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 4, 2019

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.)**

501 Fifth Avenue, Suite 1404, New York, NY 10017
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code 917-289-11170

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 4, 2019, Eyenovia, Inc. issued a press release announcing that it has initiated its Phase III trial for MicroPine with the first patient enrolled in its CHAPERONE study. 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 4, 2019.

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 4, 2019

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

Exhibit 99.1

Eyenovia Enrolls First Patient in Phase III CHAPERONE Study for Progressive Myopia

Program Follows Successful Completion of Phase III Program in Mydriasis

New York, NY – June 4, 2019 – Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose therapeutics utilizing its patented piezo-print delivery technology, today announced that it has initiated its MicroPine Phase III program with the first patient enrolled in its CHAPERONE study.

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 will investigate 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 change in refractive error from baseline through 36 months.

Currently, there are no FDA-approved therapeutics for the treatment of pediatric progressive myopia - a back-of-the-eye disease characterized by uncontrolled sclero-retinal axial elongation leading to myopia and potential associated pathologic changes, such as retinal atrophy, macular staphylomas, retinal detachment and visual impairment. It is estimated that close to 22% of young adults and children in the United States suffer from myopia, with progressive prevalence in the Caucasian population increasing more than 10-fold between the ages of 5 and 18 years, while in some regions in Asia, up to 80% of children are reported to be myopic[1,2].

"We are very pleased to have initiated enrollment in our Phase III CHAPERONE study. This program could set some first-in-class precedents – not only as the first therapeutic indicated for myopic progression, but also the first topical therapy for a back-of-the-eye disease. Level 1 evidence from recent academic, collaborative, randomized trials such as ATOM1, ATOM2 and LAMP have established that low concentration atropine eye drops can slow progressive myopia by up to 60-70%[3-4] with an acceptable risk-benefit profile, and could be a game-changer in our efforts to fight the global myopia epidemic. We plan to use the CHAPERONE study, along with the existing evidence from the previous academic collaborative trials, to submit for the FDA approval of MicroPine," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer.

Dr. Pamela Gallin, Clinical Professor of Ophthalmology in Pediatrics and Director Emeritus, NY Presbyterian – Columbia University Medical Center added, "CHAPERONE will evaluate the benefit of slowing the progression of myopia with a microdose of low concentration atropine. This may reduce the problems associated with high myopia, including a range of retinal complications."

"I believe some of the current challenges faced by clinicians and families exploring myopia control with atropine are adherence and side effects with long term treatment," commented Dr. Danielle Iacono, Assistant Clinical Professor at SUNY College of Optometry and one of the Principal Investigators within the CHAPERONE study. "The Eyenovia micro-dosed atropine formulation to be evaluated in the CHAPERONE study delivers less drug in such a way that it could increase adherence to treatment and reduce adverse effects. Since these factors are paramount to the success of all ocular medication, I am excited to begin enrolling patients into this study, which at its conclusion will inform myself and other eye care providers as to the safety and efficacy of this novel approach to myopia control."

Frequently Asked Questions about Pediatric Progressive Myopia (PPM)

What is pediatric progressive myopia (PPM)?

PPM is nearsightedness in children that worsens year after year. This progression may result in severe (or high) myopia, which can be associated with potentially serious side effects including loss of vision[5].

How common is PPM?

In 2016, there were an estimated 30 million children with myopia in the United States alone, of which approximately 5 million would be considered highly myopic. Worldwide, it is estimated that the number of individuals who are myopic could reach up to 4.7 billion, with 900 million of those forecast to be highly myopic by 2050[6,7].

How does PPM differ from the myopia that millions of adults live with?

Myopia that presents later in life tends not to progress, making it more easily corrected by glasses or contact lenses and often not associated with the potential long-term consequences of pediatric progressive myopia.

What are some of the potential long-term consequences of PPM?

Severe myopia after years of PPM in childhood is a leading cause of functional vision loss, which can in certain cases lead to retinal detachment, glaucoma, cataracts, choroidal neovascularization, staphyloma and myopic macular degeneration[8].

What is atropine?

Atropine is a well-established drug that has a wide range of uses including as a systemic agent to block the effects of nerve agents to treating strabismus or “lazy eye” when used as a higher concentration eyedrop.

What evidence is there that low concentration atropine can reduce the progression of PPM?

Administration of low concentration atropine eyedrops has been demonstrated to be a promising modality to slow PPM in multiple large clinical studies conducted primarily in Asia, including ATOM1[3], ATOM2[4] and LAMP[9].

Is atropine used today in patients with PPM?

There is currently no FDA-approved atropine product for treatment of PPM. Low concentration atropine eyedrops that are specially compounded by pharmacies are used by some patients to reduce the progression of the disease; however, these formulations are not shelf-stable over a long period of time, with the potential to affect potency as well as batch-to-batch variability. Also, because compounded eye medications are not subjected to the rigors of FDA premarket review, their safety and efficacy have not been well-characterized and in some cases have led to adverse events[10].

About Eyenovia
Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose therapeutics utilizing its patented piezo-print delivery technology. Eyenovia's pipeline is currently focused on the late-stage development of microdosed medications for mydriasis, myopia progression, glaucoma, and other eye diseases. For more Information please visit www.eyenovia.com.

About MicroStat for Mydriasis
MicroStat is Eyenovia's first-in-class fixed-combination micro-formulation product (phenylephrine 2.5% -tropicamide 1%) candidate for pharmacologic mydriasis (eye dilation) which is targeted to address the growing needs 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. We are developing MicroStat to improve the efficacy and tolerability of pharmacologic mydriasis.

Upcoming Milestone: NDA Filing 2020

About MicroPine for Progressive Myopia
MicroPine is Eyenovia's first-in-class topical treatment for progressive myopia, a back-of-the-eye disease. Progressive myopia is estimated to affect close to 5 million patients 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. Early dose finding studies by collaborative academic groups have demonstrated high therapeutic potential with low dose atropine which can reduce myopia progression by 60 – 70% with a sustained effect through three years. 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 MicroProst for Glaucoma and Ocular Hypertension
MicroProst is Eyenovia's proprietary latanoprost formulation product candidate, which is being developed as a first-line treatment for the reduction of IOP in patients with Chronic Angle Closure Glaucoma (CACG), as well as Primary Open Angle Glaucoma (POAG) and Ocular Hypertension. Currently, there are no FDA-approved therapies specifically indicated for CACG, which accounts for an estimated 10% and 50% of all glaucoma diagnoses in the United States and China, respectively. We believe there are approximately 500,000 patients with CACG in the United States and approximately 3.0 million with POAG for whom chronic, often life-long medication therapy is required.

Feasibility Dose-Finding Studies: MicroProst Phase II EYN PG21
Upcoming Milestone: MicroProst Phase III Trial Start End of 2019

About MicroTears OTC for Hyperemia, Pruritis and Dry Eye
MicroTears is a micro-droplet ocular hyperemia (red eye), pruritis (itch) and ocular lubrication product candidate for the approximately $850 million annual OTC artificial tear market in the United States.

Upcoming Milestone: Commercial launch to coincide with potential MicroStat commercialization

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 6-8 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 with minimal training in 85% of topical medication administrations compared to 40 – 50% with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

References

1. Pan CW, Ramamurthy D, Saw SM. Worldwide prevalence and risk factors for myopia. Ophthalmic Physiol Opt. 2012;32:3e16.
2. Rudnicka, A. R., Kapetanakis, V. V., Wathern, A. K., Logan, N. S., Gilmartin, B., Whincup, P. H., Owen, C. G. Global variations and time trends in the prevalence of childhood myopia, a systematic review and quantitative meta-analysis: Implications for aetiology and early prevention. British Journal of Ophthalmology, 100(7), 882-890. doi:10.1136/bjophthalmol-2015-307724
3. Chua WH, Balakrishnan V, Chan YH, Tong L, Ling Y, Quah BL, Tan D. Atropine for the treatment of childhood myopia. Ophthalmology. 2006;113(12):2285–2291.
4. Chia A, Chua WH, Cheung YB, Wong WL, Lingham A, Fong A, Tan D. Atropine for the treatment of childhood myopia: safety and efficacy of 0.5%, 0.1%, and 0.01% doses (atropine for the treatment of myopia 2). Ophthalmology. 2012;119:347–354.
5. Heiting, G. (2018, September). What is High Myopia? Retrieved from https://www.allaboutvision.com/conditions/myopia-faq/high-myopia.htm
6. Theophanous C., Modjtahedi B., Batech M., Marlin D., Luong T., Fong D. Myopia prevalence and risk factors in children. Clinical Ophthalmology. 2018;12:1581–1587. doi: 10.2147/opth.s1646
7. Holden BA, Fricke TR, Wilson DA, et al. Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. Ophthalmology. 2016;123(5):1036–1042.
8. Holden BA, Wilson DA, Jong M, et al. Myopia: a growing global problem with sight-threatening complications. Community Eye Health. 2015;28:35.
9. Yam JC, Jiang Y, Tang SM, Law AKP, Chan JJ, Wong E, et al. Low-concentration atropine for myopia progression (LAMP) study: a randomized, double-blinded, placebo-controlled trial of 0.05, 0.025, and 0.01% atropine eye drops in myopia control. Ophthalmology. 2018;126(1):113–124. doi: 10.1016/j.ophtha.2018.05.029
10. Daily Mail September 21, 2018 Health Column. Mia De Graaf author.

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: our ability to raise money; risks involved in clinical trials, including, but not limited to, the design, initiation, timing, progress and results of such trials; the timing and our ability to submit applications for, and obtain and maintain regulatory approvals for, our product candidates; our ability to timely develop and implement manufacturing, commercialization and marketing capabilities and strategies for existing product candidates; our ability to identify new product candidates; 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; 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.

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

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