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 6, 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 6, 2019, Eyenovia, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has accepted the Company's Investigational New Drug Application to initiate the Company's Phase III trial for MicroPine (the CHAPERONE study) to reduce the progression of myopia in children. 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 6, 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 6, 2019

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

Exhibit 99.1

Eyenovia Announces FDA Acceptance of IND Application for MicroPine to Reduce the Progression of Myopia

On track to initiate Phase III trial in H1 2019

New York, NY – February 6, 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 the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application to initiate the CHAPERONE study - the Company's Phase III registration trial of MicroPine to reduce the progression of myopia in children.

Currently, there are no FDA-approved therapies to slow the progression of myopia, a condition that, if uncontrolled, can in some cases be associated with major pathologic changes such as retinal atrophy, macular staphylomas, retinal detachment and visual impairment. It is estimated that approximately 9% of children in the United States have myopia resulting in a potential U.S. market for MicroPine of approximately $5 billion. Outside of the United States, we estimate the market potential for MicroPine is even larger – with up to approximately 80% of children starting out myopic in Asian markets. There is a growing body of evidence that supports the therapeutic effect of low dose atropine, potentially slowing myopia progression by 60-70%[2-3].

"We are very pleased to have received FDA acceptance of our IND application for the Phase III registration trial for our MicroPine program. This acceptance allows us to initiate Phase III trial enrollment in the first half of 2019. Our work in this area follows in the footsteps of the ATOM 1, ATOM 2, and LAMP clinical studies performed by academic-collaborative groups. The American Academy of Ophthalmology recently cited Level 1 evidence[4] that topical lower doses of atropine treatment have demonstrated robust and sustained effect in slowing progressive myopia by up to 60-70%," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "We believe that by combining the knowledge gained from these studies with our OpteJet™, high-precision piezo-print microdose technology, we have the opportunity to potentially change the odds of progressive myopia."

The CHAPERONE study is a U.S.-based, multi-center, randomized, double-masked trial that will enroll more than 400 children between 5-12 years of age. Participants will be equally randomized to receive treatment with either of two MicroPine treatment concentrations or a placebo control arm.

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.eyenoviabio.com.

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 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.

Feasibility Dose-finding Studies: MicroStat Ph I/II; MicroStat Ph II
Registration Studies: MicroStat MIST-1 Phase III
Upcoming Milestone: MicroStat MIST-2 Phase III Results / NDA Filing in Q1 2020

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 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.

References

1. Pan CW, Ramamurthy D, Saw SM. Worldwide prevalence and risk factors for myopia. Ophthalmic Physiol Opt. 2012;32:3e16.

2. 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.

3. 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.

4. Stacy L. Pineles, MD,1 Raymond T. Kraker, MSPH,2 Deborah K. VanderVeen, MD,3 Amy K. Hutchinson, MD,4 Jennifer A. Galvin, MD,5 Lorri B. Wilson, MD,6 Scott R. Lambert, MD. Atropine for the Prevention of Myopia Progression in Children. A Report by the American Academy of Ophthalmology. Ophthalmology 2017;124:1857-1866.

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.

Company Contact:
Eyenovia, Inc.
John Gandolfo
Chief Financial Officer
jgandolfo@eyenoviabio.com

Investor Contact:
Tram Bui / Alexander Lobo
The Ruth Group
646-536-7035/7037
tbui@theruthgroup.com / alobo@theruthgroup.com

Media Contact:
The Ruth Group
Kirsten Thomas
508-280-6592
kthomas@theruthgroup.com