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): August 10, 2023

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 2.02. Results of Operations and Financial Condition.

On August 10, 2023, Eyenovia, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended June 30, 2023. 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

Exhibit No.	**Description**
99.1	Eyenovia, Inc. Press Release, dated August 10, 2023.
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: August 10, 2023

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Reports Second Quarter 2023 Financial Results and Provides Business Update

Announced FDA approval of and first commercial sale of Mydcombi™, the only fixed dose combination of tropicamide and phenylephrine for mydriasis and the first FDA approved product to utilize the Optejet®

Continued to advance its Phase 3 Apersure™ (Microline) presbyopia candidate following receipt of guidance from FDA that establishes an efficient path forward for the program

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

NEW YORK—August 10, 2023—Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company commercializing Mydcombi™ (tropicamide+phenylephrine ophthalmic spray) for mydriasis and developing the Optejet® device for use both in connection with its own drug-device therapeutic product candidates for presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced its financial and operating results for the second quarter ended June 30, 2023.

Second Quarter 2023 and Recent Business Developments

- Announced first commercial sale of Mydcombi to world-renowned board-certified ophthalmologist Dr. Nathan M. Radcliffe, who becomes first to incorporate Mydcombi into his daily practice. The company will be following up with sales to key physicians in the upcoming weeks and preparing for national launch in early 2024.

- Advanced its pre-NDA presbyopia program, Apersure (Microline), and anticipates commencing the manufacture of registration batches in the fourth quarter of 2023.

- Continued to build out its manufacturing facilities in Redwood City, CA and Reno, NV, the former having a PDUFA date in November 2023 for use as a commercial facility.

- Delivered presentation at the annual OCTANE Ophthalmology Tech Forum 2023 reviewing the recent FDA approval of Mydcombi.

- Licensing partners Bausch+Lomb and Arctic Vision continued to enroll patients in their respective Phase 3 studies of Micropine (US and China) and Microline (China).

- Announced addition to widely followed Russell 2000 and Russell 3000 Indexes.

Michael Rowe, Chief Executive Officer, commented, “We achieved very significant milestones since our last quarterly update, notably the FDA approval and first commercial sale of Mydcombi, officially transitioning us to a commercial stage company. We are now executing a targeted launch of Mydcombi while in parallel ramping up our internal manufacturing capabilities in anticipation of a broader campaign incorporating our Gen 2 Optejet device beginning in 2024.

"Regarding our pre-NDA presbyopia candidate, Apersure, we continue to advance this important program following receipt of feedback from FDA that established a clear and efficient path forward. The addressable presbyopia market for topical ophthalmic medications is a nearly one-billion-dollar market opportunity in the US alone, and we believe an effective solution that leverages our novel Optejet drug delivery platform and fits within the business model of optometrists will be highly differentiated in the marketplace. We plan to initiate the manufacture of registration batches of Apersure during the fourth quarter.

“We believe the approval and commercial availability of Mydcombi will fundamentally transform the way that topical eye drugs are developed and delivered, as we now have critical validation of our Optejet platform that will benefit not only our proprietary development programs, most notably Apersure, but current and future partnerships as well. To that end, we continue to have very productive discussions with potential partners that could ultimately see the Optejet incorporated into additional large market ophthalmology indications with persistent unmet needs.

“I am extremely pleased with our progress to date and look forward to a productive back half of the year,” Mr. Rowe concluded.

Second Quarter 2023 Financial Review

For the second quarter of 2023, net loss was approximately $(6.2) million, or $(0.16) per share compared to a net loss of approximately $(7.2) million, or $(0.22) per share, for the second quarter of 2022.

Research and development expenses totaled approximately $2.8 million for the second quarter of 2023 as compared to $3.6 million for the second quarter of 2022.

For the second quarter of 2023, general and administrative expenses were approximately $3.1 million, compared to $3.5 million for the second quarter of 2022.

Total operating expenses for the second quarter of 2023 were approximately $6.0 million compared to $7.1 million for the second quarter of 2022.

As of June 30, 2023, the Company’s cash and cash equivalents were approximately $17.5 million compared to $22.9 million as of December 31, 2022.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET today, August 10. Participants should dial 1-877-407-9039 (domestic) or 1-201-689-8470 (international), and reference conference ID 13739696.

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 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.

IMPORTANT SAFETY INFORMATION for MYDCOMBI™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

INDICATIONS

MYDCOMBI is indicated to induce mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired

CONTRAINDICATIONS: In patients with known hypersensitivity to any component of the formulation

WARNINGS AND PRECAUTIONS

FOR TOPICAL OPHTHALMIC USE. NOT FOR INJECTION

This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of psychotic reaction and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be considered.

Mydriatics may produce a transient elevation of intraocular pressure.

Significant elevations in blood pressure have been reported. Caution in patients with elevated blood pressure.

Rebound miosis has been reported one day after installation.

Remove contact lenses before using.

DRUG INTERACTIONS

Atropine-like Drugs: May exaggerate the adrenergic pressor response

Cholinergic Agonists and Ophthalmic Cholinesterase Inhibitors: May interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors

Potent Inhalation Anesthetic Agents: May potentiate cardiovascular depressant effects of some inhalation anesthetic agents

ADVERSE REACTIONS

- Most common ocular adverse reactions include transient blurred vision, reduced visual acuity, photophobia, superficial punctate keratitis, and mild eye discomfort. Increased intraocular pressure has been reported following the use of mydriatics.
- Systemic adverse reactions including dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity have been reported with the use of tropicamide.

To report SUSPECTED ADVERSE REACTIONS, contact Eyenovia, Inc. At 1-833-393-6684 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch)

Please go to www.mydcombi.com for **FULL PRESCRIBING INFORMATION**

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics. Eyenovia is currently focused on the commercialization of Mydcombi and the late-stage development of microdosed medications for presbyopia and myopia progression. For more information, visit www.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; 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

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	$ 17,468,088	$ 22,863,520
Deferred clinical supply costs	3,578,326	2,284,931
License fee and expense reimbursements receivable	429,006	1,183,786
Security deposits, current	-	119,550
Prepaid expenses and other current assets	1,801,373	1,190,719
Total Current Assets	23,276,793	27,642,506
Property and equipment, net	3,698,421	1,295,115
Security deposits, non-current	198,674	80,874
Operating lease right-of-use asset	1,915,061	1,291,592
Equipment deposits	257,950	726,326
Total Assets	$ 29,346,899	$ 31,036,413
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,312,749	$ 1,428,283
Accrued compensation	1,013,118	1,747,191
Accrued expenses and other current liabilities	363,431	503,076
Operating lease liabilities - current portion	427,749	484,882
Notes payable - current portion, net of debt discount of $91,621 and $33,885 as of June 30, 2023 and December 31, 2022, respectively	947,163	174,448
Convertible notes payable - current portion, net of debt discount of $0 and $33,885 as of June 30, 2023 and December 31, 2022, respectively	-	174,448
Total Current Liabilities	4,064,210	4,512,328
Operating lease liabilities - non-current portion	1,584,218	907,644
Notes payable - non-current portion, net of debt discount of $1,120,372 and $813,229 as of June 30, 2023 and December 31, 2022, respectively	8,683,794	4,190,938
Convertible notes payable - non-current portion, net of debt discount of $507,270 and $813,229 as of June 30, 2023 and December 31, 2022, respectively	4,492,730	4,190,938
Total Liabilities	18,824,952	13,801,848
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2023 and December 31, 2022	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 38,169,398 and 36,668,980 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	3,817	3,667
Additional paid-in capital	140,703,819	135,461,361
Accumulated deficit	(130,185,689)	(118,230,463)
Total Stockholders' Equity	10,521,947	17,234,565
Total Liabilities and Stockholders' Equity	$ 29,346,899	$ 31,036,413

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating Expenses:				
Research and development	$ 2,811,061	$ 3,586,866	$ 5,333,011	$ 7,299,450
General and administrative	3,149,809	3,534,590	6,086,695	7,009,555
Total Operating Expenses	5,960,870	7,121,456	11,419,706	14,309,005
Loss From Operations	(5,960,870)	(7,121,456)	(11,419,706)	(14,309,005)
Other Income (Expense):				
Other income, net	119,450	33,376	190,443	26,303
Interest expense	(558,003)	(153,436)	(1,012,006)	(298,673)
Interest income	183,563	2,416	286,043	2,610
Net Loss	$ (6,215,860)	$ (7,239,100)	$ (11,955,226)	$ (14,578,765)
Net Loss Per Share - Basic and Diluted	$ (0.16)	$ (0.22)	$ (0.32)	$ (0.46)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	38,093,826	33,644,867	37,753,694	31,836,582