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 13, 2018

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, NY 10017
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code 917-289-1117

501 Fifth Avenue, Suite 1404, New York, NY 10017
(Former name or former address, if changed since last report)

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))

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 13, 2018, Eyenovia, Inc. (the "Company") issued a press release announcing its financial results for the fiscal third quarter and nine months ended September 30, 2018. 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 8.01. Other Events.

On November 13, 2018, the Company issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has accepted the Company's Investigational New Drug Application ("IND") to initiate Phase III trials of MicroStat for mydriasis. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated November 13, 2018 announcing the Company's financial results.
99.2	Press release dated November 13, 2018 announcing the FDA's acceptance of the Company's IND application to initiate Phase III trials of MicroStat.

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 13, 2018

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

Exhibit 99.1

Eyenovia Reports Third Quarter 2018 Financial Results

New York, NY – November 13, 2018 – Eyenovia, Inc. (NASDAQ: EYEN), a biopharmaceutical company developing a pipeline of ophthalmology products utilizing its patented piezo-print technology to deliver microdosed medications topically to the eye, today announced financial results for the third quarter ended September 30, 2018.

Q3 2018 and Recent Business Highlights

- Received investigational new drug (IND) acceptance to enter Phase III with MicroStat for mydriasis
- Results from PG21 study demonstrating a robust IOP lowering effect from a microdosed prostaglandin and high ocular delivery success rate have been accepted in the peer-reviewed journal *Clinical Ophthalmology* and are currently *In Press*
- Submitted Optejet™ as the trademark for the Company's proprietary container closure system

Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer commented, "With the acceptance of our IND application for MicroStat for mydriasis, we expect to initiate our first Phase III study this month, followed by two additional Phase III studies for myopia progression and chronic angle closer glaucoma over the next nine months. As we seek to further support these upcoming trials, our PG21 study demonstrated superior patient self-administration of 90 percent and similar intra ocular pressure lowering efficacy compared to traditional eyedrops and was recently selected for publication by *Clinical Ophthalmology*. We look forward to continuing to develop and validate our proprietary, high precision microdosing technology platform, and are very pleased to officially brand our technology, the Optejet."

Third Quarter 2018 Financial Review

For the third quarter of 2018, net loss was approximately $(4.3) million, or $(0.43) per share, compared to a net loss of approximately $(0.9) million, or $(0.10) per share for the third quarter of 2017.

Research and development expenses totaled approximately $2.5 million for the third quarter of 2018, an increase of 336%, compared to approximately $0.6 million for the same period in 2017.

For the third quarter of 2018, general and administrative expenses were approximately $1.8 million, an increase of 482%, compared to approximately $0.3 million for the third quarter of 2017.

Total operating expenses for the third quarter of 2018 were approximately $4.3 million, an increase of 388%, compared to total operating expenses of approximately $0.9 million for the same period in 2017.

As of September 30, 2018, the Company's cash balance was approximately $21.0 million compared to $24.6 million at June 30, 2018.

The Company reiterated the timeline for its 12-month key clinical milestones:

- Q4 2018: Initiate MicroStat Phase III trial
- H1 2019: Report MicroStat Phase III trial results
- H1 2019: Initiate MicroPine Phase III trial
- H1 2019: Initiate MicroProst Phase III trial
- H1 2019: MicroTears OTC registration

Conference Call and Webcast

The conference call is scheduled to begin at 8:30 am ET on Tuesday, November 13, 2018. Participants should dial 1-866-916-2921 (United States) or 1-210-874-7771 (International) with the conference code 1797567. A live webcast of the conference call will also be available on the investor relations page of the Company's corporate website at www.eyenoviabio.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 November 20, 2018. The replay can be accessed by dialing 1-855-859-2056 (United States) or 1-404-537-3406 (International) with confirmation code 1797567.

About Eyenovia

Eyenovia, Inc. (NASDAQ: EYEN) is a specialty biopharmaceutical company building a portfolio of next generation topical eye treatments based on its proprietary delivery and formulation platform for microdosing. Eyenovia's pipeline is currently focused on the late-stage development of microdosed medications for myopia progression, glaucoma, mydriasis and other eye diseases.

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. 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: risks involved in clinical trials, including, but not limited to, the initiation, 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; our ability to develop and implement commercialization, marketing and manufacturing capabilities and strategies; the potential advantages of our product candidates; our ability to attract and retain key personnel; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; intellectual property risks; our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives; our expectations regarding our ability to fund our operating expenses and capital expenditure requirements; the impact of government laws and regulations; our competitive position; and general economic conditions. 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.

Company Contact:
Eyenovia, Inc.
John Gandolfo
Chief Financial Officer
jgandolfo@eyenoviabio.com

Investor Contact:
Tram Bui / Alexander Lobo
The Ruth Group
Phone: 646-536-7035/7037
E-mail: tbui@theruthgroup.com / alobo@theruthgroup.com

Media Contact:
The Ruth Group
Kirsten Thomas
508-280-6592
kthomas@theruthgroup.com

(Financial Statements to Follow)

EYENOVIA, INC.

Condensed Balance Sheets

	September 30, 2018 (unaudited)	December 31, 2017
Assets		
Current Assets:		
Cash	$ 21,044,135	$ 5,249,511
Prepaid expenses and other current assets	298,450	37,149
Total Current Assets	21,342,585	5,286,660
Property and equipment, net	11,152	27,960
Deferred offering costs	-	328,700
Security deposit	117,800	-
Total Assets	$ 21,471,537	$ 5,643,320
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 840,230	$ 246,384
Accrued expenses and other current liabilities	888,984	306,263
Total Current Liabilities	1,729,214	552,647
Deferred rent	2,332	-
Total Liabilities	1,731,546	552,647
Commitments and contingencies		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized;		
Series A Convertible Preferred Stock, 0 and 20,000,000 shares designated		
as of September 30, 2018 and December 31, 2017, respectively,		
0 and 2,932,431 shares issued and outstanding		
as of September 30, 2018 and December 31, 2017, respectively	-	293
Series A-2 Convertible Preferred Stock, 0 and 5,714,286 shares designated		
as of September 30, 2018 and December 31, 2017, respectively,		
0 and 788,827 shares issued and outstanding		
as of September 30, 2018 and December 31, 2017, respectively	-	79
Series B Convertible Preferred Stock, 0 and 10,000,000 shares designated		
as of September 30, 2018 and December 31, 2017, respectively,		
0 and 918,983 shares issued and outstanding		
as of September 30, 2018 and December 31, 2017, respectively	-	92
Common stock, $0.0001 par value, 90,000,000 shares authorized;		
10,088,996 and 2,566,530 shares issued and outstanding		
as of September 30, 2018 and December 31, 2017, respectively	1,009	257
Additional paid-in capital	50,070,169	24,351,138
Accumulated deficit	(30,331,187)	(19,261,186)
Total Stockholders' Equity	19,739,991	5,090,673
Total Liabilities and Stockholders' Equity	$ 21,471,537	$ 5,643,320

EYENOVIA, INC.

Condensed Statements of Operations
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Operating Expenses:				
Research and development	$ 2,487,573	$ 570,422	$ 6,993,832	$ 2,233,193
General and administrative	1,832,794	314,859	4,079,249	735,759
Total Operating Expenses	4,320,367	885,281	11,073,081	2,968,952
Loss From Operations	(4,320,367)	(885,281)	(11,073,081)	(2,968,952)
Other Income (Expense):				
Interest income (expense)	(964)	665	3,080	1,396
Net Loss	$ (4,321,331)	$ (884,616)	$ (11,070,001)	$ (2,967,556)
Net Loss Per Share - Basic and Diluted	$ (0.43)	$ (0.10)	$ (1.20)	$ (0.35)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	10,030,296	8,514,906	9,219,818	8,514,906

Exhibit 99.2

Eyenovia Announces FDA Acceptance of MicroStat IND Application for Mydriasis

Company on track to initiate Phase III trials in late November

New York, NY – November 13, 2018 – Eyenovia, Inc. (NASDAQ: EYEN), a biopharmaceutical company developing a pipeline of ophthalmology products utilizing its patented piezo-print technology to deliver micro-dosed medications topically to the eye, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application to initiate Phase III trials of MicroStat for diagnostic mydriasis.

MicroStat is a first in class fixed-combination of phenylephrine and tropicamide for in office mydriasis (pupil dilation), a standard part of the approximately 80 million comprehensive exams performed every year in the United States. In an earlier published Phase II study, MicroStat, in combination with the Optejet™ dispenser, demonstrated consistent micro-dose delivery while also achieving therapeutic levels necessary for pupil dilation. With the acceptance of the IND, Eyenovia expects to initiate the Phase III trials of MicroStat later this month.

"We are very pleased to have received acceptance of our IND application for MicroStat from the FDA and are very excited to officially become a Phase III company," commented Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer. "As our first clinical program to enter Phase III trials, the MicroStat program could provide important validation of our entire platform delivery technology. We look forward to initiating the trials in late November and expect to report topline results in the first half of 2019."

About Eyenovia
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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. 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: risks involved in clinical trials, including, but not limited to, the initiation, 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; our ability to develop and implement commercialization, marketing and manufacturing capabilities and strategies; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; our estimates regarding the potential market opportunity for our product candidates; intellectual property risks; the impact of government laws and regulations; 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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Investor Contact:
Tram Bui / Alexander Lobo
The Ruth Group
Phone: 646-536-7035/7037
E-mail: tbui@theruthgroup.com / alobo@theruthgroup.com

Media Contact:
The Ruth Group
Kirsten Thomas
508-280-6592
kthomas@theruthgroup.com