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) November 13, 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 ☒

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 November 13, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal third quarter and nine months ended September 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 November 13, 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: November 13, 2019

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

Exhibit 99.1

Eyenovia Reports Third Quarter 2019 Financial Results

New York, NY – November 13, 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 third quarter ended September 30, 2019.

Third Quarter 2019 and Recent Business Highlights

- Advanced MicroLine for the improvement in near vision in patients with presbyopia towards Phase III development;
- Deferred development activities for the MicroProst (glaucoma and ocular hypertension) and MicroTears (red eye and itch relief/lubrication) programs;
- Presented data from the MicroStat Phase III MIST-1 and MIST-2 studies for pharmacologic mydriasis at AAOpt; and
- Successfully completed an underwritten public offering of our common stock in July 2019 with aggregate net proceeds to the Company of approximately $13.0 million.

"We have been very pleased with our clinical progress this year as we continue to build a robust late-stage pipeline in ophthalmology using our next generation, intelligent microdosing platform. The completion of our MicroStat Phase III studies for pharmacologic mydriasis as well as the initiation of our Phase III study for our MicroPine program for the treatment of progressive myopia earlier this year, have helped demonstrate the potential of our novel therapies," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "As we work to maximize the value of our internal portfolio, we recently conducted a comprehensive strategic review of all our programs. As a result, we decided to reprioritize our efforts to focus on MicroPine, MicroStat, and MicroLine for improving near vision in patients with presbyopia. We believe that these programs represent areas where there are currently no known drugs approved or where we can greatly improve the patient experience. As we approach year end, we are particularly focused on advancing our MicroLine program towards Phase III development and expect to initiate and complete the Phase III VISION studies in 2020."

"With the additional support of our successful capital raise this summer and the anticipated cost savings from our pipeline reprioritization, we remain well positioned to fund our programs. We appreciate the continued support of our shareholders and look forward to providing additional updates on our clinical progress," concluded Dr. Ianchulev.

Third Quarter 2019 Financial Review

For the third quarter of 2019, net loss was approximately $4.6 million, or $(0.29) per share, compared to a net loss of approximately $4.3 million, or $(0.43) per share for the third quarter of 2018.

Research and development expenses totaled approximately $3.2 million for the third quarter of 2019, compared to approximately $2.5 million for the same period in 2018, an increase of approximately 29%. The increase was primarily attributable to an increase in contracted services, expanded research and development activities and an increase in facilities and other expenses related to supplies and materials.

For the third quarter of 2019, general and administrative expenses were approximately $1.5 million compared to approximately $1.8 million for the third quarter of 2018, a decrease of approximately 19%. This decrease was primarily attributable to a decrease in legal and professional fees of $0.4 million due to higher expenses in 2018 related to activities performed to assess various financing opportunities.

Total operating expenses for the third quarter of 2019 were approximately $4.7 million, compared to total operating expenses of approximately $4.3 million for the same period in 2018, an increase of approximately 9%.

As of September 30, 2019, the Company's cash and cash equivalents balance was approximately $18.3 million.

Conference Call and Webcast

The conference call is scheduled to begin at 5:00 pm ET on Wednesday, November 13, 2019. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 6128678. 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 November 20, 2019. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 6128678.

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 presbyopia, myopia progression and mydriasis. For more Information please visit www.eyenovia.com.

About MicroLine for Presbyopia
MicroLine is Eyenovia's pharmacologic treatment for presbyopia. Presbyopia is the non-preventable, age related hardening of the lens, which causes a gradual loss of the eye's ability to focus on nearby objects and is estimated to affect nearly 113 million Americans. Current treatment options are typically device-based, such as reading glasses and contact lenses. Pilocarpine is known to constrict the pupil and improve near-distance vision by creating an extended depth of focus through its small aperture effect. Eyenovia believes that its high precision microdosing technology combined with pilocarpine could provide a meaningful improvement in near-vision while enhancing tolerability and usability.

Upcoming Milestone: Initiate and Complete MicroLine Phase III Trial in 2020

About MicroPine for Progressive Myopia
MicroPine is Eyenovia's first-in-class topical treatment for progressive myopia, a back-of-the-eye condition commonly known as nearsightedness. 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. MicroPine is designed for comfort and ease-of-use in children, with low systemic and ocular drug exposure due to microdosing. 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 in 2020

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 improve the efficiency 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. Designed for use without an anesthetic, we are developing MicroStat to improve the efficacy and tolerability of pharmacologic mydriasis.

Upcoming Milestone: File NDA in 2020

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, including estimated market opportunities in the United States for our product candidates. 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; the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our ability to identify new 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; the potential advantages of our product candidates; 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 raise money; 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.

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(Financial Statements to Follow)

EYENOVIA, INC.

Condensed Balance Sheets

	September 30, 2019 (unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 18,295,962	$ 19,728,200
Prepaid expenses and other current assets	396,977	132,756
Total Current Assets	18,692,939	19,860,956
Property and equipment, net	71,722	36,738
Security deposit	117,800	117,800
Total Assets	$ 18,882,461	$ 20,015,494
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,595,270	$ 1,509,524
Accrued compensation	591,494	912,104
Accrued expenses and other current liabilities	246,374	677,213
Total Current Liabilities	2,433,138	3,098,841
Deferred rent	45,354	41,584
Total Liabilities	2,478,492	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 September 30, 2019 and as of December 31, 2018	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 17,100,726 and 11,468,996 shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	1,710	1,147
Additional paid-in capital	68,831,827	53,388,216
Accumulated deficit	(52,429,568)	(36,514,294)
Total Stockholders' Equity	16,403,969	16,875,069
Total Liabilities and Stockholders' Equity	$ 18,882,461	$ 20,015,494

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating Expenses:				
Research and development	$ 3,201,196	$ 2,487,573	$ 10,778,114	$ 6,993,832
General and administrative	1,489,739	1,832,794	5,241,608	4,079,249
Total Operating Expenses	4,690,935	4,320,367	16,019,722	11,073,081
Loss From Operations	(4,690,935)	(4,320,367)	(16,019,722)	(11,073,081)
Other Income (Expense):				
Interest income (expense)	41,557	(964)	104,448	3,080
Net Loss	$ (4,649,378)	$ (4,321,331)	$ (15,915,274)	$ (11,070,001)
Net Loss Per Share - Basic and Diluted	$ (0.29)	$ (0.43)	$ (1.19)	$ (1.20)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	16,270,728	10,030,296	13,422,667	9,219,818