
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): June 27, 2023

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)

(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(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, 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 ☒ 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 7.01. Regulation FD Disclosure.

Eyenovia, Inc. (the “Company”) plans to use the attached slide presentation in connection with the Company’s 2023 Annual Meeting of Stockholders on June 27, 2023. A copy of the presentation 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Eyenovia, Inc. Corporate Presentation, dated June 27, 2023.</u>
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: June 27, 2023

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer



2023 Annual Meeting

Forward-looking Statements

Except for historical information, all the statements, expectations and assumptions contained in this presentation 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, 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.

An Ophthalmic Technology Company With a Common Platform



MydCombi™

The First and Only Ophthalmic Spray for Mydriasis

Designed to Enhance Office Efficiency

A Diagnostic Paid for by the Eye Care Practitioner's Office

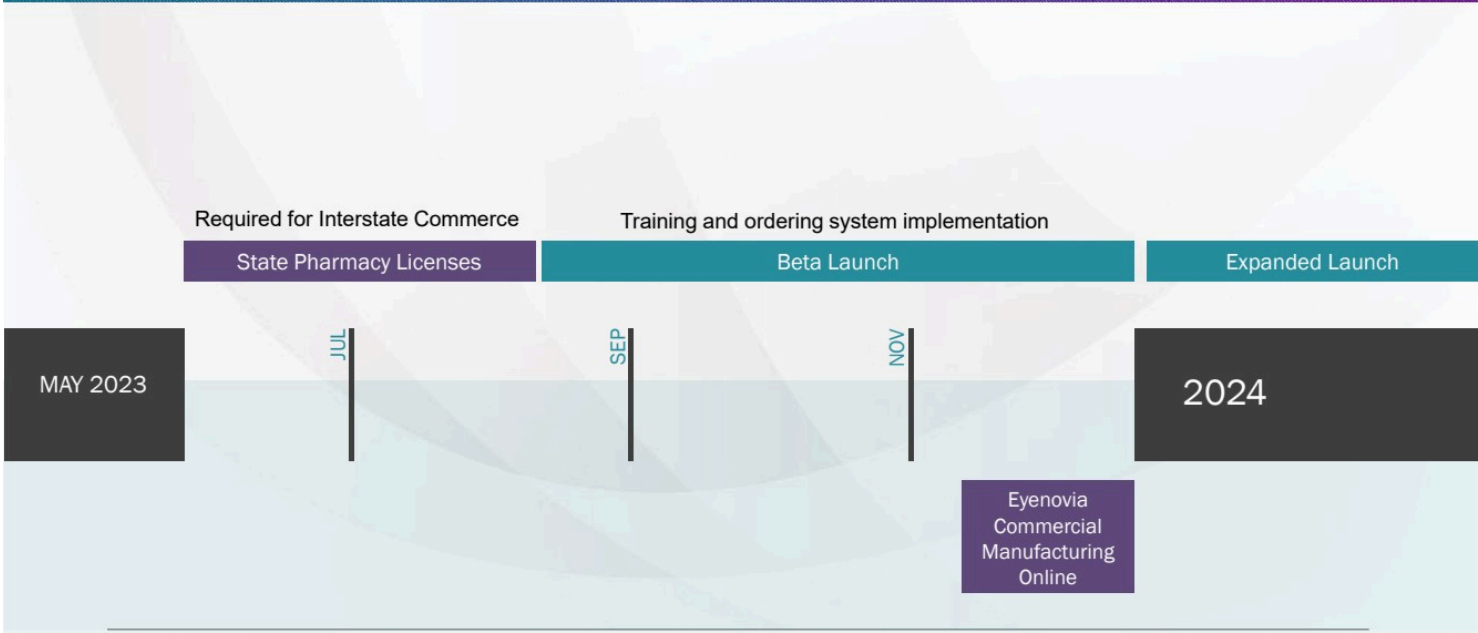
Replaces Up to Three Existing Products

Beta Launch 2H 2023 - Expanded Launch Early 2024



Indication: MYDCOMBI (tropicamide 1% and phenylephrine HCl 2.5%) ophthalmic spray is indicated to induce mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired. **IMPORTANT SAFETY INFORMATION. CONTRAINDICATIONS:** Known hypersensitivity to any component of the formulation. **WARNINGS AND PRECAUTIONS.** FOR TOPICAL OPHTHALMIC USE. NOT FOR INJECTION. This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of psychotic reaction and behavioral disturbance due to hypersensitivity to anticholinergic drugs should be considered. Mydriatics may produce a transient elevation of intraocular pressure. Significant elevations in blood pressure have been reported. Caution in patients with elevated blood pressure. Rebound miosis has been reported one day after installation. Remove contact lenses before using. **DRUG INTERACTIONS.** Atropine-like Drugs: May exaggerate the adrenergic pressor response. Cholinergic Agonists and Ophthalmic Cholinesterase Inhibitors: May interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors. Potent Inhalation Anesthetic Agents: May potentiate cardiovascular depressant effects of some inhalation anesthetic agents. **ADVERSE REACTIONS.** Most common ocular adverse reactions include transient blurred vision, reduced visual acuity, photophobia, superficial punctate keratitis, and mild eye discomfort. Increased intraocular pressure has been reported following the use of mydriatics. Systemic adverse reactions including dryness of the mouth, tachycardia, headache, allergic reactions, nausea, vomiting, pallor, central nervous system disturbances and muscle rigidity have been reported with the use of tropicamide. To report SUSPECTED ADVERSE REACTIONS, contact Eyenovia, Inc. At 1-833-393-6684 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch) www.mydcombi.com for FULL PRESCRIBING INFORMATION

MydCombi Launch Timeline



Eyenovia Has Met its Stated Corporate Objectives In The Past 12 Months

- ✔ Validation of Optejet technology with FDA approval of MydCombi
- ✔ Execution of our R&D/MFG strategic plan
- ✔ Preparations for Apersure™ (Microline) NDA in the consumer-friendly Gen-2 device

Optejet Gen-2

- Improved ability to manufacture
- Sleek ergonomic design
- On board data collection and reporting integrates with AI systems



Optejet Gen-2 is the Commercial Device for Apersure™

- 4 out of 5 patients preferred the Optejet over an eyedropper when considering presbyopia treatment¹
- Unlike presbyopia eye drops, Apersure™ may be monetized through the selling of the device by ODs
 - Business model aligns with existing retail component of the eye care practitioner's business
- In recent market research, Optejet differentiation and clinical profile leads ODs to believe Apersure will be the leading pharmacologic in presbyopia space
- Targeting end of 2024 for NDA filing at the conclusion of 12-months stability testing

Corporate Strategy is to Maximize the Value of Our Current and Potential Future Assets



Opportunities
Dry Eye
Glaucoma

Glaucoma and Dry Eye Represent 80% of the Value in Topical Ophthalmic Therapies

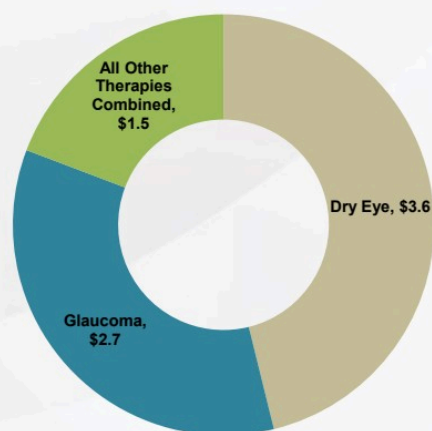
GLAUCOMA

- Addresses need for an easier to administer product with potentially fewer side effects and added benefits such as dosing reminders
- Digital technology may provide doctors and managed care organizations with an unbiased measure of patient adherence and compliance, enabling data-based decision making

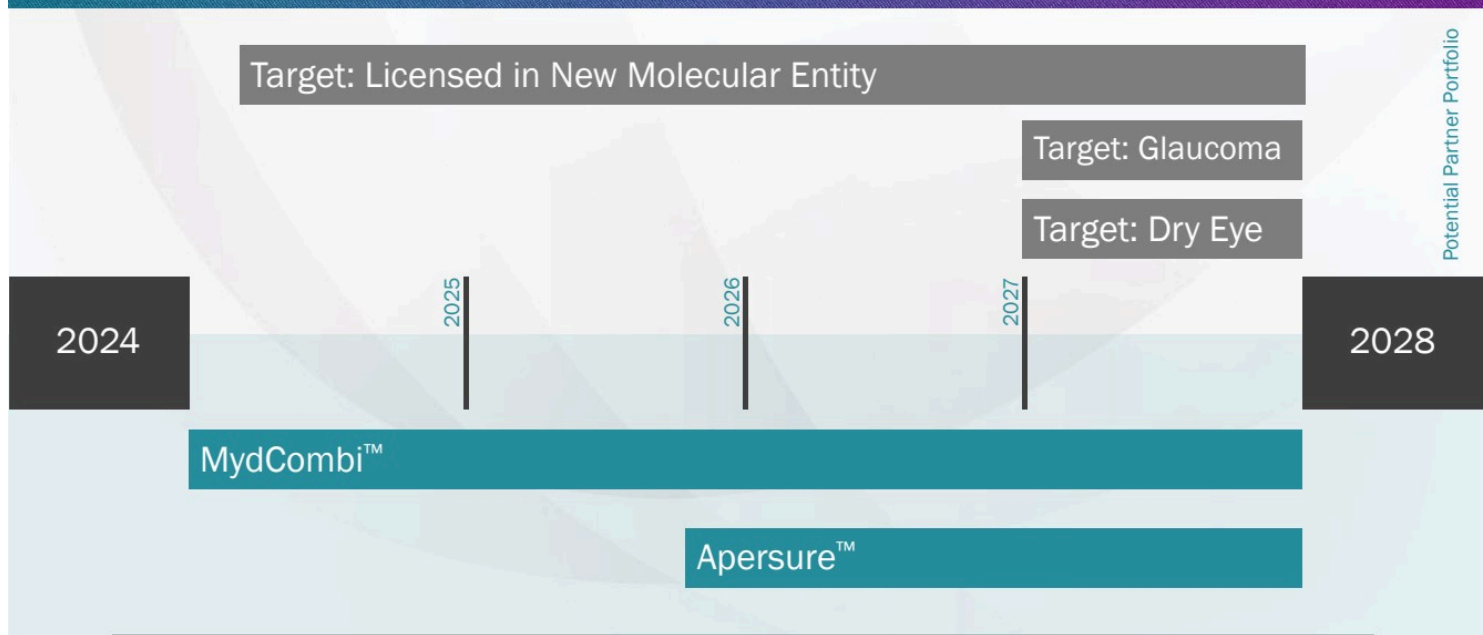
DRY EYE

- Addresses the need for an easier to administer product with potentially fewer side effects
- May reduce the detrimental impact of preservatives on the ocular surface¹
- May improve the probability of success in phase 3 trials by decreasing the placebo effect of wetting the eye

US Topical Ophthalmic Solution Market (Billions)
2022, Total Value \$7.8B



Strategic Commercialization Timeline 2024-2028



Upcoming Potential Milestones

3Q 2023

First Commercial Sale of MydCombi™

Potential Licensing and/or Partnership Agreements

Production of Pre-NDA Batches for Apersure™ (Microline)

4Q 2024

Planned NDA Filing for Apersure