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) May 12, 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 May 12, 2021, Eyenovia, Inc. issued a press release announcing its financial results for the fiscal first quarter and three months ended March 31, 2021. 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 May 12, 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: May 12, 2021

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

Exhibit 99.1

Eyenovia Reports First Quarter 2021 Financial Results

MydCombi PDUFA date confirmed for October 28, 2021

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

Secures $25 million credit facility through Silicon Valley Bank

Company to host conference call and webcast today, May 12, at 4:30pm ET

NEW YORK—May 12, 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 first quarter ended March 31, 2021.

First Quarter 2021 and Recent Business Highlights

- U.S. Food and Drug Administration (FDA) accepted the Company's New Drug Application (NDA) for the Company's pupil dilation agent MydCombi™ and has notified the Company that the PDUFA date is confirmed for October 28, 2021.
- Secured new $25 million credit facility through Silicon Valley Bank (SVB).
- Completed patient enrollment in the Company's Phase 3 VISION-1 study of MicroLine for the improvement in near vision in patients with presbyopia and anticipates top-line results in the coming weeks. Results from VISION-1 will help inform the design of a planned second Phase 3 study, VISION-2.
- Announced an exclusive partnership agreement with EVERSANA, a leading commercial service provider to the life science industry, to help commercialize and distribute MydCombi in the United States.
- Appointed Dr. Julia Haller, renowned ophthalmologist and scientific leader, to Eyenovia's Board of Directors.

Dr. Sean Ianchulev, Chief Executive Officer and Chief Medical Officer of Eyenovia, commented, "The Eyenovia team has made substantial progress in advancing towards its clinical, regulatory, and commercial goals during the first quarter of 2021. We look forward to our PDUFA date for MydCombi on October 28th of this year. In preparation for the anticipated approval, we were pleased to announce an exclusive agreement with EVERSANA to help lead distribution of MydCombi in the United States. If approved, MydCombi would be the first microdosed ocular therapeutic applied with our proprietary high precision smart delivery system, the Optejet®."

“Regarding our Phase 3 VISION-1 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, we have completed patient enrollment and anticipate top-line results in the coming weeks. We remain focused on advancing our late-stage clinical programs, while preparing to transition into a commercial-stage ophthalmology company. I believe we have set the stage for a transformational year in 2021,” concluded Dr. Ianchulev.

First Quarter 2021 Financial Review

For the first quarter of 2021, net loss was approximately $5.4 million, or $(0.21) per share, compared to a net loss of approximately $5.5 million, or $(0.31) per share, for the first quarter of 2020.

For the first quarter of 2021, the Company reported license fee revenue of $2.0 million from its license agreement with Arctic Vision (Hong Kong) Limited and a corresponding cost of revenue representing payments to Senju Pharmaceutical Co., Ltd. of $800,000.

Research and development expenses totaled approximately $4.2 million for the first quarter of 2021, compared to approximately $3.6 million for the same period in 2020, an increase of approximately 16.9%.

For the first quarter of 2021, general and administrative expenses were approximately $2.3 million compared to approximately $1.8 million for the first quarter of 2020, an increase of approximately 25.2%.

Total operating expenses for the first quarter of 2021 were approximately $6.5 million, compared to total operating expenses of approximately $5.5 million for the same period in 2020, an increase of approximately 19.7%.

As of March 31, 2021, the Company’s cash balance was approximately $24.9 million. Subsequent to the end of the first quarter, the Company announced a credit facility of up to $25 million through Silicon Valley Bank (SVB). The first tranche of $7.5 million was advanced to Eyenovia upon closing of the facility. The remaining two tranches ($7.5 million and $10.0 million) will be available to the Company subject to the satisfaction of certain milestones and covenants as outlined in the credit agreement.

Conference Call and Webcast

The conference call is scheduled to begin at 4:30pm ET on Wednesday, May 12, 2021. Participants should dial 877-407-9039 (domestic) or 201-689-8470 (international) with the conference code 13718776. 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.

About Eyenovia, Inc.

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on its proprietary microdose array print (MAP™) platform technology. Eyenovia is currently focused on the late-stage development of 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. MicroPine has been licensed to Bausch Health Companies, Inc. in the United States and Canada, and Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

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.

Condensed Balance Sheets

	March 31, 2021 (unaudited)	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 24,907,048	$ 28,371,828
Deferred license costs	800,000	1,600,000
License fee and expense reimbursements receivables	908,231	2,966,039
Prepaid expenses and other current assets	1,409,929	453,478
Total Current Assets	28,025,208	33,391,345
Property and equipment, net	707,419	396,380
Security deposit	119,035	119,035
Total Assets	$ 28,851,662	$ 33,906,760
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,815,117	$ 1,461,665
Accrued compensation	570,732	1,150,672
Accrued expenses and other current liabilities	1,189,092	1,480,692
Deferred rent - current portion	6,857	7,809
Deferred license fee	12,000,000	14,000,000
Notes payable - current portion	783,818	97,539
Total Current Liabilities	16,365,616	18,198,377
Deferred rent - non-current portion	38,634	38,684
Notes payable - non-current portion	307,291	365,814
Total Liabilities	16,711,541	18,602,875
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	-	-
Common stock, $0.0001 par value, 90,000,000 shares authorized; 25,623,577 and 24,978,585 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	2,563	2,498
Additional paid-in capital	94,930,144	92,742,306
Accumulated deficit	(82,792,586)	(77,440,919)
Total Stockholders' Equity	12,140,121	15,303,885
Total Liabilities and Stockholders' Equity	$ 28,851,662	$ 33,906,760

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended March 31,	
	2021	**2020**
Operating Income		
Revenue	$ 2,000,000	**$** -
Cost of revenue	(800,000)	-
Gross Profit	1,200,000	-
Operating Expenses:		
Research and development	4,247,726	3,634,287
General and administrative	2,300,327	1,836,782
Total Operating Expenses	6,548,053	5,471,069
Loss From Operations	(5,348,053)	(5,471,069)
Other Income (Expense):		
Interest expense	(5,148)	(3,681)
Interest income	1,534	23,840
Net Loss	$ (5,351,667)	$ (5,450,910)
Net Loss Per Share - Basic and Diluted	$ (0.21)	$ (0.31)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	25,330,563	17,308,804