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, 2021

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, 2021, Eyenovia, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 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
99.1	Press release dated March 25, 2021.

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, 2021

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

Exhibit 99.1

Eyenovia Reports Fourth Quarter and Full Year 2020 Financial Results

Announces MydCombi expected PDUFA date of October 28, 2021

Completes patient enrollment in Phase 3 VISION-1 study evaluating MicroLine for the treatment of presbyopia; topline data on track for Q2

Company to host conference call and webcast today, March 25, at 4:30 pm ET

NEW YORK— March 25, 2021—Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on its proprietary microdose array print (MAP™) platform technology, today announced its financial results for the fourth quarter and full year ended December 31, 2020.

Fourth Quarter 2020 and Recent Business Highlights

- U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for the Company's pupil dilation agent MydCombi™ and subsequently notified the Company that the expected PDUFA date is October 28, 2021.
- Completed patient enrollment in the Company's Phase 3 VISION-1 study of MicroLine for the improvement in near vision in patients with presbyopia.
- Licensed 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.
- Established exclusive collaboration and licensing agreement with Arctic Vision to develop and commercialize MicroPine and MicroLine, a 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.
- Closed a public offering of the Company's common stock for net proceeds of approximately $12.5 million.

Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia, commented, "We have made significant progress during 2020 advancing our proprietary clinical programs. Most recently, we announced that the FDA has accepted our NDA for MydCombi, our proprietary fixed combination mydriatic, or pupil dilation agent, for potential use in the over 80 million comprehensive eye exams currently conducted each year in the United States. If approved, not only would MydCombi be the first microdosed ocular therapeutic applied with our proprietary high precision smart delivery system, the Optejet®, but it would transition us into a commercial stage company. We look forward to our PDUFA date on October 28."

"Previously we announced that the first patient had been dosed in our VISION-1 Phase 3 clinical study evaluating our proprietary pilocarpine formulation, MicroLine, which is also delivered via the Optejet, for the improvement of near vision in patients with presbyopia, an estimated multi-billion-dollar indication. Today, we are pleased to report that we recently completed enrollment in VISION-1 and, as this is a relatively short study, we continue to anticipate topline data in the second quarter of this year. With our second Phase 3 program now initiated, an NDA accepted, and several robust development partnerships with ophthalmologic leaders established, we believe we have significant momentum. We look forward to building on this progress towards multiple potentially value creating milestones ahead," concluded Dr. Ianchulev.

Fourth Quarter and Full Year 2020 Financial Review

For the fourth quarter of 2020, net loss was approximately $(4.2) million, or $(0.17) per share, compared to a net loss of approximately $(5.2) million, or $(0.31) per share for the fourth quarter of 2019. For the full year ended December 31, 2020, net loss was approximately $(19.8) million, or $(0.94) per share. This compares to a net loss of approximately $(21.2) million, or $(1.47) per share, for the full year of 2019.

Total revenue was approximately $2.0 million for the fourth quarter and full year 2020. The revenue represented a milestone payment from the Company's previously announced exclusive collaboration and licensing agreement with Arctic Vision. The Company did not generate revenue in 2019.

Research and development expenses totaled approximately $3.4 million for the fourth quarter of 2020, compared to approximately $3.3 million for the same period in 2019. For the full year 2020, research and development expenses decreased approximately 6% to approximately $13.3 million compared to approximately $14.1 million in the prior year.

For the fourth quarter of 2020, general and administrative expenses were approximately $2.1 million compared to approximately $2.0 million for the fourth quarter of 2019, an increase of 5%. For the full year 2020, general and administrative expenses increased 7% to approximately $7.7 million versus approximately $7.2 million for the full year of 2019.

Total operating expenses for the fourth quarter of 2020 were approximately $5.4 million, compared to total operating expenses of approximately $5.3 million for the same period in 2019, an increase of 2%. For the full year 2020, total operating expenses decreased 1% to approximately $21 million compared to $21.3 million for the full year of 2019.

As of December 31, 2020, the Company's cash and cash equivalents were approximately $28.4 million, compared to $14.2 million as of December 31, 2019.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30 pm ET on Thursday, March 25, 2021. Participants should dial 1-877-407-9039 (United States) or 1-201-689-8470 (International) with the conference code 13716228. 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.

The webcast will be archived on Eyenovia'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 is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more Information, 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 MicroStat (MyCombi™) 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 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, Eyenovia is developing MicroStat to help improve the efficacy and tolerability of pharmacologic mydriasis.

About Optejet® and Microdose Array Print (MAP™) 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 regulatory review timing, and market opportunities for our product candidates and platform technology. 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; our ability to raise additional money to fund our operations for at least the next 12 months as a going concern; our estimates regarding the potential market opportunity for our product candidates and potential revenue from licensing transactions; reliance on third parties; risks of our and our licensees' 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 and our licensees' ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; 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; reliance on third parties to develop and commercialize certain of our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for certain of our product candidates; the potential advantages of our product candidates and platform technology; the rate and degree of market acceptance and clinical utility of our product candidates; intellectual property risks; our ability to attract and retain key personnel; 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.

Balance Sheets

	December 31, 2020 (unaudited)	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	$ 28,371,828	$ 14,152,601
Deferred license costs	1,600,000	-
License receivable	2,966,039	-
Prepaid expenses and other current assets	453,478	196,680
Total Current Assets	33,391,345	14,349,281
Property and equipment, net	396,380	230,538
Security deposit	119,035	117,800
Total Assets	$ 33,906,760	$ 14,697,619
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,461,665	$ 1,541,358
Accrued compensation	1,150,672	916,873
Accrued expenses and other current liabilities	1,480,692	453,430
Deferred rent - current portion	7,809	-
Deferred license fee	14,000,000	-
Notes payable - current portion	97,539	-
Total Current Liabilities	18,198,377	2,911,661
Deferred rent - non-current portion	38,684	45,351
Notes payable - non-current portion	365,814	-
Total Liabilities	18,602,875	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 December 31, 2020 and 2019, respectively	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 24,978,585 and 17,100,726 shares issued and outstanding as of December 31, 2020 and 2019, respectively	2,498	1,710
Additional paid-in capital	92,742,306	69,409,949
Accumulated deficit	(77,440,919)	(57,671,052)
Total Stockholders' Equity	15,303,885	11,740,607
Total Liabilities and Stockholders' Equity	$ 33,906,760	$ 14,697,619

EYENOVIA, INC.

Condensed Statements of Operations

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2020 (unaudited)	**2019 (unaudited)**	**2020 (unaudited)**	**2019**
Operating Income				
Revenue	$ 2,000,000	$ -	$ 2,000,000	$ -
Cost of revenue	(800,000)	-	(800,000)	-
Gross Profit	1,200,000	-	1,200,000	-
Operating Expenses:				
Research and development	$ 3,350,521	$ 3,324,335	$ 13,263,817	$ 14,102,449
General and administrative	2,056,097	1,964,487	7,725,408	7,206,095
Total Operating Expenses	5,406,618	5,288,822	20,989,225	21,308,544
Loss From Operations	(4,206,618)	(5,288,822)	(19,789,225)	(21,308,544)
Other Income (Expense):				
Small Business Administration Economic				
Injury Disaster Grant	-	-	10,000	
Interest expense	(2,065)	-	(17,042)	-
Interest income	1,821	47,338	26,400	151,786
Net Loss	$ (4,206,862)	$ (5,241,484)	$ (19,769,867)	$ (21,156,758)
Net Loss Per Share				
- Basic and Diluted	$ (0.17)	$ (0.31)	$ (0.94)	$ (1.47)
Weighted Average Number of Common Shares Outstanding				
- Basic and Diluted	24,891,184	17,100,726	21,054,706	14,349,738