

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, 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 August 12, 2020, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal second quarter and six months ended June 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 August 12, 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: August 12, 2020

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



Eyenovia Reports Second Quarter 2020 Financial Results

New York, NY – August 12, 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 second quarter ended June 30, 2020.

Second Quarter 2020 and Recent Business Highlights

- Announced exclusive license agreement with Arctic Vision (Hong Kong) Limited to develop and commercialize MicroPine and MicroLine in Greater China and South Korea;
- Resumed recruitment of Phase III CHAPERONE study for pediatric progressive myopia; and
- Preparing to submit the New Drug Application for MicroStat by the end of 2020.

“Earlier this week, we entered into a license agreement with Arctic Vision, a China-based ophthalmology company, to develop and commercialize MicroPine and MicroLine for the Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korean markets. This transaction, which includes payments of up to \$45.75 million in potential license and product development fees as well as commercial supply terms or royalties, expands the commercial reach of our programs into markets where the number of myopic children is estimated at greater than 240 million, more than eight times that of the United States,” commented Dr. Sean Ianchulev, Eyenovia’s Chief Executive Officer and Chief Medical Officer. “In the coming months and subject to any impacts of COVID-19, we also look forward to initiating our Phase III VISION trials for MicroLine and plan to submit our New Drug Application for MicroStat to the FDA by the end of the year.”

Second Quarter 2020 Financial Review

For the second quarter of 2020, net loss was approximately \$5.0 million, or \$(0.25) per share, compared to a net loss of approximately \$5.3 million, or \$(0.44) per share for the second quarter of 2019.

Research and development expenses totaled approximately \$2.9 million for the second quarter of 2020, compared to approximately \$3.6 million for the same period in 2019, a decrease of approximately 18.3%.

For the second quarter of 2020, general and administrative expenses were approximately \$2.1 million compared to approximately \$1.8 million for the second quarter of 2019, an increase of approximately 16.3%.

Total operating expenses for the second quarter of 2020 were approximately \$5.0 million, compared to total operating expenses of approximately \$5.4 million for the same period in 2019, a decrease of approximately 6.7%. Operating expenses for the second quarter of 2020 include approximately \$0.6 million of non-cash stock compensation expense.

As of June 30, 2020, the Company’s cash balance was approximately \$10.2 million.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30pm ET on Wednesday, August 12, 2020. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 7380187. 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, 2020. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 7380187.

About Eyenovia

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAPTM) 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 MicroPine for Progressive Myopia

MicroPine (atropine ophthalmic solution) is 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)

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 MicroStat for Mydriasis

MicroStat 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. 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: impacts of and uncertainty related to COVID-19; fluctuations in our financial results, 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; our ability 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 potential impacts of COVID-19 on our supply chain; the timing and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; 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; the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; 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.
Condensed Balance Sheets

	June 30, 2020 <small>(unaudited)</small>	December 31, 2019
Assets		
Current Assets:		
Cash	\$ 10,186,171	\$ 14,152,601
Prepaid expenses and other current assets	809,083	196,680
Total Current Assets	10,995,254	14,349,281
Property and equipment, net	313,438	230,538
Security deposit	119,035	117,800
Total Assets	<u>\$ 11,427,727</u>	<u>\$ 14,697,619</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,078,700	\$ 1,541,358
Accrued compensation	573,906	916,873
Accrued expenses and other current liabilities	681,225	453,430
Notes payable - current portion	421,599	-
Total Current Liabilities	2,755,430	2,911,661
Deferred rent	45,345	45,351
Notes payable - non-current portion	307,646	-
Total Liabilities	<u>3,108,421</u>	<u>2,957,012</u>
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, 2020 and as of December 31, 2019	-	-
Common stock, \$0.0001 par value, 90,000,000 shares authorized; 19,943,683 and 17,100,726 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	1,994	1,710
Additional paid-in capital	76,454,839	69,409,949
Accumulated deficit	(68,137,527)	(57,671,052)
Total Stockholders' Equity	<u>8,319,306</u>	<u>11,740,607</u>
Total Liabilities and Stockholders' Equity	<u>\$ 11,427,727</u>	<u>\$ 14,697,619</u>

EYENOVIA, INC.
Condensed Statements of Operations
(unaudited)

	For the Three Months Ended		For the Six Months Ended	
	June 30, 2020	2019	June 30, 2020	2019
Operating Expenses:				
Research and development	\$ 2,915,250	\$ 3,568,022	\$ 6,549,537	\$ 7,576,918
General and administrative	<u>2,104,163</u>	<u>1,809,106</u>	<u>3,940,945</u>	<u>3,751,869</u>
 Total Operating Expenses	 <u>5,019,413</u>	 <u>5,377,128</u>	 <u>10,490,482</u>	 <u>11,328,787</u>
Loss From Operations	<u>(5,019,413)</u>	<u>(5,377,128)</u>	<u>(10,490,482)</u>	<u>(11,328,787)</u>
Other Income:				
Small Business Administration Economic Injury Disaster grant	10,000	-	10,000	-
Interest expense	(6,351)	-	(10,032)	-
Interest income	<u>199</u>	<u>43,616</u>	<u>24,039</u>	<u>62,891</u>
 Net Loss	 <u>\$ (5,015,565)</u>	 <u>\$ (5,333,512)</u>	 <u>\$ (10,466,475)</u>	 <u>\$ (11,265,896)</u>
 Net Loss Per Share				
- Basic and Diluted	<u>\$ (0.25)</u>	<u>\$ (0.44)</u>	<u>\$ (0.56)</u>	<u>\$ (0.94)</u>
 Weighted Average Number of Common Shares Outstanding				
- Basic and Diluted	<u>19,821,215</u>	<u>12,034,450</u>	<u>18,563,864</u>	<u>11,975,035</u>