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 15, 2023

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)

(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 1.01. Entry Into a Material Definitive Agreement.

On August 15, 2023, Eyenovia, Inc. (the "Company"), entered into a license agreement (the "License Agreement") with Formosa Pharmaceuticals, Inc. ("Formosa"). Pursuant to the License Agreement, Formosa granted to the Company an exclusive sublicensable license to commercialize, in the United States and its territories and possessions (including the District of Columbia and Puerto Rico) (the "Territory"), any product related to a novel formulation of Clobetasol Proprionate (Clobetasol Proprionate Ophthalmic Nanosuspension, 0.05%) (the "Licensed Product"), which is currently under review by the U.S. Food and Drug Administration (the "FDA"), for ophthalmic use for inflammation and pain after ocular surgery and supplemental disease indications, if any, associated with the New Drug Application for the Licensed Product. The Company has agreed to use commercially reasonable efforts to launch, at its own expense, the Licensed Product in the United States within a specified time frame following FDA approval and to commercialize the Licensed Product in the Territory.

Formosa will initially be the sole supplier of the Licensed Product to the Company and its affiliates and sublicensees in the Territory. Pursuant to the License Agreement, the Company and Formosa expect to enter into separate supply, pharmacovigilance and quality agreements related to the Licensed Product.

In connection with the Company's entry into the License Agreement, the Company is required to pay Formosa $2 million within 45 days of the effective date of the agreement, with half to be paid in cash, and the other half to be in the form of 487,805 shares of the Company's common stock. Under the License Agreement, the Company has also agreed to pay Formosa up to $4 million upon the achievement of certain development milestones and up to $80 million upon the achievement of certain sales milestones.

The License Agreement will remain effective for ten years after the first commercial sale of a Licensed Product unless earlier terminated. Either party may terminate the License Agreement if (a) the other party is in material breach of the agreement, subject to a cure period, where applicable, or (b) the other party is insolvent or becomes subject to a bankruptcy or insolvency petition or proceeding. The Company may terminate the License Agreement (i) on written notice to Formosa if a material unexpected or new safety concern is reported and is deemed uncured or uncurable after a specified period, or (ii) on written notice to Formosa if approval of the Licensed Product by the FDA is revoked after issuance, subject to certain determination and cure requirements. Formosa may terminate the License Agreement (x) if the Company undergoes a change of control and the surviving entity is engaged in a competing regulatory program, with such termination to become effective 120 days after notice is given or at any time after the change of control has occurred and commercialization of the Licensed Product has ceased, (y) if, following the first commercial sale of the Licensed Product, certain specified net sales and annual unit sales figures are not achieved, with termination to become effective 120 days after notice is given, or (z) upon the termination of the supply agreement that the Company and Formosa expect to enter into. The License Agreement may also be terminated by the Company and Formosa upon mutual agreement. The Company and Formosa each agreed to indemnify the other party against certain third-party claims.

A copy of the License Agreement will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the three months ended September 30, 2023.

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 Licensed Product. 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 7.01. Regulation FD Disclosure.

On August 16, 2023, the Company issued a press release announcing entry into the License 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.

Also on August 16, 2023, the Company began using an updated corporate presentation with various investors and analysts. A copy of the presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 7.01, including Exhibits 99.1 and 99.2, 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 Exhibits 99.1 and 99.2, 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

Exhibit No.	**Description**
99.1	Press release dated August 16, 2023.
99.2	Eyenovia, Inc. updated corporate presentation, dated August 2023.
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: August 16, 2023

/s/ John Gandolfo
John Gandolfo
Chief Financial Officer

Exhibit 99.1

Eyenovia Acquires U.S. Commercial Rights to APP13007 (Clobetasol Propionate Ophthalmic Nanosuspension, 0.05%) from Formosa Pharmaceuticals

APP13007, if approved, may have an advantageous profile in dosing frequency and side effects while reducing the inflammation and pain associated with ocular surgery

Further leverages Eyenovia's Mydcombi sales force and represents additional near-term potential revenue source

Eyenovia plans to evaluate novel clobetasol formulations in its proprietary Optejet® dispensing platform as a potential treatment for dry eye, estimated to be a $3.6 billion market in the U.S.

NEW YORK— August 16, 2023—Eyenovia, Inc. (NASDAQ: EYEN), an ophthalmic technology company commercializing Mydcombi™ (tropicamide and phenylephrine hydrochloride ophthalmic spray) 1%/2.5% for mydriasis and developing the Optejet® device for use both in connection with its own drug-device therapeutic product candidates for presbyopia and pediatric progressive myopia as well as out-licensing for additional indications, today announced that it has entered into an agreement with Taiwan-based Formosa Pharmaceuticals (TWO:6838) whereby Eyenovia has acquired the exclusive U.S. rights to distribute and sell APP13007 (clobetasol propionate ophthalmic nanosuspension, 0.05%), which is currently under review by the U.S. Food and Drug Administration (FDA). The agency has assigned a Prescription Drug User Fee Act (PDUFA) action date for APP13007 of March 4, 2024.

Per the terms of the agreement, Eyenovia will make single-digit million dollar payments to Formosa in cash and shares of Eyenovia common stock upon the signing of the agreement, upon FDA approval of APP13007 and the transfer of the NDA to Eyenovia, and following the first commercial sale of APP13007. Additionally, Formosa will be eligible for payments related to the attainment of sales milestones by Eyenovia.

Clobetasol is a potent steroid not yet available in ophthalmology that, if approved, may have an advantageous profile in dosing frequency (2x/day versus 4x/day for most other post-surgical eye drops) and tolerability while reducing the inflammation and pain associated with ocular surgery. It is estimated that there are more than seven million ocular surgeries in the U.S. each year with topical ocular steroids and steroid combinations currently totaling $1.3 billion in sales.

“We are pleased to have entered into this agreement with our development partner, Formosa Pharmaceuticals, to acquire the U.S. commercial rights to APP13007. If approved, APP13007 would be an attractive new treatment option for the aftereffects of ocular surgery, most notably inflammation and pain,” stated Michael Rowe, chief executive officer of Eyenovia. “The acquisition of APP13007 is an opportunistic addition to our product portfolio, and a new potential source of near-term revenue, at what we believe are very favorable terms for both parties. Alongside our mydriasis product, Mydcombi, we can bring additional value to ophthalmic surgeons and their patients through the use of MydCombi for pre-operative dilation and APP13007 post-operatively, both supported by a single dedicated sales force.”

“We will also be discussing with the FDA the opportunity to develop novel clobetasol formulations as a late-stage asset for use with the Optejet as a potential treatment for dry eye, a market estimated to be worth over $3.6 billion. This agreement ushers in an exciting new chapter in Eyenovia’s emergence as a commercial ophthalmic company,” Mr. Rowe concluded.

“Formosa Pharma enters this partnership with Eyenovia with great enthusiasm. The complementarity of each company’s products, as well as corporate strategies, lay the foundation for a long-term and rewarding alliance for all stakeholders,” said Erick Co, President and CEO of Formosa Pharmaceuticals. “With Eyenovia’s bold and creative marketing strategies, we are confident that APP13007 will realize its potential in providing a formidable choice for ophthalmologists and patients for the relief of inflammation and pain following ocular surgery.”

“Given my focus on new ophthalmic technologies, having worked on the clinical development of both Eyenovia’s Mydcombi and Formosa’s clobetasol ophthalmic nanosuspension, I can speak directly to the significant advancements that each represents in its respective indication,” stated William J. Flynn, M.D., Research Director of R & R Eye Research in San Antonio. “I look forward to the potential of prescribing APP13007 in the first half of next year and intend to incorporate it and Mydcombi into my practice as soon as possible.”

APP13007 is the first product developed using Formosa’s proprietary APNT™ nanoparticle formulation platform. Formosa’s APNT™ platform reduces an active pharmaceutical ingredient’s particle size with high uniformity and purity, thereby allowing penetration to relevant compartments in the eye, and ultimately enhancing bioavailability.

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. Eyenovia is currently focused on the commercialization of Mydcombi for mydriasis, as well as the ongoing late-stage development of medications in the Optejet device for 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 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.

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Exhibit 99.2


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Boldly Go Where Eyecare Has Never Gone Before
August 2023

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.

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The Optejet® boldly brings eyecare into the 21st Century

Optejet® with replaceable drug cartridge

Proprietary, pre-filled drug cartridge manufactured by Eyenovia

On-board technology with Bluetooth and memory functions

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1. German, E., Hurst, M. & Wood, D. Reliability of drop size from multi-dose eye drop bottles: is it cause for concern?. Eye 13, 93–100 (1999). https://doi.org/10.1038/eye.1999.17. | Ahmed, S., Amin, M.M. & Sayed, S. Ocular Drug Delivery: a Comprehensive Review. AAPS PharmSciTech 24, 66 (2023). https://doi.org/10.1208/s12249-023-02516-9

Is the Optejet® the best option to address the limitations of topical ophthalmic drug delivery?

- **Usability**[1]
  - No head-tilting
  - Fixation light assist
  - Push of a button
- **Tolerability**[2]
  - Lower drug and preservative exposure
  - Less ocular impact
  - Less systemic exposure
- **Connectivity**[3]
  - To mobile device for dose reminders and compliance support
  - To the cloud for healthcare system patient outcomes analyses

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1. Optejet® is designed to deliver solution horizontally to the eye, a blue mirror light surrounds the ejector, and a button actuates doses
2. Wirta DL, et al, Mydriasis with micro-array print touch-free tropicamide-phenylephrine... Ther Deliv. 2021 Mar;12(3):201-214. doi: 10.4155/tde-2021-0011. Epub 2021 Mar 15.| Ianchulev T. et al, Therapeutic Delivery 2018
3. Data on file. Optejet® has Bluetooth and dose time-stamp tracking capability

Where the Optejet® can make a bold difference

	Market Opportunity[1]	Usability	Tolerability	Connectivity
Pediatric Myopia	$4.5B	●	●	●
Dry Eye	$3.6B	●	●	●
Glaucoma	$3.0B	●	●	●
Presbyopia	$0.9B	●	●	
Mydriasis	$0.3B	●	●	
Total	$12.3B			

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1. Estimates from various sources

MydCombi™: Mydriasis as it has never been done before

MydCombi™
(tropicamide and phenylephrine HCl ophthalmic spray) 1%/2.5%

+ Only fixed combination of the most used dilating medications in the US
+ Only ophthalmic spray approved for mydriasis
= Together, designed to streamline the pupil dilation process

- Efficacy[1]
  - 61% of patients fully dilated in 20min; nearly all at 35min
- Usability[1]
  - 83% of doses were successfully administered on the first attempt
- Tolerability[1]
  - 97% of patients studied reported no adverse event
- Cost[2]
  - Priced comparably with current eye drop options

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1. Wirta DL, et al, Mydriasis with micro-array print touch-free tropicamide-phenylephrine... Ther Deliv. 2021 Mar;12(3):201-214. doi: 10.4155/tde-2021-0011. Epub 2021 Mar 15.| Ianchulev T. et al, Therapeutic Delivery 2018
2. Assumes $120/cartridge of MydCombi™. Current options: 15ml of Phenylephrine $138, 15ml of Tropicamide $9.95, 15ml of Anesthetic $30 (~$180)

Clobetasol[1]: A potent steroid with a future in the Optejet ®

- Eyenovia licensed the US rights to this unique post-surgical eye drop
- PDUFA date of March 2024
- Provides significant short and mid-term revenue opportunity ($1.3B market size)
- Synergistic commercialization with MydCombi™
- Potential future Optejet-based product for Dry Eye

API	Clobetasol Propionate
Target Use	Ophthalmic nanosuspension for inflammation and pain after ocular surgery
Dosing	Twice a day for two weeks
Efficacy	Sustained inflammation-free and pain-free
Safety	Observed safety profile comparable to that of placebo; Well-tolerated and comfortable
IOP Increase	Minimal

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1. Data supplied by Formosa Pharmaceuticals

Optejet® technology will be targeted for Dry Eye

- Clobetasol may provide a unique profile that has the promise of quick relief and the ability to use alongside other drugs
  - Optejet would provide a lower dose and added safety margin
- When developed with clobetasol, or another molecule, the Optejet may increase the odds of a successful Phase 3 program
  - Many dry eye products fail vs placebo due to the lubricating action of a large volume eye drop
  - Optejet, due to its low-volume spray, may minimize the performance of the placebo
- A dry eye NDA program could be completed in less than 4 years

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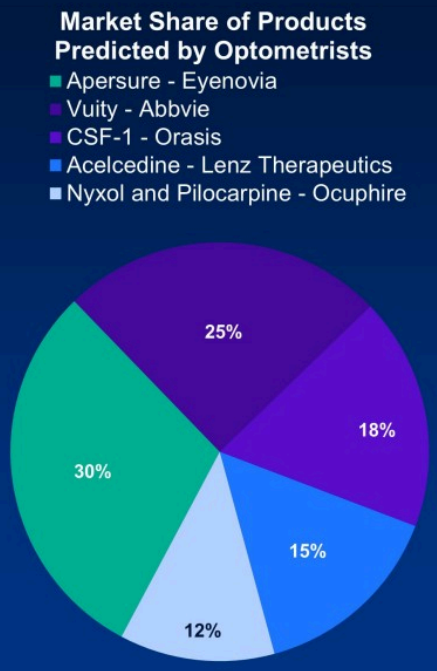
Apersure™: Your invisible second pair of glasses

- Target population is 40-55 year olds who have never needed vision correction prior to the onset of presbyopia in the top half of income
- Apersure provides functional vision for approximately 4 hours post-dose with very few side effects
- Optometrists can offer this Optejet based product alongside glasses as an additional benefit for their patients
  - Easy and neat application
  - Discreet on-demand dosing
- In a market research survey consisting of 100 Optometrists across the US, Apersure was predicted to have the largest market share of approved and potential products



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1. VISION-1 & 2 Studies, data on file.
2. Survey conducted in May 2022 by J. Reckner and Associates, data on file.
3. Survey conducted in May 2023 by J. Reckner and Associates , data on file.

Optejet® technology will be targeted for Glaucoma

- A full line of products, all in the Optejet
  - PGAs, Beta Blockers, CAIs, Rock Inhibitors, etc.
  - All may benefit from Optejet delivery
- Addressing significant issues in the treatment of glaucoma[1]
  - Compliance
  - Tolerability and side effects
  - Ease of use
- Equipping HCPs with compliance data allows for more informed treatment decisions
  - Patients will be reminded to take doses
  - HCPs will have real-time information to make informed decisions
  - Payers could benefit from population-based efficacy analyses

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1. Stone JL, Robin AL, Novack GD, Covert DW, Cagle GD. An objective evaluation of eyedrop instillation in patients with glaucoma. Arch Ophthalmol. 2009 Jun;127(6):732-6. doi: 10.1001/archophthalmol.2009.96. | Haga C, Waller T, Ahuja AS, Farford B, Dawson N, Yin M. There's Danger in the Drops: Systemic Effects of Ophthalmic Drops Used to Treat Glaucoma. Cureus. 2022 Jan 4;14(1):e20945. doi: 10.7759/cureus.20945

Changing how glaucoma is managed with the Optejet®

- The Optejet records each dose administered and can send information to a companion app
- Companion app could:
  - Track compliance rates
  - Send patient dosing reminders
  - Share information with HCPs via the cloud
  - Be used by healthcare systems and payers to measure patient outcomes

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By 2030, Optejet® technology is expected to underpin major launches in the US and China

- Pediatric Myopia affects 41% of US children and 52% of Chinese children
  - The highest-risk children are put on atropine drops to slow the progression
  - Children take these drops for years
  - Compliance issues lead to severe vision problems
- B+L has the licensing rights to our atropine formulation in the US and Canada
- Arctic Vision has the licensing rights to our atropine formulation in China and South Korea
- Adherence and treatment compliance can be addressed directly with the Optejet®
- Milestone and royalty payments expected to begin in 2028 from our partners

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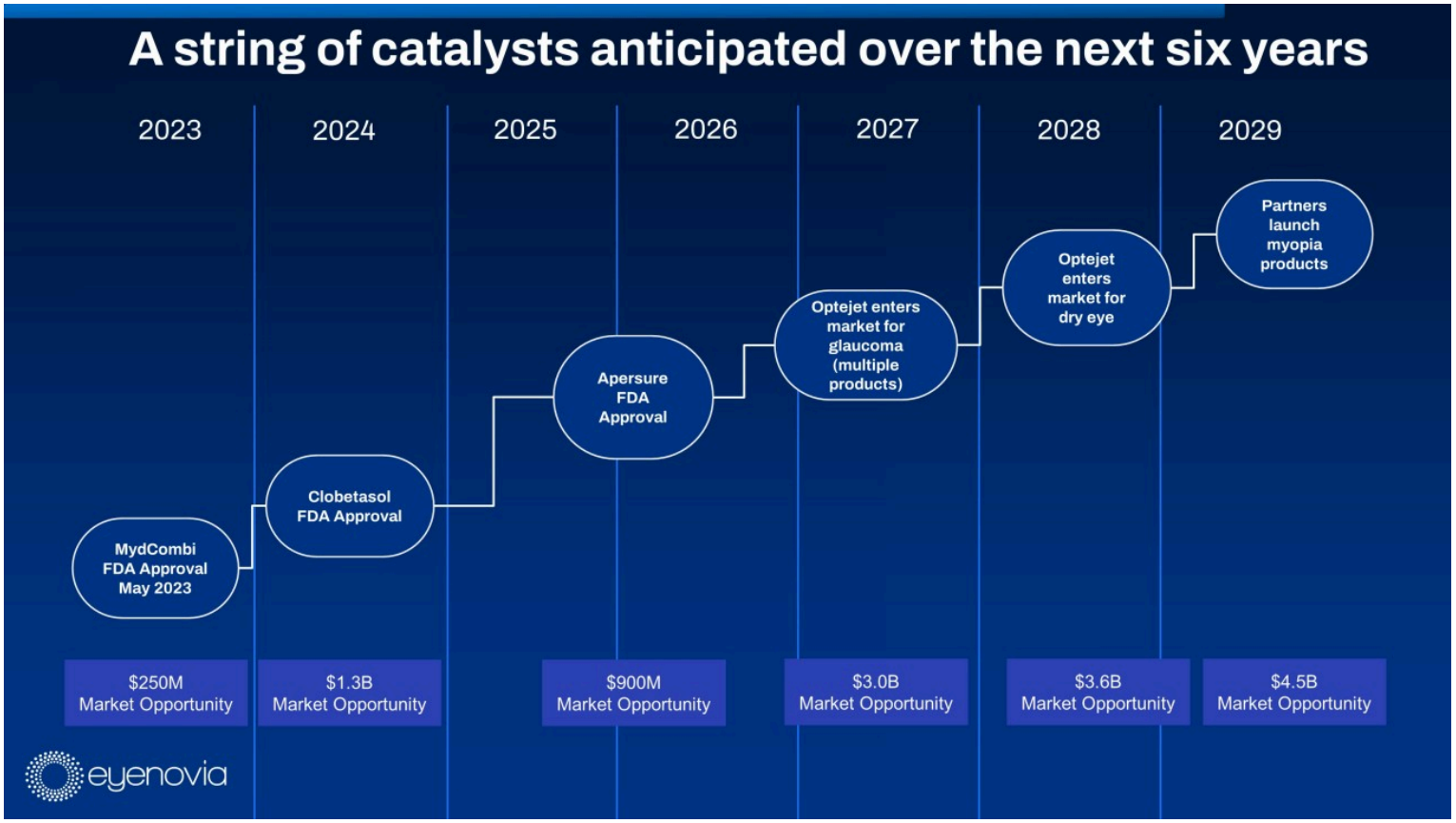
1. Theophanous C, Modjtahedi BS, Batech M, Marlin DS, Luong TQ, Fong DS. Myopia prevalence and risk factors in children. Clin Ophthalmol. 2018 Aug 29;12:1581-1587. doi: 10.2147/OPTH.S164641. | Yin Y, Qiu C, Qi Y. Myopia in Chinese Adolescents: Its Influencing Factors and Correlation with Physical Activities. Comput Math Methods Med. 2022 Aug 24;2022:4700325. doi: 10.1155/2022/4700325.


A string of catalysts anticipated over the next six years
2023
2024
2025
2026
2027
2028
2029
MydCombi FDA Approval May 2023
Clobetasol FDA Approval
Apersure FDA Approval
Optejet enters market for glaucoma (multiple products)
Optejet enters market for dry eye
Partners launch myopia products
$250M Market Opportunity
$1.3B Market Opportunity
$900M Market Opportunity
$3.0B Market Opportunity
$3.6B Market Opportunity
$4.5B Market Opportunity
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Eyenovia. Boldly moving eyecare into the future.

- The first FDA-approved metered spray ophthalmic product
- Now commercializing MydCombi
- Second product (clobetasol) with PDUFA date in March, 2024 and potential for a dry eye indication
- Apersure (presbyopia) potential approval 4Q 2025
- Inbound interest from multiple potential partners

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Thank you

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NASDAQ: EYEN