

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 10, 2020

EYENOVIA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-38365

(Commission File Number)

47-1178401

(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 10, 2020, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal third quarter and nine months ended September 30, 2020. 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
<u>99.1</u>	<u>Press release dated November 10, 2020.</u>

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 10, 2020

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



Eyenovia Reports Third Quarter 2020 Financial Results

Company to host conference call and webcast today, November 10, at 4:30pm ET

New York, NY, Nov. 10, 2020 – Eyenovia, Inc., (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics, today reported its financial results for the third quarter ended September 30, 2020.

“During the third quarter and subsequent period, we continued to execute on our growth strategy to advance our late-stage ophthalmic portfolio while in parallel securing global development and commercialization partnerships to further extend the reach of our proprietary Optejet® microdosing technology,” commented Dr. Sean Ianchulev, Eyenovia’s Chief Executive Officer and Chief Medical Officer. “We announced important licensing agreements with both Bausch Health and Arctic Vision. We believe these companies can help introduce MicroPine and MicroLine to some of the biggest eyecare markets in the world, while at the same time providing us with non-dilutive capital to advance our corporate initiatives.”

“We remain on track to file an NDA for Mydcombi™, our intended brand name for MicroStat, for pharmacologic mydriasis by the end of this year and to initiate our Phase 3 presbyopia program imminently, subject to any impacts of COVID-19. Presbyopia is one of the leading therapeutic opportunities in ophthalmology, estimated to affect more than 100 million people in the U.S. alone. And while there are other companies working on new treatments for presbyopia, we believe Eyenovia could be among the first to deliver Phase 3 results, potentially in the first quarter of 2021. With a current cash position of approximately \$31 million, which includes a \$10 million upfront payment from Bausch Health last month, we believe we are well funded to pursue these important milestones,” Dr. Ianchulev concluded.

Third Quarter 2020 and Recent Business Highlights

- Licensed our atropine ophthalmic solution, MicroPine, an investigational treatment for the reduction of pediatric myopia progression in children ages 3-12, to Bausch Health for an upfront payment of \$10 million, up to \$35 million in milestone payments, and royalties ranging from mid-single digit to mid-teen percentages of gross profit on sales in the U.S. and Canada.
- Closed a public offering of our common stock for net proceeds of approximately \$12.5 million.
- Announced an exclusive collaboration and license agreement with Arctic Vision to develop and commercialize MicroPine and MicroLine, our Phase 3-ready treatment for presbyopia in Greater China and South Korea, with potential licensing and development payments of up to \$41.75 million, and additional royalty or supply payments.
- Presented positive clinical study results on our Phase 3 MIST-1 and MIST-2 studies, evaluating a novel microdosed fixed combination of tropicamide and phenylephrine for touchless pharmaceutical mydriasis, at the American Academy of Optometry Annual Meeting and remain on track to file an NDA for Mydcombi by the end of this year.

Third Quarter 2020 Financial Review

For the third quarter of 2020, net loss was approximately \$5.1 million, or \$(0.23) per share, compared to a net loss of approximately \$4.6 million, or \$(0.29) per share for the third quarter of 2019.

Research and development expenses totaled approximately \$3.4 million for the third quarter of 2020, compared to approximately \$3.2 million for the same period in 2019, an increase of approximately 5.1%.

For the third quarter of 2020, general and administrative expenses were approximately \$1.7 million compared to approximately \$1.5 million for the third quarter of 2019, an increase of approximately 16.0%.

Total operating expenses for the third quarter of 2020 were approximately \$5.1 million, compared to total operating expenses of approximately \$4.7 million for the same period in 2019, an increase of approximately 8.6%.

As of September 30, 2020, the Company's cash balance was approximately \$22.9 million.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30pm ET today, November 10, 2020. Participants should dial 877-407-9039 (domestic) or 201-689-8470 (international) with the conference code 13713084. 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 the Company's website for one year.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP) therapeutics. 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 a 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.

About MicroPine for Progressive Myopia

MicroPine (atropine ophthalmic solution) is Eyenovia's investigational, potentially first-in-class topical treatment for the reduction of pediatric myopia progression, also known as nearsightedness, in children ages 3-12. It has been developed for comfort and ease-of-use in children, and its microdose administration is designed to potentially result in low systemic and ocular drug exposure.

About Mydcombi for Mydriasis

Mydcombi is Eyenovia's first-in-class fixed-combination micro-formulation product (tropicamide 1% - phenylephrine 2.5%) 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.

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 μ L 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 for our product candidates and any potential revenue from licensing transactions. 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 U.S. Securities and Exchange Commission. In addition, such statements could be affected by risks and uncertainties related to, among other things: fluctuations in our financial results; volatility and uncertainty in the global economy and financial markets in light of the evolving COVID-19 pandemic and uncertainties arising from the recent U.S. elections; our estimates regarding the potential market opportunity for our product candidates and potential revenue from licensing transactions; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could still be adversely impacted by COVID-19 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 impacts of COVID-19 on our supply chain; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; our ability to raise additional capital; intellectual property risks; our ability to attract and retain key personnel; 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, Eyenovia does not undertake any obligation to update any forward-looking statements.



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Eyenovia, Inc.

Condensed Balance Sheets

	September 30, 2020	December 31, 2019
	(unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 22,864,578	\$ 14,152,601
Deferred license costs	1,600,000	-
Prepaid expenses and other current assets	903,090	196,680
Total Current Assets	25,367,668	14,349,281
Property and equipment, net	360,956	230,538
Security deposit	119,035	117,800
Total Assets	<u>\$ 25,847,659</u>	<u>\$ 14,697,619</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,464,762	\$ 1,541,358
Accrued compensation	744,555	916,873
Accrued expenses and other current liabilities	373,609	453,430
Deferred rent - current portion	7,809	-
Deferred license revenue	4,000,000	-
Notes payable - current portion	145,942	-
Total Current Liabilities	6,736,677	2,911,661
Deferred rent - non-current portion	36,423	45,351
Notes payable - non-current portion	424,338	-
Total Liabilities	7,197,438	2,957,012
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, 2020 and as of December 31, 2019	-	-
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 24,884,251 and 17,100,726 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	2,488	1,710
Additional paid-in capital	91,881,790	69,409,949
Accumulated deficit	(73,234,057)	(57,671,052)
Total Stockholders' Equity	18,650,221	11,740,607
Total Liabilities and Stockholders' Equity	<u>\$ 25,847,659</u>	<u>\$ 14,697,619</u>



Eyenovia, Inc.

Condensed Statements of Operations (unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating Expenses:				
Research and development	\$ 3,363,759	\$ 3,201,196	\$ 9,913,296	\$ 10,778,114
General and administrative	1,728,366	1,489,739	5,669,311	5,241,608
Total Operating Expenses	5,092,125	4,690,935	15,582,607	16,019,722
Loss From Operations	(5,092,125)	(4,690,935)	(15,582,607)	(16,019,722)
Other Income:				
Small Business Administration Economic Injury Disaster grant	-	-	10,000	-
Interest expense	(4,945)	-	(14,977)	-
Interest income	540	41,557	24,579	104,448
Net Loss	\$ (5,096,530)	\$ (4,649,378)	\$ (15,563,005)	\$ (15,915,274)
Net Loss Per Share				
- Basic and Diluted	\$ (0.23)	\$ (0.29)	\$ (0.79)	\$ (1.19)
Weighted Average Number of Common Shares Outstanding				
- Basic and Diluted	22,206,195	16,270,728	19,802,999	13,422,667