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) November 26, 2018

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, NY 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))

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 ☒

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 November 26, 2018, Eyenovia, Inc. (the "Company") issued a press release announcing that it has enrolled the first patient in the first of two Phase III trials (MIST-1 and MIST-2) of the Company's MicroStat program for pharmacologic mydriasis, or dilation of the pupil for an eye exam. The studies will investigate the safety and efficacy of the Company's first-in-class fixed-combination phenylephrine 2.5% - tropicamide 1% ophthalmic solution, administered as a micro-dose using the Optejet™ dispenser. 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	Press release dated November 26, 2018.

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: November 26, 2018

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

Exhibit 99.1

Eyenovia Initiates Phase III MicroStat Program for Pharmacologic Mydriasis: Enrolls First Patient in MIST-1 Study

Topline results for Phase III MicroStat program expected H1 2019

New York, NY – November 26, 2018 – Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose therapeutics utilizing its patented piezo-print technology, today announced that it has enrolled the first patient in the first of two Phase III trials (MIST-1 and MIST-2) of the Company's MicroStat program for pharmacologic mydriasis, or dilation of the pupil for an eye exam. The studies will investigate the safety and efficacy of the Company's first-in-class fixed-combination phenylephrine 2.5% - tropicamide 1% ophthalmic solution, administered as a micro-dose using the Optejet™ dispenser. Pharmacologic mydriasis is an important part of an estimated 80 million office-based comprehensive and diabetic eye exams performed each year in the United States and is essential for the standard dilated retinal fundoscopic examination.

"With the enrollment of the first patient in the first pivotal trial of MicroStat for pharmacologic mydriasis, Eyenovia officially transitions into a Phase III company," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "We believe that our fixed-combination of phenylephrine and tropicamide has the potential to significantly improve both the patient experience and physician workflow during eye exams. We look forward to announcing topline results from both trials in our Phase III MicroStat program in the first half of 2019."

The two Phase III trials are randomized, double-blind, multicenter-superiority studies, which will each enroll approximately 65 participants in the United States. In the MIST-1 study, both eyes of the participants will be treated on separate days with Eyenovia's proprietary fixed combination mydriatic solution and each of the component solutions. In the MIST-2 study, participants will receive Eyenovia's fixed combination mydriatic solution and a placebo on separate days. All treatments will be administered using the Optejet dispenser. The primary endpoint for both studies is the mean change in baseline pupil diameter at 35 minutes after administration of study treatment.

About Eyenovia
Eyenovia, Inc. (NASDAQ: EYEN) is a specialty biopharmaceutical company building a portfolio of next generation topical eye treatments based on its proprietary delivery and formulation platform for microdosing. Eyenovia's pipeline is currently focused on the late-stage development of microdosed medications for myopia progression, glaucoma, mydriasis and other eye diseases.

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. 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 SEC. In addition, such statements could be affected by risks and uncertainties related to, among other things: risks involved in clinical trials, including, but not limited to, the initiation, timing, progress and results of such trials; the timing and our ability to submit applications for, obtain and maintain regulatory approvals for, our product candidates; our ability to develop and implement commercialization, marketing and manufacturing capabilities and strategies; the potential advantages of our product candidates; 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; intellectual property risks; the impact of government laws and regulations; 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, we do not undertake any obligation to update any forward-looking statements.

Caution: New Drug—Limited by Federal (United States) law to investigational use.

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