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) August 12, 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, New York 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))

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 2.02. Results of Operations and Financial Condition.

On August 12, 2019, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal second quarter and six months ended June 30, 2019. 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 August 12, 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: August 12, 2019

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

Exhibit 99.1

Eyenovia Reports Second Quarter 2019 Financial Results

New York, NY – August 12, 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 second quarter ended June 30, 2019.

Second Quarter 2019 and Recent Business Highlights

- Enrolled first patient in Phase III CHAPERONE study for progressive myopia in children;
- Presented positive results from the MicroStat Phase III MIST-1 and MIST-2 registration studies for pharmacologic mydriasis at the joint American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Administrators (ASOA) annual meeting; and
- Successfully completed an underwritten public offering of its common stock in July 2019 with aggregate net proceeds to the Company of approximately $13.0 million.

"We are very pleased with the progress we made last quarter as we steadily advance our late stage clinical pipeline and continue to validate our platform technology to change the treatment paradigm of front and back-of-the-eye diseases. We recently initiated our Phase III CHAPERONE study for progressive myopia in children. Progressive myopia represents an estimated $5 billion U.S. market opportunity for Eyenovia and has the potential to be the first topical therapeutic to treat myopia progression. In addition, we expect the MILAGRO trial for MicroProst for the lowering of intraocular pressure in glaucoma to begin enrollment by the end of this year. MILAGRO will be our third product candidate to enter Phase III development over the last nine months," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "With our recent successful capital raise, we believe Eyenovia is well positioned to continue advancing both the MicroPine and MicroProst trials and we intend to move our MicroStat program towards an NDA submission in 2020. We look forward to executing on our milestones through the remainder of the year and would like to thank our shareholders for their continued support."

Second Quarter 2019 Financial Review

For the second quarter of 2019, net loss was approximately $5.3 million, or $(0.44) per share, compared to a net loss of approximately $3.3 million, or $(0.33) per share for the second quarter of 2018.

Research and development expenses totaled approximately $3.6 million for the second quarter of 2019, compared to approximately $2.4 million for the same period in 2018, an increase of approximately 48%, due to the continuing advancement of the Company's clinical drug pipeline.

For the second quarter of 2019, general and administrative expenses were approximately $1.8 million compared to approximately $0.9 million for the second quarter of 2018, an increase of approximately 99%.

Total operating expenses for the second quarter of 2019 were approximately $5.4 million, compared to total operating expenses of approximately $3.3 million for the same period in 2018, an increase of approximately 62%.

As of June 30, 2019, the Company's cash and cash equivalents balance was approximately $9.2 million. This amount does not include the approximately $13.0 million in aggregate net proceeds from Eyenovia's underwritten public offering which closed in July 2019.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET on Monday, August 12, 2019. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 6217226. 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 August 19, 2019. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 6217226.

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 people 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)
Upcoming Milestone: Complete Enrollment of the Phase III CHAPERONE Study End of 2020

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.

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 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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(Financial Statements to Follow)

EYENOVIA, INC.

Condensed Balance Sheets

	June 30, 2019 (unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 9,239,609	$ 19,728,200
Prepaid expenses and other current assets	569,561	132,756
Total Current Assets	9,809,170	19,860,956
Property and equipment, net	31,632	36,738
Deferred offering costs	77,376	-
Security deposit	117,800	117,800
Total Assets	$ 10,035,978	$ 20,015,494
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,802,386	$ 1,509,524
Accrued compensation	437,700	912,104
Accrued expenses and other current liabilities	133,146	677,213
Total Current Liabilities	2,373,232	3,098,841
Deferred rent	44,817	41,584
Total Liabilities	2,418,049	3,140,425
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2019 and as of December 31, 2018	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 12,053,963 and 11,468,996 shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	1,205	1,147
Additional paid-in capital	55,396,914	53,388,216
Accumulated deficit	(47,780,190)	(36,514,294)
Total Stockholders' Equity	7,617,929	16,875,069
Total Liabilities and Stockholders' Equity	$ 10,035,978	$ 20,015,494

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
Operating Expenses:				
Research and development	$ 3,568,022	$ 2,412,164	$ 7,576,918	$ 4,506,259
General and administrative	1,809,106	908,806	3,751,869	2,246,455
Total Operating Expenses	5,377,128	3,320,970	11,328,787	6,752,714
Loss From Operations	(5,377,128)	(3,320,970)	(11,328,787)	(6,752,714)
Other Income:				
Interest income	43,616	1,907	62,891	4,044
Net Loss	$ (5,333,512)	$ (3,319,063)	$ (11,265,896)	$ (6,748,670)
Net Loss Per Share - Basic and Diluted	$ (0.44)	$ (0.33)	$ (0.94)	$ (0.77)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	12,034,450	9,998,646	11,975,035	8,807,864