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) June 30, 2020

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, 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))

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 June 30, 2020, Eyenovia, Inc. issued a press release announcing that it has resumed patient enrollment for its Phase III CHAPERONE study for the treatment of pediatric progressive myopia. 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 June 30, 2020.

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: June 30, 2020

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

Exhibit 99.1

Eyenovia Resumes Recruitment of Phase III CHAPERONE Study for Progressive Myopia

New York, NY – June 30, 2020 – Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics, today announced that the Company has resumed patient enrollment for its Phase III CHAPERONE study for the treatment of progressive myopia, following a temporary pause due to the COVID-19 pandemic.

"We are excited to resume enrollment in our Phase III CHAPERONE study among nearly all of our clinical sites for the treatment of progressive myopia in children. Despite conditions caused by COVID-19, we continued to follow-up with and monitor previously enrolled CHAPERONE patients via telemedicine and remote monitoring processes. We are pleased to report that all patients previously randomized to treatment have continued to progress in the study. We are working in close partnership with our investigational sites as we advance to complete trial enrollment, which will depend on the continued improvement of the COVID-19 pandemic," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer.

The CHAPERONE study is a U.S.-based, multi-center, randomized, double-masked trial that will enroll more than 400 children between 3-12 years of age. The study is investigating the safety and efficacy of MicroPine for the reduction of progressive myopia using Eyenovia's proprietary atropine topical micro-formulation delivered by the Optejet™ dispenser. Subjects will be randomized to receive treatment with either of two MicroPine concentrations or a placebo. The primary endpoint of the study is the proportion of eyes with < 0.5 D increase in refractive error from baseline through 36 months.

About Eyenovia

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

About MicroPine for Progressive Myopia

MicroPine (atropine ophthalmic solution) is Eyenovia's first-in-class topical treatment for progressive myopia, a back-of-the-eye condition commonly known as nearsightedness. Progressive myopia is estimated to affect close to 5 million children in the United States who suffer from uncontrolled axial elongation of the sclera leading to increasing levels of myopia and in some cases major pathologic changes such as retinal atrophy, macular staphylomas, retinal detachment and visual impairment. MicroPine has been developed for comfort and ease-of-use in children. Microdose administration of MicroPine is anticipated to result in low systemic and ocular drug exposure. A recent therapeutic evidence assessment and review by the American Academy of Ophthalmology indicates Level 1 (highest) evidence of efficacy for the role of low dose atropine for progressive myopia (Ophthalmology 2017;124:1857-1866; Ophthalmology 2016; 123(2) 391:399).

Feasibility Dose-finding Atropine Studies: ATOM 1; ATOM 2; LAMP (Independent Collaborative Group Trials)

About MicroLine for Presbyopia

MicroLine is Eyenovia's pharmacologic treatment for presbyopia. Presbyopia is the non-preventable, age related hardening of the lens, which causes a gradual loss of the eye's ability to focus on nearby objects and is estimated to affect nearly 113 million Americans. Current treatment options are typically device-based, such as reading glasses and contact lenses. Pilocarpine ophthalmic solution is known to constrict the pupil and improve near-distance vision by creating an extended depth of focus through its small aperture effect. Eyenovia believes that its administration of pilocarpine using the company's high precision microdosing technology may provide a meaningful improvement in near vision while enhancing tolerability and usability.

About MicroStat for Mydriasis

MicroStat is Eyenovia's first-in-class fixed-combination micro-formulation product (tropicamide 1% - phenylephrine 2.5%) candidate for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 80 million office-based comprehensive and diabetic eye exams performed every year in the United States, as well as the estimated 4 million pharmacologic mydriasis applications for cataract surgery. Developed for use without anesthetic, we are developing MicroStat to improve the efficacy and tolerability of pharmacologic mydriasis.

About Optejet™ and MicroRx Ocular 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 believe the volume of ophthalmic solution administered with the Optejet is less than 75% 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% with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

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 in the United States for our product candidates. 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: impacts of and uncertainty related to COVID-19; 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 and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; fluctuations in our financial results, particularly given market conditions and the potential economic impact of COVID-19; our need to raise additional money to fund our operations for at least the next 12 months as a going concern; the potential impacts of COVID-19 on our supply chain; the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our estimates regarding the potential market opportunity for our product candidates; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; our ability to timely develop and implement anticipated manufacturing, commercialization and marketing capabilities and strategies for existing product candidates; our ability to attract and retain key personnel; 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, we do not undertake any obligation to update any forward-looking statements.

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