
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): February 15, 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)

(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 8.01. Other Events.

On February 15, 2023, Eyenovia, Inc. (the “Company”) announced that it has entered into a development collaboration agreement with Taiwan-based Formosa Pharmaceuticals, Inc. (“Formosa”). The agreement seeks to combine the Company’s Optejet® dispensing technology with Formosa’s unique APNT™ nanoparticle formulation platform for the potential development of new topical ophthalmic therapeutics that employ the Optejet® dispenser. Attached hereto as Exhibit 99.1 is the press release reporting the agreement and attached hereto as Exhibit 99.2 is a slide deck regarding the agreement.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Eyenovia, Inc. Press Release Dated February 15, 2023.</u>
<u>99.2</u>	<u>Eyenovia, Inc. Slide Deck Regarding the Collaboration with Formosa Pharmaceuticals, Inc.</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.

Date: February 15, 2023

EYENOVIA, INC.

/s/ Michael Rowe

Michael Rowe

Chief Executive Officer



Eyenovia Announces Development Collaboration Agreement with Formosa Pharmaceuticals

Collaboration will combine Eyenovia's Optejet® dispensing technology with Formosa's APNT™ nanoparticle formulation platform for the potential development of new topical therapeutics in high-value ophthalmic indications with significant unmet medical needs.

NEW YORK— February 15, 2023—Eyenovia, Inc. (NASDAQ: EYEN), a pre-commercial ophthalmic technology company developing the Optejet® delivery system for use both in connection 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 the company has entered into a development collaboration agreement with Taiwan-based Formosa Pharmaceuticals, Inc. (6838.TWO). The agreement seeks to combine Eyenovia's Optejet® dispensing technology with Formosa's unique APNT™ nanoparticle formulation platform for the potential development of new topical ophthalmic therapeutics that employ the Optejet® dispenser.

Formosa's proprietary and innovative 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. This reduction in ingredient size may also expand the universe of existing and future drugs that could benefit from delivery using the Optejet®.

"We have assembled a large and growing body of evidence demonstrating the many benefits of Optejet®, including improved patient compliance and the achievement of therapeutic doses of medication with far less stress on the ocular surface than other forms of administration, such as standard eye drops," stated Michael Rowe, Chief Executive Officer of Eyenovia. "Through this development collaboration, we not only gain access to Formosa's proven ophthalmic formulation expertise for further development using Optejet®, but also its APNT™ formulation technology which opens up several new and large market indications for potential expansion of our own development pipeline. We look forward to a long and mutually beneficial partnership."

"Ophthalmology represents a core focus of our company and a significant part of our long-term growth plan," stated Erick Co, Chief Executive Officer of Formosa Pharmaceuticals. "With Eyenovia's novel Optejet® dispensing platform, we believe we can access a broad new range of potential uses for both existing and newly developed ophthalmic compounds. We are excited about the possibilities and look forward to launching this collaboration as quickly as possible."

Both companies intend to collaborate on testing formulations and engaging in discussions with the Food and Drug Administration (FDA), with the goal of executing a Development and Commercialization Agreement under which the companies would work to develop new drugs leveraging APNT™ formulations in the Optejet® dispenser. Additional information may be found at eyenovia.com/formosa.



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 ~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. 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 Formosa Pharmaceuticals, Inc.

Formosa Pharmaceuticals, Inc. (6838.TWO) is a clinical stage biotechnology company focused primarily in the areas of ophthalmology and oncology. The company's proprietary nanoparticle formulation technology (APNT™) improves the dissolution and bioavailability of active pharmaceutical ingredients (APIs) for topical, oral, and inhaler administration of therapeutics. Formosa's lead program, APP13007, a novel nanosuspension derived through APNT™ for the treatment of inflammation and pain following ocular surgery, successfully completed Phase 3 trials and will be submitted to the FDA later this year for approval. For more information about APNT™ and Formosa Pharmaceuticals, visit www.formosapharma.com.

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 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.

Eyenovia Contact:

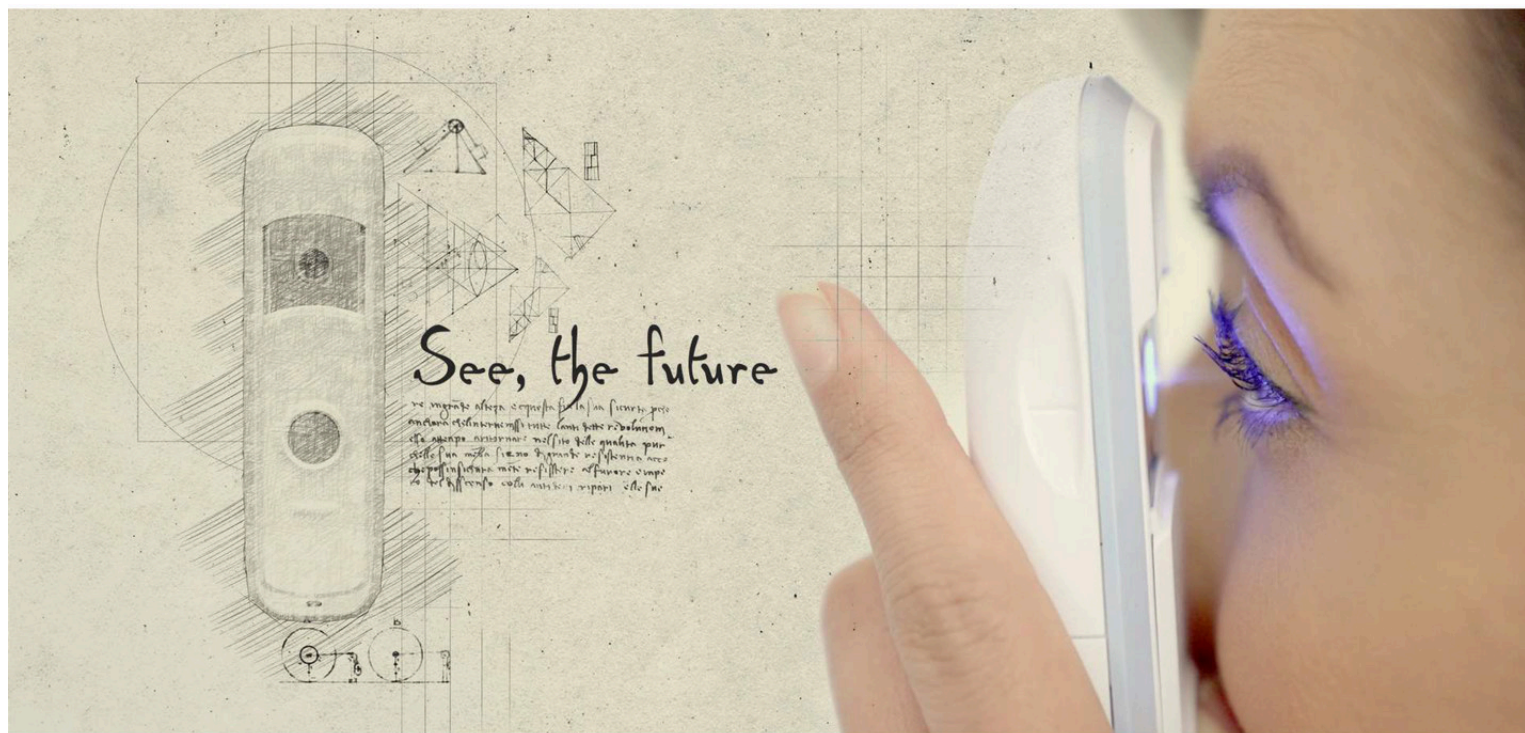
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Formosa – Eyenovia Collaboration

Formosa Pharmaceuticals

- Publicly traded (6838.TWO) Taiwanese clinical stage biotechnology company
 - Market cap \$200M
 - Ophthalmology and oncology (biosimilars) focus
- In topical eye care, Formosa's proprietary nanoparticle formulation technology improves the dissolution and bioavailability of drugs
 - Drugs used in suspensions and possibly emulsions
- Ophthalmic products in development using this technology include:
 - Post-surgical inflammation and pain eye drop (to be filed with the US FDA in 2023)
 - Anti-infective eye drop with potential for meibomian gland dysfunction and dry eye disease

Formosa Pipeline

Ophthalmic (2)

Product	Indication	Clinical Trial and Regulatory Timing				
		Pre-Clin	Phase 1	Phase 2	Phase 3	Reg
APP13007	Inflammation and Pain After Ocular Surgery					USA 2023
						CHINA
APP13002	Anterior Ocular Infections (Including: Bacterial Conjunctivitis, Keratitis, Blepharitis, Meibomian Gland Dysfunction)					

Oncology (2)

TSY-0110, Ph 1, Breast Cancer

MPT0E028, Ph 1, Solid Tumor

Anti-infective (1)

TSY-0210, Pre-Clinical, Drug-resistant infections

APNT™ Technology

- APNT™ (Active Pharmaceutical Nanoparticle Technology) works to reduce particle size leading to improved dissolution, bioavailability, and lowers the risk of contamination
 - Reduces particle size by using common salts and sugars as milling media which can remain a part of the final formulation
 - The resulting formulation has high uniformity and purity allowing for penetration and enhanced bioavailability
- Leading product candidate clobetasol propionate ophthalmic nanosuspension for post-surgical inflammation has completed Phase 3 trials and is being prepared for NDA submission
 - In clinical trials, shows comparable safety profile to placebo with a low incidence of IOP elevation, and potent clearance of inflammation with rapid pain relief

Synergistic Technology

- Formosa's APNT™ technology can adjust the particle size of formulations increasing the probability of success with the Optejet® Broadens the Optejet's usability to existing suspension and emulsion products with viscosities that currently make them incompatible
- Ophthalmic suspensions and emulsions make up over \$1.5B in US sales in the dry eye, glaucoma, inflammation, anti-infective/inflammation combination categories
- The APNT™ platform may:
 - improve stability and lead to longer shelf life
 - improve dispersion properties eliminating shake before use requirements
 - improve bioavailability that when combined with Optejet's targeted corneal delivery could lead to potent efficacy results

Collaboration Agreement

- Eyenovia and Formosa Pharmaceuticals have agreed to collaborate in the development of an APNT™ formulation to be dispensed using the Optejet®
- In 2023, Eyenovia will conduct feasibility testing of novel APNT™ formulations in the Optejet and request a pre-IND meeting with the FDA
- Formosa will develop and optimize new APNT™ formulations for use in the Optejet and deliver to Eyenovia for device qualification and validation
- If successful, the companies will discuss an agreement for the co-development of a differentiated asset in a multi-billion dollar market