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) January 30, 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 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 January 30, 2019, Eyenovia, Inc. (the "Company") issued a press release announcing positive results in its Phase III trial, MIST-1, of the Company's MicroStat program for pharmacologic mydriasis. The Company will host a conference call at 8:30 a.m. ET on January 30, 2019 to discuss the topline results of the MIST-1 trial. A copy of the press release and the slides that the Company will use in connection with the conference call are attached hereto as Exhibits 99.1 and 99.2, respectively, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated January 30, 2019.
99.2	MIST-1 topline results presentation.

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: January 30, 2019

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

Exhibit 99.1

Eyenovia Announces Positive Results in the MicroStat MIST-1 Phase III Registration Study for Mydriasis

MIST-1 study met primary endpoint

First-in-class fixed combination mydriatic agent demonstrated robust efficacy, high tolerability; Study further validates OpteJet™ platform delivery technology

Company to host conference call at 8:30 AM ET on January 30, 2019

New York, NY – January 30, 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 positive results from the MicroStat Phase 3 MIST-1 study. 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 study was a U.S. -based, randomized, double-masked, superiority trial that enrolled 64 subjects, in whom both eyes were treated on separate days with Eyenovia's proprietary MicroStat fixed combination formulation of phenylephrine 2.5% - tropicamide 1%. MicroStat was compared against each component formulation of tropicamide and phenylephrine, respectively. All treatments were administered using Eyenovia's OpteJet technology.

For the primary efficacy outcome of mean pupil dilation at 35 minutes post-administration, the MicroStat group demonstrated a statistically and clinically superior mydriatic effect as compared to either component formulation. Additional outcomes demonstrated 94% of eyes achieved 6 mm or greater pupil dilation at 35 minutes post-administration. This compared with 78% and 1.6% for the tropicamide-only and phenylephrine-only groups, respectively. At 20 minutes, 57% of the MicroStat-treated eyes achieved 6 mm dilation or greater versus 38% of the tropicamide treated eyes and none in the phenylephrine treated eyes.

Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer commented, "We are excited with the results of the Phase 3 MIST-1 study. The MicroStat fixed-combination administered with the OpteJet delivered strong efficacy and was well tolerated by all subjects. We believe this is the first time in a Phase III FDA registration program that drugs have been delivered to the ocular surface using a smart microdose eyedropper-free delivery system – a meaningful step forward as we try to modernize the legacy eyedropper paradigm. These data from a well-controlled FDA registration study further validate our microdose technology platform and support our extensive clinical development pipeline for other microdosed ophthalmic solutions. We look forward to announcing topline data from our MIST-2 study in short order."

Dr. David Wirta, MD, principal investigator of the MIST-1 study added, "There are an estimated 80 million in-office exams performed each year in the United States requiring mydriasis, an integral part of comprehensive eye exams. Eyenovia's MIST-1 study results demonstrate that not only does MicroStat successfully induce significant pupil dilation, but it does so rapidly. We believe that having a fixed combination option to achieve mydriasis has the potential to streamline the in-office examination process, potentially increasing physician efficiency and patient through-put volume."

The Company expects to present the detailed results from the MIST-1 trial in a forthcoming scientific forum.

Conference Call Information

Eyenovia will host a conference call and webcast with slides today, January 30, 2019 at 8:30 AM Eastern to discuss the topline results of the MIST-1 study. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 2699153. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.eyenoviabio.com.

After the live webcast, the event will be archived on Eyenovia's website for one year. In addition, a telephonic replay of the call will be available until February 6, 2019. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 2699153.

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 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
Upcoming Milestone: NDA Filing In Q1 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 (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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Exhibit 99.2


Making it Possible
MIST-1 Topline Results
January 30th, 2019
eyenovia

Forward-Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this presentation 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.

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Pharmacologic Mydriasis: ~80M office administrations & ~4M surgical per year in the United States

- Pharmacologic mydriasis, or dilation of the pupil of the eye with drugs, is the cornerstone of today's ophthalmic/optometric care
- Indispensable part of:
  - Comprehensive Eye Exam
  - Diabetic Retinal Exam
  - Macular Degeneration Retinal Exam
  - Retinopathy of Prematurity Screening
- Current eyedropper paradigm can use two medications which can overdose the eye (100µL vs 7 µL)[1]
  - Phenylephrine 2.5% 1-2 drops
  - Tropicamide 1% 1-2 drops
- Can be inefficient and result in patient discomfort…and increased systemic/ocular exposure

[1] Bhurayanontachai, P., Saengkaew, S., & Apiromruck, P. (2016). Efficacy of an eye drop mixture for pupillary dilatation: A randomized comparative study. Journal of optometry, 10(2), 111-116.

Why should we be concerned about overdosing with eye drops?

- Many eye drugs are compounds that were designed for cardiovascular or other systemic effects (beta blockers, phenylephrine and others)
- When these drugs are overdosed to eye, they can seep into systemic circulation through periocular absorption and via nasolacrimal duct (bypassing liver metabolism, similar to IV delivery)
- The result can be changes in blood pressure, heart rate and lung function

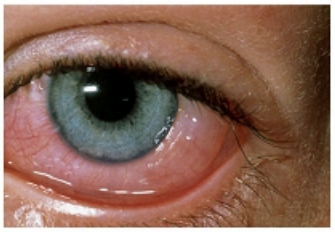
"Mean blood pressure increased significantly in infants given standard dilating drops.."[1]

"Cardiovascular effects of ophthalmic Timolol"[2]

[1] Acta Ophthalmol Scand. 1997
[2] Ann Intern Med. 1986;104(2):197–198

MicroStat

Designed for the estimated 80 million mydriatic exams performed every year in the United States and the estimated 4 million pharmacologic mydriasis applications for cataract surgery



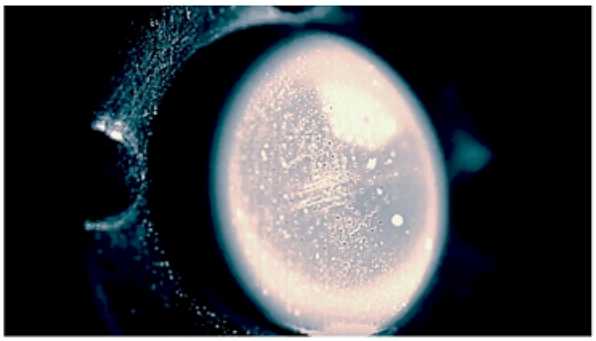
- Current eyedropper paradigm is approximately 100 year old
- Legacy technology can be inefficient, wasteful and imprecise
- Eyedroppers overdose the ocular surface by more than 300%[1-3]
- Overdosing of drug (30-50µL vs physiologic 7 µL tear film capacity)[1-3]
- Overdosing of preservative and excipients which are known in higher quantities to be toxic to the ocular surface (>90% of ophthalmic formulations)[4]

[1] Washington N, Washington C, Wilson CG. Ocular drug delivery. In: Physiological Pharmaceutics: Barriers to Drug Absorption. 2nd ed. Boca Raton, FL: CRC Press; 2001:249–270.
[2] Mishima S, Gasset A, Klyce SD, Baum JL. Determination of tear volume and tear flow. Invest Ophthalmol. 1966;5(3):264–276.
[3] Scherz W, Doane MG, Dohlman CH. Tear volume in normal eyes and keratoconjunctivitis sicca. Albrecht Von Graefes Arch Klin Exp Ophthalmol. 1974;192(2):141–150.
[4] Epstein et al, J Ocul Pharmacol Ther. 2009

MicroStat

- Eyenovia's OpteJet™ technology is designed to revolutionize ophthalmic drug delivery
- We believe our piezo-print micro-dosing can increase efficiency, precision and reduce waste
- The Optejet aims to eliminate ocular overdose to the ocular surface

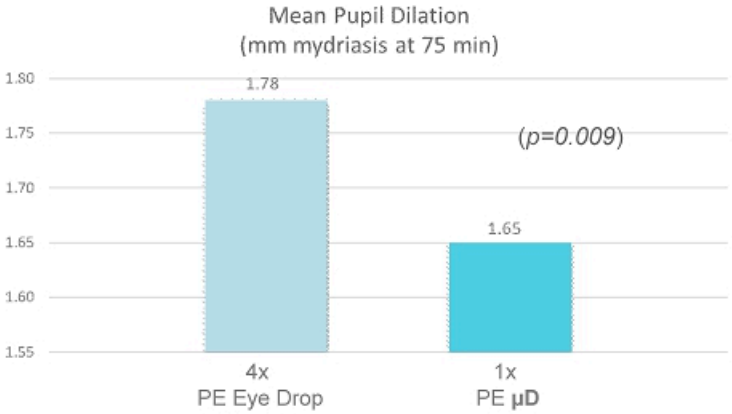
Smart… Precise… Brilliant



Eyenovia's Optejet: 21st century platform for smarter eyecare…

EYE 102: Phase II Trial demonstrated the advantages Eyenovia's microdosing approach

- Comparable clinical efficacy with ¼ the dose of traditional eye drops
- Significant improvement in tolerability and systemic exposure for same formulation microdose versus eye drops



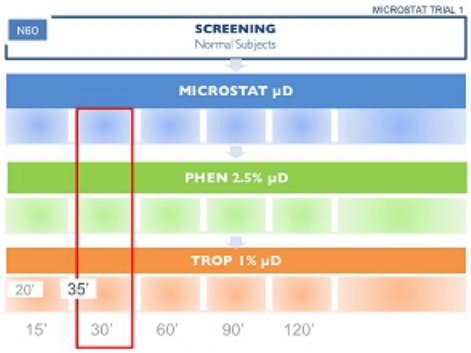
Ocular Adverse Events by Treatment

Adverse Event	PE 10%	EYN-1601
Ocular blurriness	1	0
Ocular burning/stinging/irritation	4	1
Ocular dryness	2	0
Subtotal by Treatment Group	7	1

MicroStat Registration Program: Two Phase 3 Superiority Studies (MIST-1 and MIST-2)

- Double-masked, active-controlled, cross-over design
- MIST-1 (N64 randomized):µD phenylephrine-tropicamide vs µD tropicamide vs µD phenylephrine
- MIST-2 (N70 randomized):µD phenylephrine-tropicamide VS µD placebo

MIST-1



MIST-2

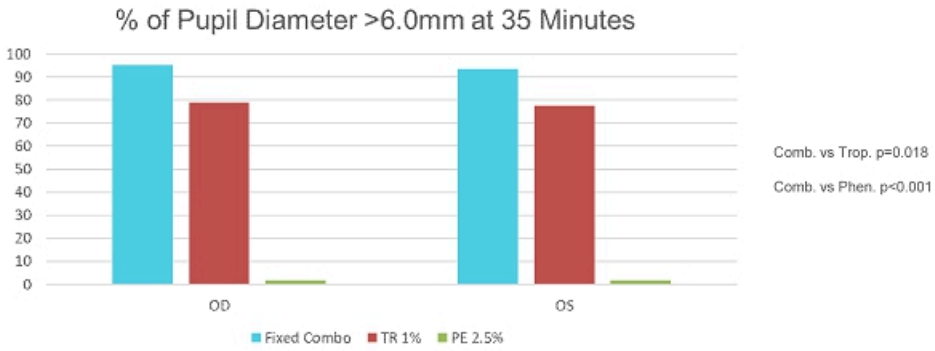
- Primary endpoint: Mean change in pupil diameter at 35 minutes vs baseline
- Hypothesis: MicroStat superior to Phen, Trop (MIST-1) and placebo eye wash (MIST-2)
- Power at 90% for each study, assuming 54 evaluable subjects

MIST-1 Results: Primary Endpoint Analysis

1. 64 subjects randomized
2. MIST-1 met primary efficacy endpoint: pupil dilation change from Baseline at 35 minutes
3. Statistically larger 35 minute dilation for MicroStat vs components
4. Additional outcomes:
   - 94% of eyes achieved 6 mm or greater pupil dilation at 35 minutes compared with 78% and 1.6% for the tropicamide-only and phenylephrine-only groups, respectively
   - 57% of the MicroStat-treated eyes achieved 6 mm dilation or greater at 20 minutes versus 38% of the tropicamide treated eyes and none in the phenylephrine treated eyes

MIST-1 Results: Other Efficacy Results

Highest proportions of pupil diameter values above 6.0mm observed in the combination solution group



MIST-1 Results: Safety Results

- Treatment emergent adverse events were ocular, related to mydriasis, mild and transient
- No non-ocular adverse events


Making it Possible
MIST-1 Topline Results
January 30th, 2019
eyenovia