agreements with Vision Source and the University of California have been executed.
- Reduced the Company's anticipated cash-based expenses by approximately \$0.8 million per quarter from first quarter 2024 actual levels.

Michael Rowe, Chief Executive Officer, commented, "During the first quarter of 2024, we took tangible steps to increase the inherent value of our company, which currently includes our novel Optejet technology, two FDA-approved products, and a third in late Phase 3 development. With highly differentiated and desirable products such as Mydcombi for mydriasis and clobetasol for post-surgical pain and inflammation, we look forward to meaningful sales growth over the next 18 months that we anticipate will lead us towards profitability. And our crown jewel, MicroPine for progressive myopia, if approved, would add significant value to the company by addressing a key unmet medical need of the approximately five million at-risk children in the U.S. alone."



“We believe the progress that we continue to make toward optimizing our platform technology has laid a strong foundation towards transforming Eyenovia into a leader in the development and commercialization of topical ophthalmic products and medications. We are committed to demonstrating the value of our existing and near-term products as well as future product candidates in ophthalmic markets with high unmet needs.”

“At the same time, we completed the build-out of our manufacturing capabilities, with FDA approval of our Redwood City location in addition to our Reno facility and Coastline International as our contract manufacturer. With all three facilities online, we are currently producing commercial supply of Mydcombi while at the same time supporting both current and future development partnerships as well as our transition from the Gen-1 to Gen-2 Optejet dispenser. To that end, we recently requested a meeting with the FDA to discuss our validation of the Gen-2 dispenser, which we anticipate will occur this summer,” Mr. Rowe concluded.

First Quarter 2024 Financial Review

For the first quarter of 2024, net loss was approximately \$10.9 million, or \$0.23 per share, as compared to a net loss of \$5.7 million, or \$0.15 per share, for the first quarter of 2023. The first quarter 2024 net loss includes \$2.5 million of expense, or \$0.05 loss per share, associated with the reacquisition of the license rights from Bausch for MicroPine and the write off of related clinical trial inventory.

Research and development expenses totaled approximately \$4.4 million for the first quarter of 2024, compared to \$2.5 million for the first quarter of 2023, an increase of approximately 75.7%.

For the first quarter of 2024, general and administrative expenses were approximately \$3.8 million, compared to \$2.9 million for the first quarter of 2023, an increase of approximately 30.6%.

Total operating expenses for the first quarter of 2024 were approximately \$10.3 million, including the previously referenced \$2.5 million of expenses associated with the Bausch transaction, compared to approximately \$5.5 million for the first quarter of 2023. This represents an increase of approximately 88.1%. The first quarter 2024 operating expense figure includes approximately \$1.5 million of non-cash expenses.

As of March 31, 2024, the Company’s unrestricted cash and cash equivalents were approximately \$8.0 million, not including \$2.2 million in additional capital the Company raised in April 2024.



Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, May 15th. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international), and reference conference ID 13746269.

To access the Call me™ feature, which avoids having to wait for an operator, click [here](#).

A live webcast of the conference call will also be available [here](#) and 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.

PLEASE GO TO MYDCOMBI.COM FOR IMPORTANT SAFETY INFORMATION for MYDCOMBI™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

PLEASE GO TO CLOBETASOLBID.COM FOR IMPORTANT SAFETY INFORMATION for Clobetasol Propionate Ophthalmic Suspension 0.05%

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its Optejet platform. Eyenovia is currently focused on the commercialization of Mydcombi (tropicamide+phenylephrine ophthalmic spray) for mydriasis, as well as clobetasol propionate ophthalmic nanosuspension 0.05% to reduce pain and inflammation following ocular surgery, which was approved by the FDA on March 4, 2024.

Eyenovia is also advancing late-stage development of medications in the Optejet device for presbyopia (Apersure) and myopia progression (MicroPine, partnered with Arctic Vision in China and South Korea).

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 products, 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, 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 any disruptions on our supply chain, including the availability of sufficient components and materials used in 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; the risk of defects in, or returns of, our products; 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 Sheet

	<u>March 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
	<u>(unaudited)</u>	
Assets		
Current Assets		
Cash and cash equivalents	\$ 7,976,106	\$ 14,849,057
Inventories	3,513,860	109,798
Deferred clinical supply costs	846,301	4,256,793
License fee and expense reimbursements receivable	88,045	123,833
Security deposits, current	1,506	1,506
Prepaid expenses and other current assets	2,025,267	1,365,731
Total Current Assets	<u>14,451,085</u>	<u>20,706,718</u>
Property and equipment, net	3,155,710	3,374,384
Security deposits, non-current	197,168	197,168
Intangible assets	6,122,945	2,122,945
Operating lease right-of-use asset	1,538,814	1,666,718
Equipment deposits	711,441	711,441
Total Assets	<u>\$ 26,177,163</u>	<u>\$ 28,779,374</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 2,145,272	\$ 1,753,172
Accrued compensation	828,286	1,658,613
Accrued expenses and other current liabilities	4,751,755	287,928
Operating lease liabilities - current portion	579,585	501,250
Notes payable - current portion, net of debt discount of \$621,712 and \$503,914 as of March 31, 2024 and December 31, 2023, respectively	8,155,025	5,329,419
Total Current Liabilities	<u>16,459,923</u>	<u>9,530,382</u>
Operating lease liabilities - non-current portion	1,140,231	1,292,667
Notes payable - non-current portion, net of debt discount of \$200,711 and \$448,367 as of March 31, 2024 and December 31, 2023, respectively	2,103,456	4,355,800
Convertible notes payable - net of debt discount of \$344,219 and \$398,569 as of March 31, 2024 and December 31, 2023, respectively	4,655,781	4,601,431
Total Liabilities	<u>24,359,391</u>	<u>19,780,280</u>
Stockholders' Equity:		
Preferred stock, \$0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023		
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 47,386,349 and 45,553,026 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	4,738	4,555
Additional paid-in capital	158,226,694	154,486,098
Accumulated deficit	(156,413,660)	(145,491,559)
Total Stockholders' Equity	<u>1,817,772</u>	<u>8,999,094</u>
Total Liabilities and Stockholders' Equity	<u>\$ 26,177,163</u>	<u>\$ 28,779,374</u>



EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended March 31,	
	2024	2023
Operating Income		
Revenue	\$ 4,993	\$ -
Cost of revenue	(4,993)	-
Gross Profit	-	-
Operating Expenses:		
Research and development	4,431,601	2,521,950
General and administrative	3,835,223	2,936,886
Reacquisition of license rights	2,000,000	-
Total Operating Expenses	10,266,824	5,458,836
Loss From Operations	(10,266,824)	(5,458,836)
Other Income (Expense):		
Other (expense) income, net	(97,558)	70,993
Interest expense	(678,658)	(454,003)
Interest income	120,939	102,480
Total Other Expense	(655,277)	(280,530)
Net Loss	<u>\$ (10,922,101)</u>	<u>\$ (5,739,366)</u>
Net Loss Per Share - Basic and Diluted	<u>\$ (0.23)</u>	<u>\$ (0.15)</u>
Shares Outstanding - Basic and Diluted	<u>46,606,790</u>	<u>37,410,587</u>