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) February 25, 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.)**

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 February 25, 2019, Eyenovia, Inc. (the "Company") issued a press release announcing positive results in its previously announced Phase III trial, MIST-2, of the Company's MicroStat program for pharmacologic mydriasis. 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 February 25, 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: February 25, 2019

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

Exhibit 99.1

Eyenovia Announces Confirmatory Results from Second MicroStat Phase III Registration Study for Mydriasis

MIST-2 study meets primary endpoint

First-in-class fixed combination mydriatic agent demonstrated robust efficacy, good tolerability in confirmatory MIST-2 Study

NEW YORK, February 25, 2019 (GLOBE NEWSWIRE) — 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 positive results from its second MicroStat Phase III study, called MIST-2. The study examined the safety and efficacy of the Company's first-in-class, MicroStat fixed-combination formulation, with target markets including the estimated 80 million annual pharmacologic mydriasis market in the United States.

The MIST-2 study was a U.S.-based, multi-center, randomized, double-masked, superiority trial that enrolled 70 subjects, in whom both eyes were treated on separate days with Eyenovia's proprietary MicroStat fixed combination formulation of phenylephrine 2.5% and tropicamide 1%. MicroStat was compared against a placebo solution, both of which were administered using Eyenovia's Optejet™ dispenser.

For the primary efficacy outcome of mean pupil dilation at 35 minutes post-administration, MicroStat was clinically and statistically superior to placebo in terms of mydriatic effect, with a treatment group difference of 4.6 mm. Additional outcomes demonstrated that, in the MicroStat group, 93% of eyes achieved 6 mm or greater pupil dilation and 68% of eyes achieved 7 mm or more pupil dilation at 35 minutes post-administration. None of the eyes in the placebo group achieved similar results.

Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer commented, "The MIST-2 study outcomes are consistent with those from our first MicroStat Phase 3 study, MIST-1, in which the safety and efficacy of MicroStat was compared to its individual product components of phenylephrine 2.5% and tropicamide 1%. We are pleased to see that the outcomes of these two Phase III studies continue to validate the bioavailability and efficacy of microdose drug administration to the ocular surface using Eyenovia's Optejet dispenser."

Dr. William Flynn, MD, principal investigator of the MIST-2 study added, "These results confirm that a novel fixed combination of the two mydriatic agents currently used individually can provide a real benefit to eye care practitioners. I look forward to when this combination becomes available, as it has the potential to positively impact the efficiency of my practice and the satisfaction of my patients."

The Company expects to present the detailed results from the MIST-2 trial at the American Academy of Cataract and Retinal Surgery (ASCRS) meeting in May 2019.

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-tropicamide) 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 help improve efficacy, usability and tolerability of pharmacologic mydriasis.

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** (Independent Collaborative Group Trials)
Upcoming Milestone: MicroPine Phase III Trial First Patient In H1 2019

About MicroProst for Glaucoma
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 Ocular Hypertension and Primary Open Angle Glaucoma (POAG). 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 close to 700,000 patients with CACG in the United States and more than 3.5 million with POAG for whom chronic, often life-long medication therapy is required.
Feasibility Dose-Finding Studies: **MicroProst Phase II PG21**
Upcoming Milestone: MicroProst Phase III Trial First Patient In H1 2019

About MicroTears OTC for Dry Eye
MicroTears is a micro-droplet ocular surface tear replenishment product candidate for the estimated $2 billion+ (200 million units) global annual OTC artificial tear market.

Upcoming Milestone: OTC Registration H1 2019

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 in less than 80 milliseconds beating the ocular blink reflex. The Optejet's targeted delivery system has demonstrated 85% topical delivery efficacy compared to 40-50% with the conventional eyedropper, and 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. 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, and obtain and maintain regulatory approvals for, our product candidates, and to raise money, including in light of U.S. government shut-downs; 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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