
**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 10, 2020

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, New York, NY 10017
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code 917-289-1117

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(s)	Name of each exchange on which registered
Common Stock, \$0.0001 Par Value	EYEN	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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

On August 10, 2020, Eyenovia, Inc. (the “Company”) entered into a License Agreement, (the “License Agreement”) with Arctic Vision (Hong Kong) Limited (“Arctic Vision”). Pursuant to the License Agreement, the Company granted to Arctic Vision the exclusive right to research, develop, manufacture and commercialize certain products (the “Licensed Products”) in Greater China (mainland China, Hong Kong, Macao and Taiwan) and South Korea (the “Territory”). The Licensed Products include those using the Optejet Dispenser Base with (i) atropine sulfate as its sole active ingredient to treat myopia in humans and (ii) pilocarpine as its sole active ingredient to treat presbyopia in humans.

Within three business days of the effective date of the License Agreement, Arctic Vision must pay the Company an upfront payment of \$4.0 million. Arctic Vision also must pay the Company up to an aggregate of approximately \$41.75 million in milestone payments and development costs, depending on the achievement of various development and regulatory milestones and subject to the satisfaction of certain other conditions. Arctic Vision must pay the Company for each unit of a Licensed Product supplied by the Company at a set price or, for Licensed Products not supplied by the Company, under the terms of the License Agreement, Arctic Vision must pay the Company a mid-single digit percentage royalty on net sales of Licensed Products, subject to the satisfaction of certain other conditions and certain adjustments in the event of generic entry, patent expiration, introduction of a competitive combination product, or the payment of third party royalties.

Arctic Vision may terminate the License Agreement, with respect to any Licensed Product or country in its territory, at any time for convenience upon 90 days’ written notice. Both parties have the right to terminate the License Agreement in the event of (i) an uncured material breach after a 90-day period (or a 30-day period in the case of a failure to pay) or (ii) insolvency.

Eyenovia will pay a mid-double digit percentage of any payments, royalties, or net proceeds from the License Agreement or from products not supplied to Arctic Vision by the Company to Senju Pharmaceutical Co., Ltd. (“Senju”) pursuant to the April 8, 2020 amendment to the Exclusive License Agreement, dated March 8, 2015, between the Company and Senju (as amended, the “Senju License Agreement”), by which Eyenovia reacquired rights to such products in Greater China and South Korea from Senju. On August 10, 2020, in connection with the Company’s entry into the License Agreement with Arctic Vision, the Company and Senju entered into a Letter Agreement (the “Senju Letter Agreement”) which clarifies certain terms of the Senju License Agreement to permit the Company to enter into a definitive agreement with a third party to research, develop, manufacture and commercialize the Licensed Products in the Territory.

The foregoing description of the License Agreement and Senju Letter Agreement is qualified in its entirety by reference to the License Agreement and Senju Letter Agreement, respectively, copies of which will be filed with the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2020.

Item 8.01. Other Events.

On August 11, 2020, the Company issued a press release regarding the matters discussed in this Current Report on Form 8-K. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	<u>Press release dated August 11, 2020.</u>

SIGNATURE

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 11, 2020

By: /s/ John Gandolfo
Name: John Gandolfo
Title: Chief Financial Officer



Eyenovia and Arctic Vision Announce Exclusive Collaboration and License Agreement to Develop and Commercialize MicroPine and MicroLine in Greater China and South Korea

Eyenovia Eligible to Receive up to a Total of \$45.75 million in Upfront Payments and Development and Commercialization Milestones and Development Costs

Arctic Vision to Lead Expansion of Novel Approach to Treating Myopia and Presbyopia in Greater China and South Korea

New York, NY and Shanghai, China – August 11, 2020 – Eyenovia, Inc. (NASDAQ: EYEN), a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAP™) therapeutics and Arctic Vision, a clinical stage biotech company focused on developing and commercializing innovative ophthalmology therapies in China and Asia, today announced that they have entered into an exclusive license agreement for Arctic Vision to develop and commercialize MicroPine for the treatment progressive myopia and MicroLine for the treatment of presbyopia in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea.

Under the terms of the agreement, Eyenovia may receive up to a total of \$45.75 million in upfront payments as well as additional payments, based on various development and regulatory milestones, including the initiation of clinical research and approvals in Greater China and South Korea, and development costs. In addition, Arctic Vision will purchase its supply of MicroPine and MicroLine from Eyenovia or, for such products not supplied by Eyenovia, pay Eyenovia a mid-single digit percentage royalty on net sales of such products, subject to certain adjustments. Eyenovia will pay a mid-double digit percentage of such payments, royalties, or net proceeds of such supply to its Asian licensee pursuant to the arrangement by which Eyenovia reacquired rights to such products in Greater China and South Korea from the original licensee.

“This licensing agreement with Arctic Vision grows our commercial reach to address some of the largest progressive myopia markets in the world,” commented Dr. Sean Ianchulev, Eyenovia’s Chief Executive Officer and Chief Medical Officer. “With the continued validation of our therapeutic approach, the agreement also provides non-dilutive capital to further support our planned launch of MicroStat in the United States next year, as well as the ongoing development of our late stage ophthalmology pipeline including MicroPine for progressive myopia and MicroLine for improvement in near vision.”

Eddy (Hoi Ti) Wu, Ph.D., Founder and CEO, Arctic Vision added, “Eyenovia is a leader in the field of novel microdosing technology to treat myopia and presbyopia and we are committed to accelerating the development of MicroPine and MicroLine in Greater China and South Korea. In Asia, it is estimated that up to 50% of children in some regions are myopic, and the figure is increasing. On the other end of the spectrum, many people over the age of 40 are gradually suffering from age related presbyopia, which is currently corrected exclusively with medical devices or surgery-based modalities. We believe MicroPine and MicroLine have the potential to address the needs unmet by conventional eye drops and can play an important role in growing Arctic Vision’s innovative pipeline. Through this new partnership, we believe we can lead the Chinese ophthalmology market into the future.”

About MicroPine for Progressive Myopia

MicroPine (atropine ophthalmic solution) is for progressive myopia, a back-of-the-eye condition commonly known as nearsightedness. Progressive myopia is estimated to affect close to 5 million children in the United States who suffer from uncontrolled axial elongation of the sclera leading to increasing levels of myopia and in some cases major pathologic changes such as retinal atrophy, macular staphylomas, retinal detachment and visual impairment. MicroPine has been developed for comfort and ease-of-use in children. Microdose administration of MicroPine is anticipated to result in low systemic and ocular drug exposure. A recent therapeutic evidence assessment and review by the American Academy of Ophthalmology indicates Level 1 (highest) evidence of efficacy for the role of low dose atropine for progressive myopia (Ophthalmology 2017;124:1857-1866; Ophthalmology 2016; 123(2):391-399).

Feasibility Dose-finding Atropine Studies: ATOM 1; ATOM 2; LAMP (Independent Collaborative Group Trials)

About MicroLine for Presbyopia

MicroLine is a pharmacologic treatment for presbyopia. Presbyopia is the non-preventable, age related hardening of the lens, which causes a gradual loss of the eye's ability to focus on nearby objects and is estimated to affect nearly 113 million Americans. Current treatment options are typically device-based, such as reading glasses and contact lenses. Pilocarpine ophthalmic solution is known to constrict the pupil and improve near-distance vision by creating an extended depth of focus through its small aperture effect. Eyenovia believes that its administration of pilocarpine using the company's high precision microdosing technology could provide a meaningful improvement in near vision while enhancing tolerability and usability.

About Optejet® and MicroRx Ocular Therapeutics

Eyenovia's Optejet microdose formulation and delivery platform for ocular therapeutics uses high-precision piezo-print technology to deliver 6-8 μ L of drug, consistent with the capacity of the tear film of the eye. We believe the volume of ophthalmic solution administered with the Optejet is less than 75% 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% with conventional eyedroppers. Additionally, its smart electronics and mobile e-health technology are designed to track and enhance patient compliance.

About Eyenovia

Eyenovia, Inc. (NASDAQ: EYEN) is a clinical stage ophthalmic biopharmaceutical company developing a pipeline of microdose array print (MAPTM) therapeutics. Eyenovia's pipeline is currently focused on the late-stage development of microdosed medications for presbyopia, myopia progression and mydriasis. For more information, please visit www.eyenovia.com.

About Arctic Vision

Arctic Vision is a China-based clinical stage specialty ophthalmology company with a leading portfolio of breakthrough technologies. The company's vision is to address ophthalmology's unmet needs through innovative therapies in China, Asia and globally. Arctic Vision is established by top-tier life sciences investors, and led by an elite team of ophthalmic industry veterans with substantial and compelling China and global experiences in R&D and commercialization of eye care products. For more information, please visit www.arcticvision.com.

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 in the United States for our product candidates. 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 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 SEC. In addition, such statements could be affected by risks and uncertainties related to, among other things: our ability to timely develop, implement and maintain manufacturing, commercialization and marketing capabilities and strategies for our product candidates; our estimates regarding the potential market opportunity for our product candidates; the potential advantages of our product candidates; the rate and degree of market acceptance and clinical utility of our product candidates; impacts of and uncertainty related to COVID-19; fluctuations in our financial results, particularly given market conditions and the potential economic impact of COVID-19; our need to raise additional money to fund our operations for at least the next 12 months as a going concern; the potential impacts of COVID-19 on our supply chain; 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 and our ability to submit applications for, obtain and maintain regulatory approvals for our product candidates; the potential success of our reprioritized pipeline; any cost savings related to our reprioritized pipeline; our ability to attract and retain key personnel; 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, we do not undertake any obligation to update any forward-looking statements.

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