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 13, 2018

EYENOVIA, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-38365	47-1178401
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

501 Fifth Avenue, Suite 1404, New York, NY 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))

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 7.01. Regulation FD Disclosure.

On August 13, 2018, Eyenovia, Inc. issued a press release announcing the positive results of its EYN PG21 proof-of-concept study of microdose latanoprost for the lowering of intraocular pressure and patient usability. 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 7.01, 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 August 13, 2018.

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 13, 2018

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

Exhibit 99.1

Eyenovia's EYN PG21 Trial Evaluating High-Precision Microdose of Latanoprost Demonstrates Robust Intraocular Pressure Lowering and Patient Usability

Positive results validate Eyenovia's piezo-print technology for topical eye treatment as Company prepares for Phase III trials in progressive myopia, CACG and mydriasis

New York, NY – August 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 positive results of its EYN PG21 proof-of-concept study of microdose latanoprost for the lowering of intraocular pressure (IOP) and patient usability.

The EYN PG21 clinical study investigated the medication administration effectiveness and IOP lowering effect of microdose latanoprost 0.005% in 60 eyes of 30 healthy volunteers. Participants received once daily microdose treatment over 2 consecutive days and underwent diurnal (4 times/day) IOP assessments. The primary outcome was success of microdose delivery, with additional outcomes evaluating diurnal IOP change each day.

In the study, after a brief medication administration training session, investigators successfully administered high-precision piezo-print latanoprost with a single spray 95% of the time. A separate evaluation of patient self-administration showed an 88% success rate following limited training. This is a substantive improvement from the 39%-47% success rate reported in the literature using a conventional eyedropper. In addition, each single medication administration was within 1 µL of the prescribed dose and the tear capacity of the eye. This differs from traditional eyedropper administration, which may deliver as much as 300% more drug than the eye can hold with high variability of dosing.

The study results also demonstrated that, while reducing drug administration volume by 75% by delivering the microdose accurately and directly on the corneal surface, piezo-print micro-formulated latanoprost achieved a very robust reduction in diurnal IOP of up to 29% from baseline unmedicated IOP. This is consistent with the reported reduction of up to 26% achieved with the same concentration of standard latanoprost eye drops.

Dr. Sean Ianchulev, Eyenovia's Chief Executive Officer and Chief Medical Officer, commented, "We believe these compelling results further validate Eyenovia's high-precision microdosing smart technology and build on the positive results from our Phase II mydriasis study. These data are very informative for all of our upcoming Phase III programs in prevention of myopia progression, chronic angle closure glaucoma and mydriasis by demonstrating that medications applied with our piezo-print technology are both effective and easy for patients to use."

Dr. Louis R. Pasquale, MD, FARVO, Professor of Ophthalmology at Harvard Medical School, commented, "Conventional eye drops may overdose the eye's tear film capacity by as much as 300%, causing significant ocular and systemic side effects leading to hyperemia, sunken globe (peri-orbitopathy), pharmacologic dermatitis and bradycardia, and ultimately the poor compliance that plagues almost all front-of-the-eye treatments. Microdosing has the potential to address all those problems by providing physiologic high-precision dosing to the eye that stays in the eye."

Dr. Robert N. Weinreb, Chairman and Professor of Ophthalmology at the University of California, San Diego, added, "Following Eyenovia's earlier studies, these data demonstrate that microdosing can open a new chapter in topical eye disease therapy with high-precision microdosing that dramatically improves the therapeutic index of many front-of-the-eye therapies. Eyenovia's upcoming Phase III programs in myopia, glaucoma and mydriasis are first-in-class indications that have the potential to introduce a new wave of formulations with improved safety, tolerability and smart-compliance monitoring."

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 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.

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