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 2, 2021

EYENOVIA, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-38365	47-1178401
(Commission File Number)	(IRS Employer Identification No.)

295 Madison Avenue, Suite 2400, New York, New York 10017
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code (917) 289-1117

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(s)	Name of each exchange on which registered
Common Stock, $0.0001 Par Value	EYEN	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 (§230.405 of this Chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this Chapter).

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 March 2, 2021, Eyenovia, Inc. (the "Company") issued a press release announcing that the U. S. Food and Drug Administration has accepted the Company's New Drug Application for MydCombi™ and that the Company expects a Prescription Drug User Fee Act ("PDUFA") date in the fourth quarter of 2021.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 2, 2021.

SIGNATURE

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 2, 2021

By: /s/ John Gandolfo
Name: John Gandolfo
Title: Chief Financial Officer

Exhibit 99.1

Eyenovia Announces FDA Acceptance of the MydCombi NDA

PDUFA Date Expected 4Q 2021

NEW YORK— March 2, 2021—Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for MydCombi™, a unique fixed combination mydriatic (pupil dilation) agent for potential use in the over 80 million comprehensive eye exams currently conducted each year in the United States. If approved, MydCombi would be the first microdosed ocular therapeutic applied with a high precision smart delivery system, the Optejet®.

"We are excited to see MydCombi, with our proprietary microdose array print technology, move closer to potential approval, with an expected PDUFA date in the fourth quarter of this year. MydCombi may address many of the current shortfalls of pupil dilation, which according to market research may be responsible for millions of people choosing not to undergo a comprehensive eye exam," said Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia. "If approved, we believe MydCombi would provide patients with one of the biggest advances in clinical mydriasis in the last few decades."

Approximately 90% of eye care providers reported that they encounter situations where patients avoid pharmaceutical pupil dilation often due to discomfort with the procedure, according to market research conducted by J. Reckner Associates.

MydCombi was developed with the goal of providing a touchless fixed combination microdose formulation to improve the patient's clinical experience. MydCombi is delivered by Eyenovia's proprietary Optejet dispenser, designed to ensure consistent and easy application of two mydriatic medications in a quick, touchless micro-mist application. The Optejet is also designed with no protruding parts, which may help prevent accidental touching of the ocular surface.

The NDA submission was based on the MIST-1 and MIST-2 studies. In these two Phase 3 studies, a fixed combination of micro-dosed tropicamide 1% and phenylephrine 2.5% ophthalmic solution met the studies' primary endpoints and was shown to be safe and effective for pharmacologic mydriasis. Approximately 94% of treated eyes achieved 6mm or greater dilation at 35 minutes post-instillation. Adverse events were infrequent, with fewer than 1% of patients reporting blurred vision, reduced acuity, photophobia or instillation site pain.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more Information, visit www.eyenovia.com.

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 regulatory review timing, and 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 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: the timing and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; 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; 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 certain of our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for certain of our product candidates; intellectual property risks; 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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