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): February 8, 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 x

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 February 8, 2022, Eyenovia, Inc. (the "Company") issued a press release announcing that it successfully completed a Type A meeting with the U.S. Food and Drug Administration ("FDA") related to the refiling of the new drug application ("NDA") for MydCombi, the Company's proprietary, first-in-class combination of tropicamide and phenylephrine for in-office-pupil dilation. Following the Type A meeting, the Company and the FDA reached alignment on the path forward toward an NDA resubmission. The Company expects to resubmit the NDA during the third quarter of 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Eyenovia, Inc. Press Release dated February 8, 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: February 8, 2022

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Concludes Type A Meeting with FDA Related to MydCombi™ NDA Resubmission

No additional clinical work required; NDA resubmission anticipated in Q3 2022

NEW YORK—February 8, 2022—Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that the company successfully completed a Type A meeting with the U.S. Food and Drug Administration (FDA) related to the refiling of the NDA for MydCombi.

On October 22, 2021, Eyenovia received a complete response letter (CRL) from the FDA stating that MydCombi, the company's proprietary, first-in-class combination of tropicamide and phenylephrine for in-office pupil dilation, had been reclassified as a drug-device combination product. Following the recent Type A meeting, Eyenovia and the agency reached alignment on the path forward toward an NDA resubmission. Specifically, FDA has requested that the company conduct additional device testing related to the Optejet® dispenser. Importantly, no additional clinical studies of MydCombi were requested.

"We had a very constructive meeting with the FDA and confirmed the additional non-clinical items to be addressed. We are in the process of conducting these requested validation studies and plan to resubmit our NDA in Q3 2022," stated Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia. "Of note, now that our product candidates are classified as combination drug/device products, we will be taking advantage of this requested validation work to streamline development activities for our future programs. One such potential benefit is the potential to reference this device validation work in future regulatory applications, reducing the time and expense of repeating these tests for each program.

"All in all, while we certainly would have preferred not to have this delay, we understand the legal necessity of the reclassification. Ultimately, we believe that our work today will lay the regulatory groundwork for future products."

"In parallel with these activities, our second Phase 3 VISION-2 clinical trial of MicroLine, our proprietary pilocarpine formulation for the temporary improvement in near vision in people with presbyopia, continues to enroll and we anticipate reporting results in the second quarter of this year. We believe the presbyopia market is a nearly $8 billion addressable market in the U.S. alone."

The company will elaborate further on these and other recent corporate developments during its fourth quarter update conference call in mid-March.

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 approximately 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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