

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) December 29, 2020

**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, 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 December 29, 2020, Eyenovia, Inc. issued a press release announcing that it has submitted a New Drug Application to the U. S. Food and Drug Administration for MydCombi®, a unique fixed combination mydriatic (pupil dilation) agent. 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

<b>Exhibit No.</b>	<b>Description</b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press release dated December 29, 2020.</u></a>

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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: December 29, 2020

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

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### **Eyenovia Submits New Drug Application to FDA for Pharmacologic Mydriasis with MydCombi Targeting 80 Million Patient Encounters in the U.S. Annually**

NEW YORK—December 29, 2020—Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company with Phase 3 programs in presbyopia, myopia and mydriasis, today announced that it has submitted a New Drug Application (NDA) to the U. S. Food and Drug Administration (FDA) for MydCombi™, a unique fixed combination mydriatic (pupil dilation) agent. If approved, MydCombi would be the first microdosed ocular therapeutic with a high precision smart delivery system.

The NDA submission follows the initial enrollment of the VISION-1 study, Eyenovia's Phase 3 study for MicroLine in presbyopia, with top-line data expected the first half of 2021.

MydCombi was developed to address several needs of the eye care practitioner's office. Pupil dilation is conducted during most of the estimated 80 million office-based comprehensive and diabetic eye exams performed in the U.S. annually. The current standard of care for pupil dilation requires multiple eye drops given at least several minutes apart, which can take considerable time and often cause both discomfort and drug overflow. The design of eyedroppers also lends itself to the possibility of inadvertent contact with the eye itself, which may be an issue as the same eyedropper bottle is often shared among a number of patients. In contrast, 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 product is also designed with no protruding parts, which may help prevent accidental touching of the ocular surface.

"The NDA application for MydCombi represents a milestone for Eyenovia. It is the first of our three late-stage programs to complete Phase 3 studies leading to this FDA submission, which not only validates our platform technology, but also demonstrates the passion and tireless efforts of all Eyenovians. If approved, MydCombi could be available late next year or early 2022 and improve a common clinical practice that has not advanced in nearly a century," said Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia. "MydCombi, delivered by our proprietary Optejet touchless dispenser, may have several advantages over the current standard of care for in-office mydriasis that are especially important in today's environment. With no protruding parts and recessed nozzle and shutter, Optejet's design enables touch-free mydriasis and helps reduce the risk of cross contamination."

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 phenylephrine 2.5% and tropicamide 1% ophthalmic solution 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. All adverse events were infrequent at 3.1%; fewer than 1% of patients reported blurred vision, reduced acuity, photophobia or instillation site pain.

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“Pupil dilation is a necessity for most eye exams. The process today can add several minutes to each exam, which over the course of the day often translates to fewer patients examined. MydCombi has the potential to significantly improve patient flow and make the in-office mydriasis process more efficient and more comfortable for patients,” said Dr. James Tsai, president of New York Eye and Ear Infirmary of Mount Sinai and a member of the Eyenovia Scientific Advisory Board.

**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](http://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 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; 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 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; 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.

**Eyenovia Contact:**

Eyenovia, Inc.  
John Gandolfo  
Chief Financial Officer  
[jgandolfo@eyenovia.com](mailto:jgandolfo@eyenovia.com)

**Eyenovia Investor Contact:**

Eric Ribner  
LifeSci Advisors, LLC  
[eric@lifesciadvisors.com](mailto:eric@lifesciadvisors.com)  
(646) 751-4363

**Eyenovia Media Contact:**

Diana Soltesz  
Pazanga Health Communications  
[dsoltesz@pazangahealth.com](mailto:dsoltesz@pazangahealth.com)  
(818) 618-5634

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