

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) April 8, 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, Suite 2400, New York, New York 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 April 8, 2020, Eyenovia, Inc. (the “Company”) entered into an amendment (the “License Amendment”) to the Exclusive License Agreement, dated March 18, 2015, by and between the Company and Senju Pharmaceutical Co., Ltd. (“Senju Pharmaceutical”). Pursuant to the License Amendment, the Company can license to any third party the right to research, develop, commercialize, manufacture or use certain products (the “Licensed Products”) previously licensed to Senju Pharmaceutical in China (including Hong Kong, Macao, and Taiwan) and South Korea (the “Territory”) if such a license is executed by the Company by April 8, 2021. The Licensed Products include those using piezo-print technology in a microdose dispenser 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.

Pursuant to the License Amendment, the Company must pay Senju Pharmaceutical (a) close to a mid-double digit percentage of revenue on any lump-sum payments the Company receives from the third party, revenue (net of costs) obtained by the Company from contract research and/or development of the Licensed Product in the Territory, and revenue (net of costs) obtained by the Company from contract manufacture for the device of the Licensed Product in the Territory, the aggregate of which must be at least a high seven figure dollar amount minimum payment to Senju Pharmaceutical; and (b) a lower-double digit percentage of any sales royalty revenue the Company receives from the third party. Unless a third-party license is executed by the Company prior to April 8, 2021 (in which case, subject to early termination as provided below, the License Amendment shall remain in effect for the duration of such license), the License Amendment terminates on April 8, 2021, but may be terminated earlier by Senju Pharmaceutical upon the Company’s material breach of the License Amendment, subject to a 60-day cure period.

The foregoing description of the License Amendment is qualified in its entirety by reference to License Agreement, a copy of which will be filed with the Company’s Quarterly Report on Form 10-Q for the period ending June 30, 2020.

Item 8.01. Other Information.

The Company previously provided anticipated milestones for its product candidates, including filing an NDA for MicroStat (mydriasis) in 2020, completing enrollment of its MicroPine (progressive myopia) Phase III CHAPERONE study in 2020, and initiating and completing its MicroLine (presbyopia) Phase III VISION trials in 2020. The Company currently remains on track to file an NDA for MicroStat in 2020, although the novel coronavirus, or COVID-19, pandemic, could change that. Also, due to that pandemic, the Company is experiencing delays in trial enrollment and initiation as a result of reduced clinical trial activities and operations at investigator sites such that it is unable to advance its CHAPERONE and VISION trials in the previously anticipated timeframes. The Company continues to assess the impact of COVID-19 on its business.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward looking statements within the meaning of applicable U.S. securities law. 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 our future activities or other future events or conditions. 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: impacts of and uncertainty related to COVID-19; risks of our clinical trials, including, but not limited to, the costs, design, initiation and enrollment (which could continue to be adversely impacted by the coronavirus pandemic 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; fluctuations in our financial results and stock price, particularly given market conditions and the economic impact of COVID-19, including on our ability 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; our ability to timely develop and implement anticipated manufacturing, commercialization and marketing capabilities and strategies for existing product candidates. 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.

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: April 13, 2020

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