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): January 16, 2024

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.)**

295 Madison Avenue, Suite 2400, New York, NY 10017
(Address of Principal Executive Offices, and Zip Code)

(833) 393-6684
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© under the Exchange Act (17 CFR 240.13©(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, par value $0.0001 per share	**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 ☐

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 1.01. Entry Into a Material Definitive Agreement.

In 2020, Eyenovia licensed MicroPine, our lead candidate in development for pediatric progressive myopia, to Bausch Health Ireland Limited, an Ireland corporation and wholly owned subsidiary of Bausch Health Companies Inc. ("Bausch Health"), in exchange for an up-front fee, milestone payments associated with regulatory and launch success and sales-based royalties . The license agreement was subsequently assigned to Bausch + Lomb Ireland Limited ("B&L"), in connection with Bausch Health's planned spinoff transaction of its eye health business.

The pediatric progressive myopia market represents a potential multi-billion dollar opportunity, according to the Review of Optometric Business. It is estimated that about one in three children in the United States are affected by myopia, which is a chronic, progressive disease characterized by the eye growing too long. This lengthening of the eye changes its ability to focus on distant objects, resulting in blurry vision (nearsightedness). It may also increase the risk of permanent vision loss.

Since 2020, pediatric progressive myopia has received much greater attention, especially as the COVID pandemic left many children to learn at home in front of computer and tablet screens, which often caused their myopia to worsen at an accelerated pace.

On January 12, 2024, after successful negotiations between Eyenovia and B&L regarding the pediatric progressive myopia program, B&L and Eyenovia entered into a Letter Agreement (the "Letter Agreement"), pursuant to which Eyenovia will reacquire the rights to this program. The terms of the agreement include the transfer of the rights and certain assets relating to the pediatric progressive myopia program from B&L to Eyenovia in exchange for cash and common stock consideration. In addition, under the terms of the Letter Agreement, Eyenovia has also agreed to pay B&L a low single-digit royalty on Eyenovia's net sales of MicroPine in the United States and Canada for a period of ten years from the date of the first commercial sale by Eyenovia or its affiliates or licensees of MicroPine in the United States. Under the Letter Agreement, (i) Eyenovia will re-acquire any and all licenses and other rights granted by Eyenovia to B&L under the original License Agreement, (ii) any and all licenses and other rights granted by B&L to Eyenovia under the License Agreement shall terminate, other than as set forth in the Letter Agreement, and (iii) other than as set forth in the Letter Agreement, B&L shall be released from all of their ongoing obligations under the License Agreement, including development and commercialization obligations thereunder.

Over the next 90 days, both companies will be working together to facilitate the transfer to Eyenovia of the regulatory files and clinical study materials and assignment of certain contracts relating to the CHAPERONE trial from B&L to Eyenovia (the "Regulatory Transfers"). During that period, B&L will continue to fund the ongoing CHAPERONE trial, a multi-year pivotal study of atropine 0.1%, 0.01% and placebo, each delivered by the Optejet device. The Letter Agreement has no impact on Eyenovia's partnership with Arctic Vision which covers Greater China and South Korea.

In connection with the entry into the Letter Agreement, Eyenovia will issue B&L $3 million in shares of the Company's common stock, $0.0001 par value per share, within ten business days of the completion of the Regulatory Transfers. Under the Letter Agreement, the Company has also agreed to pay B&L an upfront payment of $2 million in cash.

Michael Rowe, chief executive officer of Eyenovia, said, "I am thankful to Bausch and Lomb for the meaningful work that they have done for the continued development of MicroPine since 2020**.** This gives Eyenovia an opportunity to have 100% ownership of MicroPine in our late-stage drug portfolio. The myopia market remains underserved and a differentiated product like MicroPine, with the potential to deliver an effective dose with less systemic absorption, side effects, greater ease of use and increased compliance, could become a leader in this potential multi-billion dollar market. From a financial vantage point, we believe owning 100% of this asset going forward adds significant accretive value to our portfolio which we can focus on to extract maximum value. "

Eyenovia anticipates that more than half of CHAPERONE's planned enrollment will have completed at least three years of therapy by mid-2024. To date, we have not been informed of any serious drug-related adverse events. Eyenovia plans to consult with the FDA as soon as possible to explore pathways that could provide faster availability of MicroPine to millions of children affected by this progressive disease in the United States. We plan to thoroughly evaluate all strategic alternatives to bring MicroPine to children around the world, including through new strategic partnerships.

For the next four years, Eyenovia sees no material effect of this development on cash flow except for the cost of completing the study, which will be managed within its current clinical capabilities. In addition to MicroPine as a compelling addition to its late-stage portfolio, Eyenovia also has MydCombi™, the first FDA approved product to utilize the Optejet dispenser (commercial launch planned for February 2024), APP13007 for post-surgical pain and inflammation with an FDA PDUFA target action date of March 4, 2024, and Apersure™, our pre-NDA stage asset for presbyopia.

The foregoing descriptions of the Letter Agreement and the License Agreement are qualified in their entirety by the full text of the Letter Agreement, which will be filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and by the full text of the License Agreement, which is filed as Exhibit 10.15 to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 31, 2023.

Item 1.02. Termination of a Material Definitive Agreement.

The information provided in Item 1.01 of this Current Report on Form 8-K regarding the Letter Agreement is incorporated by reference into this Item 1.02.

Item 3.02. Unregistered Sales of Equity Securities.

The information provided in Item 1.01 of this Current Report on Form 8-K regarding the Letter Agreement is incorporated by reference into this Item 3.02.

Item 7.01. Regulation FD Disclosure.

On January 16, 2024, the Company issued a press release announcing entry into the Letter Agreement. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 7.01, including Exhibit 99.1, is being "furnished" and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The information contained in this Item 7.01, including Exhibit 99.1, shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act or into any filing or other document pursuant to the Exchange Act, except as otherwise expressly stated in any such filing.

Forward-Looking Statements

Except for historical information, all the statements, expectations and assumptions contained in this Current Report on Form 8-K are forward-looking statements. Forward-looking statements include, but are not limited to, statements that express the Company's intentions, beliefs, expectations, strategies, predictions or any other statements relating to the Company's future activities or other future events or conditions, including statements regarding the development, supply and commercialization of the Company's product candidates. These statements are based on current expectations, estimates and projections about the Company's 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 the Company files with the U.S. Securities and Exchange Commission.

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, the Company does not undertake any obligation to update any forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated January 16, 2024.
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: January 16, 2024

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Re-Acquires Development and Commercialization Rights to MicroPine in the U.S. and Canada

MicroPine, currently in late phase III for pediatric progressive myopia, to complement Eyenovia's commercial-stage asset, Mydcombi, as well as its pre-PDUFA candidate, APP13007

Part of corporate strategy to expedite commercialization of advanced products using the Optejet device

Market estimated to be nearly $2 billion annually in the U.S. by Review of Myopia Management

NEW YORK— January 16, 2024—Eyenovia, Inc. (NASDAQ: EYEN), a commercial-stage, ophthalmic company, today announced that it has re-acquired the rights to MicroPine in the U.S. and Canada.

MicroPine, an investigational eight microliter ophthalmic spray of atropine delivered by Eyenovia's proprietary Optejet device, is being evaluated as a potential treatment for pediatric progressive myopia (worsening near-sightedness), which is characterized by elongation of the sclera/retina. Eyenovia estimates that more than 25 million children in the U.S. suffer from myopia, and, of these, five million are believed to be at high risk for progressive myopia. If left untreated, progressive myopia can ultimately lead to significant vision loss and potential blindness. Prior studies have demonstrated that atropine can slow myopia progression by as much as 60%, and there is a significant unmet need for safe and effective FDA-approved treatment options.

The re-acquisition of MicroPine greatly expands Eyenovia's phase III pipeline and commercial opportunities, as follows:

- As Eyenovia accelerates its commercial capabilities in 2024 with the expanded launch of MydCombi and the anticipated introduction of APP-13007 (pending FDA approval anticipated in March), MicroPine adds a major late-stage asset in a large market with high unmet medical need;
- Based upon the Company's internal forecast, by acquiring back the MicroPine rights, the overall asset value of the MicroPine program to Eyenovia more than doubles compared to what the Company would have been eligible to receive under the original license agreement;
- Eyenovia will work to accelerate the ongoing CHAPERONE phase III trial and engage with FDA to explore options to expedite development and registration of MicroPine;
- Expands the territories in which the CHAPERONE study may be conducted to support registration as well as the field of potential collaborators to engage for future partnering or strategic discussions.

"With the FDA approval of MydCombi for in-office mydriasis (pupil dilation), together with our recent announcement that we in-licensed the U.S. commercial rights to APP13007 for post-ocular surgical pain and inflammation from Formosa Pharmaceuticals, our commercialization strategy is accelerating," stated Michael Rowe, chief executive officer of Eyenovia. "We believe the addition of MicroPine, if approved, would be highly complementary to these products."

"MicroPine would also utilize our Optejet dispensing technology, which is highly differentiated and confers significant advantages to eye doctors and patients as compared to traditional eye drops, including less systemic exposure, better compliance among children, ease of use, and potentially better local tolerability. Our re-acquisition of the rights to MicroPine in the U.S. and Canada is consistent with our broader corporate strategy to expedite commercialization of advanced products using the Optejet.

"We believe we are ideally positioned to complete remaining development steps in an expedited and capital efficient manner, and, to that end, we plan to meet with the FDA early this year to align on a path forward for this high-value program," Mr. Rowe concluded.

In connection with this transaction, Eyenovia will pay Bausch + Lomb Ireland Limited an upfront payment consisting of $2 million in cash and $3 million in shares of common stock, as well as a low single-digit royalty on Eyenovia's net sales of MicroPine in the United States and Canada.

This agreement has no impact on Eyenovia's ongoing partnership with Arctic Vision, which covers development of MicroPine (as well as Mydcombi and MicroLine/Apersure) for Greater China and South Korea.

PLEASE GO TO MYDCOMBI.COM FOR IMPORTANT SAFETY INFORMATION for MYDCOMBI™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5%

About Eyenovia, Inc.
Eyenovia, Inc. (NASDAQ: EYEN) is a commercial-stage ophthalmic pharmaceutical technology company developing a pipeline of microdose array print therapeutics based on its Optejet platform. Eyenovia is currently focused on the commercialization of Mydcombi (tropicamide+phenylephrine ophthalmic spray) for mydriasis.

In addition to commercializing Mydcombi, in August 2023, Eyenovia acquired the U.S. commercial rights to APP13007 (clobetasol propionate ophthalmic nanosuspension, 0.05%) from Formosa Pharmaceuticals. APP13007, which is currently under review by the FDA, is a potent steroid being developed to reduce pain and inflammation following ocular surgery. The agency has assigned a Prescription Drug User Fee Act (PDUFA) action date for APP13007 of March 4, 2024.

Eyenovia is also advancing late-stage development of medications in the Optejet device for presbyopia and myopia progression (partnered with Arctic Vision in China and South Korea).

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 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, and the potential for approval of APP13007. 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, 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 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, legislative and geopolitical 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.

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

Eyenovia Investor Contact:
Eric Ribner
LifeSci Advisors, LLC
eric@lifesciadvisors.com
(646) 751-4363

Eyenovia Media Contact:
Eyenovia, Inc.
Norbert Lowe
Vice President, Commercial Operations
nlowe@eyenovia.com