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 8, 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)

(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 8.01. Other Events.

On May 8, 2023, Eyenovia, Inc. (the "Company") issued a press release announcing the receipt of approval from the U.S. Food and Drug Administration for Mydcombi (tropicamide 1% plus phenylephrine 2.5% ophthalmic spray) for mydriasis (in-office and pre-surgical pupil dilation). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Eyenovia, Inc. Press Release, dated May 8, 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: May 8, 2023

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Announces FDA Approval of Mydcombi™, the First Ophthalmic Spray for Mydriasis, Which Also Leverages the Company's Proprietary Optejet® Device Platform

Represents the first FDA approved fixed-combination of tropicamide and phenylephrine for mydriasis

Provides critical validation of key technology that is core to Eyenovia's proprietary development programs as well as current and future partnerships

NEW YORK— May 8, 2023—Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company 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 that the U.S. Food and Drug Administration (FDA) has approved Mydcombi (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5% for inducing mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired. This represents the first approved fixed dose combination of tropicamide and phenylephrine in the United States and also the first product using Eyenovia's proprietary Optejet device to be approved by any regulatory authority.

Mydcombi is designed to improve the efficiency of the estimated 106 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. The product is contraindicated and should not be used in patients with known hypersensitivity to any component of the formulation.

"The approval of Mydcombi, our first FDA approved product, represents the culmination of years of tireless effort by the entire Eyenovia team, and I would like to express my sincere gratitude to the associates and technical experts who helped advance this important program through this transformational milestone," stated Michael Rowe, chief executive officer of Eyenovia. "We look forward to introducing Mydcombi to key offices beginning this summer while we bring our internal manufacturing capabilities on-line for 2024."

"Perhaps more importantly, FDA approval of Mydcombi provides critical validation of the Optejet as it is the first product approved using the Optejet platform, which is core not only to our internal development programs, including MicroLine for presbyopia, but our partnered programs as well. We see opportunities to unlock significant opportunities in the future treatment of other ophthalmic conditions including glaucoma and dry eye. I am confident in our ability to maintain our current momentum."

"I am proud of our team for this significant achievement – which represents many 'firsts' for eye care," stated Dr. Sean Ianchulev, Founder and Chairman of Eyenovia's Board of Directors. "The use of eye dropper bottles has presented challenges for dosing in ophthalmologic settings in millions of patients. We can do better now using sophisticated micro-array print delivery with physiologic dosing that is similar to the natural tear film volume."

Eyenovia management will provide additional updates on Mydcombi as well as its ongoing development programs and partnerships during its regularly scheduled first quarter 2023 update conference call and webcast on May 11th, 2023.

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

Not for Injection: Topical ophthalmic use

Significant Elevations in Blood Pressure: Caution in pediatric patients less than 5 years of age, and in patients with cardiovascular disease or hyperthyroidism. In patients at high risk, monitor blood pressure post treatment.

Central Nervous System Disturbances: Caution in pediatric patients where rare incidences of central nervous system disturbances have been reported.

Intraocular Pressure: May produce a transient elevation

Rebound Miosis: Reported 1 day after administration

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 a commercial stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics. Eyenovia is currently focused on the commercialization of Mydcombi for mydriasis, as well as the ongoing late-stage development of medications in the Optejet device for 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 the statements, expectations and assumptions contained in this presentation 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, 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 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, legislative and geopolitical 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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