
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): December 5, 2022

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, NY 10017
(Address of Principal Executive Offices, and Zip Code)

(917) 289-1117
Registrant's Telephone Number, Including Area Code

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)	(Name of each exchange on which registered)
Common stock, \$0.0001 par value	EYEN	The Nasdaq Stock Market (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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☒ x

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 5.02. Departure of Directors or Principal Officers; Election of Directors; Appointment of Principal Officers; Compensatory Arrangements of Certain Officers.

On December 5, 2022, the Board of Directors (the “Board”) of Eyenovia, Inc. (the “Company”) appointed Bren Kern, the Company’s current Senior Vice President of Manufacturing and Operations, as the Company’s Chief Operating Officer, effective January 1, 2023.

Mr. Kern joined the Company in June 2022 as the Senior Vice President of Manufacturing and Operations. Mr. Kern has spent his career helping companies transition from research and development into scaled commercial manufacturing organizations. Over the last 20 years, Mr. Kern has honed his skills by leading product optimization, supporting regulatory approvals and establishing cGMP compliant manufacturing solutions worldwide. Prior to joining the Company, Mr. Kern held leadership positions in multiple medical device and diagnostic companies, including Hound Labs, Inc. (a THC breathalyzer), Second Source Medical LLC (a medical device contract manufacturer), BioLux Research Ltd (an orthodontia acceleration device), BAROnova Inc. (a removable weight loss implant) and Bigfoot Biomedical Inc. /Asante Solutions, Inc. (an insulin delivery device). Mr. Kern holds a B.S. in Mechanical Engineering Technology from Oregon Institute of Technology.

Mr. Kern is 41 years old and has no familial relationships with any executive officer or director of the Company. Other than Mr. Kern’s prior compensation for his service as the Company’s Senior Vice President of Manufacturing and Operations, there have been no transactions in which the Company has participated and in which Mr. Kern has had a direct or indirect material interest that would be required to be disclosed under Item 404(a) of Regulation S-K.

The Company will also enter into an Employment Agreement (the “Employment Agreement”) with Mr. Kern under which he will serve as Chief Operating Officer of the Company. Under the terms of the Employment Agreement, Mr. Kern will receive an annual salary of \$345,000. He is eligible to receive a cash bonus of up to 30% of his base salary. Additionally, Mr. Kern shall receive an option to purchase 120,000 shares of the Company’s common stock. Mr. Kern will also continue to participate in any and all benefit plans, from time to time, in effect for senior management, along with vacation, sick and holiday pay in accordance with the Company’s policies established and in effect from time to time.

The Employment Agreement will be filed as an exhibit to the Company’s Annual Report on Form 10-K for the year ending December 31, 2022, and the foregoing description is subject in all respects to the actual terms of the Employment Agreement.

In addition, the Company hereby announces the resignation of Dr. Julia Haller from the Board, effective as of December 6, 2022. This was not the result of any disagreement with the Company, its management or the Board. The Company thanks Dr. Haller for her distinguished service and many contributions to the Board.

On December 8, 2022, the Company issued a press release announcing the appointment of Mr. Kern as its Chief Operating Officer and the resignation of Dr. Haller from the Board. A copy of the press release is filed hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Eyenovia, Inc. Press Release, dated December 8, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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: December 8, 2022

/s/ John Gandolfo

John Gandolfo

Chief Financial Officer



Eyenovia Announces Promotion of Bren Kern to Chief Operating Officer and Corporate Vice President

Company also announces that Julia Haller, MD, is stepping down from its Board of Directors

NEW YORK—December 8, 2022—Eyenovia, Inc. (NASDAQ: EYEN), a pre-commercial ophthalmic technology company developing the Optejet® delivery system for use both in combination with its own drug-device therapeutic programs for mydriasis, presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced that Bren Kern, who currently serves as Eyenovia's Senior Vice President of Manufacturing and Operations, has been promoted to Chief Operating Officer and Corporate Vice President, effective January 1st.

"Since joining the company earlier this year, Bren has made significant contributions preparing our manufacturing facility in Redwood City to commence operations, and I believe he is the ideal candidate to serve as the company's Chief Operating Officer going forward," stated Michael Rowe, Chief Executive Officer of Eyenovia. "As we approach the potential approval of MydCombi next year while continuing to support our development stage programs and strategic partnerships, we will rely heavily on Bren's operations and manufacturing expertise, and I am very pleased to have him as part of our executive team."

Mr. Kern has spent his career helping companies transition from research and development entities into scaled commercial manufacturing organizations. Over the past 20 years, he honed his skills by leading product optimization, supporting regulatory approvals (510K & PMA) and establishing cGMP compliant manufacturing solutions worldwide. Prior to joining the Company, Mr. Kern held leadership positions in multiple medical device and diagnostic companies, including Hound Labs, Inc. (a THC breathalyzer), Second Source Medical LLC (a medical device contract manufacturer), BioLux Research Ltd (an orthodontia acceleration device), BAROnova Inc. (a removable weight loss implant) and Bigfoot Biomedical Inc. /Asante Solutions, Inc. (an insulin delivery device). Mr. Kern holds a B.S. in Mechanical Engineering Technology from Oregon Institute of Technology.

Julia Haller, MD, to Step Down from the Board

Eyenovia also announced today that independent director Julia Haller, MD is stepping down from the company's Board of Directors. Upon her departure, Eyenovia's Board will be reduced to seven seats from eight.

"On behalf of the entire Board, I would like to thank Dr. Haller for her service during what was a crucial time for our company," stated Sean Ianchulev, MD, MPH, Chairman of Eyenovia's Board of Directors. "As a world-renowned retinal surgeon-scientist and innovator in the field of ophthalmology, Dr. Haller brought unique perspectives and advised us through some of our most important activities and events, including the evolution of our strategy. We wish her well in her future endeavors."

About Mydcombi™ for Mydriasis

Mydcombi is Eyenovia's investigational, first-in-class fixed-dose-combination product (tropicamide 1% and phenylephrine 2.5% ophthalmic spray) for pharmacologic mydriasis (eye dilation), which is targeted to improve the efficiency of the estimated 100 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 as a micro-formulation for use without anesthetic, Eyenovia believes Mydcombi will help improve the efficacy, tolerability, and efficiency of pharmacologic mydriasis. Mydcombi has been licensed to Arctic Vision (Hong Kong) Limited in Greater China and South Korea.

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 estimate the volume of ophthalmic solution administered with the Optejet is less than 20% 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% historically seen with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

**About Eyenovia, Inc.**

Eyenovia, Inc. (NASDAQ: EYEN) is an ophthalmic pharmaceutical technology company developing a pipeline of microdose array print (MAP™) therapeutics. Eyenovia is currently focused on the late-stage development of microdosed medications for mydriasis, presbyopia and myopia progression. For more information, visit Eyenovia.com.

The Eyenovia Corporate Information slide deck may be found at ir.eyenovia.com/events-and-presentations.

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 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 in some cases 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: 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 timing of, and our ability to submit applications for, obtaining and maintaining regulatory approvals for our product candidates; the potential impacts of COVID-19 on our supply chain; the potential advantages of our product candidates and platform technology; 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; reliance on third parties to develop and commercialize our product candidates; the ability of us and our partners to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; 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, Eyenovia does not undertake any obligation to update any forward-looking statements.

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