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 25, 2020

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 March 25, 2020, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal fourth quarter and full year ended December 31, 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 March 25, 2020.

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 25, 2020

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

Exhibit 99.1

Eyenovia Reports Fourth Quarter and Full Year 2019 Financial Results

New York, NY – March 25, 2020 –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, 2019.

Fourth 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;
- Expanded Scientific Advisory Board with the addition of Mark Bullimore, PhD and April Jasper, OD; and
- Successfully completed a private placement of units comprised of common stock and warrants with aggregate net proceeds to the Company of approximately $5.3 million in March 2020.

“2019 was a very successful year for Eyenovia, as we made significant advancements in our late stage ophthalmology pipeline that continued to validate our high precision microdosing platform,” commented Dr. Sean Ianchulev, Eyenovia’s Chief Executive Officer and Chief Medical Officer. “We completed our MicroStat Phase III MIST-1 and MIST-2 studies for pharmacologic mydriasis, which support our novel approach to treating front and back of the eye conditions. These results also paved the way for the initiation of our MicroPine Phase III CHAPERONE study for progressive myopia, which is currently enrolling subjects. In 2019, we also reprioritized our pipeline to focus on our highest value opportunities and introduced our Phase III ready MicroLine program for presbyopia. We believe that we could transform the primarily device-based treatment paradigm for an estimated 43 million people in the United States with a cash-pay prescription therapy with our proprietary microdose formulation of pilocarpine. With a bolstered balance sheet, we have anticipated milestones in our Phase III programs for presbyopia and myopia, as well as the planned MicroStat NDA this year, although we are closely monitoring the evolving situation of the COVID-19 pandemic and its potential impact on our business.”

Fourth Quarter and Full Year 2019 Financial Review

For the fourth quarter of 2019, net loss was approximately $5.2 million, or $(0.31) per share, compared to a net loss of approximately $6.2 million, or $(0.60) per share for the fourth quarter of 2018. For the full year ended December 31, 2019, net loss was approximately $21.2 million, or $(1.47) per share. This compares to a net loss of approximately $17.3 million, or $(1.82) per share for the full year of 2018.

Research and development expenses totaled approximately $3.3 million for the fourth quarter of 2019, compared to approximately $4.1 million for the same period in 2018, a decrease of 19.4%. For the full year 2019, research and development expenses increased 26.8% to approximately $14.1 million compared to approximately $11.1 million in the prior year.

For the fourth quarter of 2019, general and administrative expenses were approximately $2.0 million compared to approximately $2.1 million for the fourth quarter of 2018, a decrease of 4.5%. For the full year 2019, general and administrative expenses increased 17.4% to approximately $7.2 million versus approximately $6.1 million for the full year of 2018 due largely to an increase in non-cash stock compensation expense of approximately $0.9 million.

Total operating expenses for the fourth quarter of 2019 were approximately $5.3 million, compared to total operating expenses of approximately $6.2 million for the same period in 2018, a decrease of 14.5%. Operating expenses for the fourth quarter of 2019 include approximately $0.6 million of non-cash stock compensation expense. For the full year 2019, total operating expenses increased 23.5% to approximately $21.3 million compared to $17.3 million for the full year of 2018. 2019 operating expenses include approximately $2.5 million of non-cash stock compensation expenses.

As of December 31, 2019, the Company's cash and cash equivalents was approximately $14.2 million. This excludes approximately $5.3 million of net proceeds from Eyenovia's private placement which closed on March 24, 2020.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET on Wednesday, March 25, 2020. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 7487792. 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 1, 2020. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 7487792.

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 ophthalmic solution 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 administration of pilocarpine using the company's high precision microdosing technology could provide a meaningful improvement in near vision while enhancing tolerability and usability.

Anticipated Milestone: Initiate and Complete Phase III VISION Trials in 2020

About MicroPine for Progressive Myopia
MicroPine (atropine ophthalmic solution) 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 children 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 has been developed for comfort and ease-of-use in children. Microdose administration of MicroPine is anticipated to result in low systemic and ocular drug exposure. 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)

Anticipated 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. Developed for use without anesthetic, we are developing MicroStat to improve the efficacy and tolerability of pharmacologic mydriasis.

Anticipated 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 more than 85% of the time after basic training in a variety of clinical settings 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 and stock price, particularly given market conditions and the potential economic impact of COVID-19; our need to raise additional money to fund our operations for at least the next 12 months as a going concern; the potential impacts of the coronavirus pandemic on our supply chain; risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could be adversely impacted by the coronavirus pandemic and resulting social distancing), timing, progress and results of such trials; the timing and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our estimates regarding the potential market opportunity for our product candidates; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; our ability to timely develop and implement anticipated manufacturing, commercialization and marketing capabilities and strategies for existing product candidates; our ability to attract and retain key personnel; 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.

Balance Sheets

	December 31, 2019 (unaudited)	December 31, 2018
Assets		
Current Assets:		
Cash and cash equivalents	$ 14,152,601	$ 19,728,200
Prepaid expenses and other current assets	196,680	132,756
Total Current Assets	14,349,281	19,860,956
Property and equipment, net	230,538	36,738
Security deposit	117,800	117,800
Total Assets	$ 14,697,619	$ 20,015,494
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,541,358	$ 1,509,524
Accrued compensation	916,873	912,104
Accrued expenses and other current liabilities	453,430	677,213
Total Current Liabilities	2,911,661	3,098,841
Deferred rent	45,351	41,584
Total Liabilities	2,957,012	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 December 31, 2019 and 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 December 31, 2019 and 2018, respectively	1,710	1,147
Additional paid-in capital	69,409,949	53,388,216
Accumulated deficit	(57,671,052)	(36,514,294)
Total Stockholders' Equity	11,740,607	16,875,069
Total Liabilities and Stockholders' Equity	$ 14,697,619	$ 20,015,494

EYENOVIA, INC.

Condensed Statements of Operations

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2019 (unaudited)	**2018 (unaudited)**	**2019 (unaudited)**	**2018**
Operating Expenses:				
Research and development	$ 3,324,335	$ 4,125,264	$ 14,102,449	$ 11,119,096
General and administrative	1,964,487	2,058,098	7,206,095	6,137,347
Total Operating Expenses	5,288,822	6,183,362	21,308,544	17,256,443
Loss From Operations	(5,288,822)	(6,183,362)	(21,308,544)	(17,256,443)
Other Income (Expense):				
Interest income (expense)	47,338	255	151,786	3,335
Net Loss	$ (5,241,484)	$ (6,183,107)	$ (21,156,758)	$ (17,253,108)
Net Loss Per Share				
- Basic and Diluted	$ (0.31)	$ (0.60)	$ (1.47)	$ (1.82)
Weighted Average Number of Common Shares Outstanding				
- Basic and Diluted	$ 17,100,726	$ 10,240,644	$ 14,349,738	$ 9,476,706