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) March 27, 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 Ave., 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 2.02. Results of Operations and Financial Condition.

On March 27, 2019, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal fourth quarter and full year ended December 31, 2018. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

The information contained in, or incorporated into, Item 2.02, including the press release attached as Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the " Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated March 27, 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: March 27, 2019

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

Exhibit 99.1

Eyenovia Reports Fourth Quarter and Full Year 2018 Financial Results

New York, NY – March 27, 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 its financial results for the fourth quarter and full year ended December 31, 2018.

Q4 2018 and Recent Business Highlights

- Reported positive results in the MicroStat Phase III MIST-1 and MIST-2 registration studies for mydriasis;
- U.S Food and Drug Administration (FDA) accepted investigational new drug (IND) application to initiate MicroPine Phase III CHAPERONE registration study to reduce the progression of myopia in children;
- Expanded and streamlined the MicroProst Phase III program to include chronic angle closure glaucoma (CACG), as well as open angle glaucoma (OAG) and ocular hypertension (OHT) patients in a single registration study;
- Published positive results from the EYN PG21 trial evaluating high-precision microdose latanoprost demonstrating robust intraocular pressure lowering; and
- Completed underwritten follow-on public offering of Company common stock with gross proceeds of approximately $3.4 million, excluding underwriting discounts and commissions and offering-related expenses.

Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer commented, "Throughout 2018, we worked diligently to advance all of our clinical programs and further validate the efficacy of our high-precision microdosing platform technology. We were very excited to announce positive results from our first Phase III program, MicroStat, for pharmacologic mydriasis. The results from the MIST-1 and MIST-2 trials confirmed that our fixed-combination phenylephrine-tropicamide formulation met the primary efficacy outcome of mean pupil dilation at 35 minutes post administration. We believe that these results not only further validate our microdose platform technology, but also demonstrate its potential to increase physician efficiency and patient through-put volume in real world applications. We are now preparing to initiate registration and stability manufacturing lots for MicroStat and expect to file our NDA in 2020."

"In addition to our success with MicroStat, the FDA acceptance of our MicroPine IND application represents another milestone achievement that will allow us to initiate the Phase III registration trial this year. We also expect to initiate another Phase III program with MicroProst this year with an expanded study population including patients with CACG, OAG and OHT representing what we believe is one of the broadest patient populations in glaucoma drug development to date."

"I would like to thank our highly motivated team as well as our shareholders who helped us make 2018 a success. We look forward to continuing to execute on our clinical initiatives, including the OTC monograph registration of MicroTears this year. We believe that our novel platform technology has the potential to transform the treatment of front and back-of-the-eye diseases," concluded Dr. Ianchulev.

Fourth Quarter and Full Year 2018 Financial Review

For the fourth quarter of 2018, net loss was approximately $6.2 million, or $(0.60) per share, compared to a net loss of approximately $2.2 million, or $(0.84) per share for the fourth quarter of 2017. For the full year ended December 31, 2018, net loss was approximately $17.3 million, or $(1.82) per share. This compares to a net loss of approximately $5.1 million, or $(2.19) per share for 2017.

Research and development expenses totaled approximately $4.1 million for the fourth quarter of 2018, compared to approximately $1.7 million for the same period in 2017, an increase of 144%. For the full year 2018, research and development expenses increased 191% to approximately $11.1 million compared to approximately $3.8 million in the prior year.

For the fourth quarter of 2018, general and administrative expenses were approximately $2.1 million compared with approximately $0.5 million for the fourth quarter of 2017, an increase of 335%. For the full year 2018, general and administrative expenses increased 366% to approximately $6.1 million versus approximately $1.3 million for the full year of 2017.

Total operating expenses for the fourth quarter of 2018 were approximately $6.2 million, compared to total operating expenses of approximately $2.2 million for the same period in 2017, an increase of 186%. For the full year 2018, total operating expenses increased 236% to approximately $17.3 million compared to $5.1 million for the full year of 2017.

As of December 31, 2018, the Company’s cash balance was approximately $19.7 million.

Conference Call and Webcast

The conference call is scheduled to begin at 8:30 am ET on Wednesday, March 27, 2019. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 4075747. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.eyenovia.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 April 3, 2019. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 4075747.

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.

Feasibility Dose-finding Studies: MicroStat Ph I/II; MicroStat Ph II
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 (Independent Collaborative Group Trials)
Upcoming Milestone: MicroPine Phase III Trial Start 2019

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 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: OTC Monograph Registration 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, where solution is dispensed to the ocular surface in approximately 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: fluctuations in our financial results; risks involved in clinical trials, including, but not limited to, the design, initiation, timing, progress and results of such trials; the timing and our need and ability to submit applications for, and obtain and maintain regulatory approvals for, our product candidates, and to raise money, including in light of any 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

(Financial Statements to Follow)

EYENOVIA, INC.

Balance Sheets

	December 31, 2018 (unaudited)	December 31, 2017
Assets		
Current Assets:		
Cash	$ 19,728,200	$ 5,249,511
Prepaid expenses and other current assets	132,756	37,149
Total Current Assets	19,860,956	5,286,660
Property and equipment, net	36,738	27,960
Deferred offering costs	-	328,700
Security deposit	117,800	-
Total Assets	$ 20,015,494	$ 5,643,320
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,509,524	$ 246,384
Accrued compensation	923,981	-
Accrued expenses and other current liabilities	665,336	306,263
Total Current Liabilities	3,098,841	552,647
Deferred rent	41,584	-
Total Liabilities	3,140,425	552,647
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; Series A Convertible Preferred Stock, 0 and 20,000,000 shares designated as of December 31, 2018 and 2017, respectively, 0 and 2,932,431 shares issued and outstanding as of December 31, 2018 and 2017, respectively	-	293
Series A-2 Convertible Preferred Stock, 0 and 5,714,286 shares designated as of December 31, 2018 and 2017, respectively, 0 and 788,827 shares issued and outstanding as of December 31, 2018 and 2017, respectively	-	79
Series B Convertible Preferred Stock, 0 and 10,000,000 shares designated as of December 31, 2018 and 2017, respectively, 0 and 918,983 shares issued and outstanding as of December 31, 2018 and 2017, respectively	-	92
Common stock, $0.0001 par value, 90,000,000 shares authorized; 11,468,996 and 2,566,530 shares issued and outstanding as of December 31, 2018 and 2017, respectively	1,147	257
Additional paid-in capital	53,388,216	24,351,138
Accumulated deficit	(36,514,294)	(19,261,186)
Total Stockholders' Equity	16,875,069	5,090,673
Total Liabilities and Stockholders' Equity	$ 20,015,494	$ 5,643,320

EYENOVIA, INC.

Statements of Operations

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2018	**2017**	**2018**	**2017**
	(unaudited)	(unaudited)	(unaudited)	
Operating Expenses:				
Research and development	$ 4,125,264	$ 1,690,739	$ 11,119,096	$ 3,816,732
General and administrative	2,058,098	472,676	6,137,347	1,315,635
Total Operating Expenses	6,183,362	2,163,415	17,256,443	5,132,367
Loss From Operations	(6,183,362)	(2,163,415)	(17,256,443)	(5,132,367)
Other Income:				
Interest income	255	984	3,335	2,380
Net Loss	$ (6,183,107)	$ (2,162,431)	$ (17,253,108)	$ (5,129,987)
Net Loss Per Share - Basic and Diluted	$ (0.60)	$ (0.84)	$ (1.82)	$ (2.19)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	10,240,644	2,566,530	9,476,706	2,344,712