

**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): **January 25, 2024**

OCULAR THERAPEUTIX, INC.

(Exact Name of Company as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36554
(Commission
File Number)

20-5560161
(IRS Employer
Identification No.)

**24 Crosby Drive
Bedford, MA 01730**
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: **(781) 357-4000**

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 per share	OCUL	The Nasdaq Global 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 8.01. Other Events.

On January 25, 2024, Ocular Therapeutix, Inc. (the “Company”) announced that the U.S. Food and Drug Administration (the “FDA”) had agreed to a Special Protocol Assessment (“SPA”) Agreement Modification for the Company’s pivotal Phase 3 clinical trial (the “SOL trial”) evaluating AXPAXLI™ (axitinib intravitreal implant) for the treatment of wet age-related macular degeneration (“wet AMD”).

The SPA Agreement Modification enables the SOL trial to include treatment naïve wet AMD subjects with visual acuity of approximately 20/80 or better at the initial screening visit. After two aflibercept injections in the screening period, eligible participants would need to gain at least 10 Early Treatment of Diabetic Retinopathy Study (ETDRS) letters from the initial screening visit to Day 1 or achieve a visual acuity of approximately 20/20 or better at Day 1, in addition to satisfying other criteria, to qualify for enrollment in the SOL trial. The SPA Agreement Modification also allows the SOL trial to evaluate a single optimized implant of AXPAXLI with a drug load of 450 µg of a more soluble form of axitinib. This optimized configuration is expected to provide for a slightly increased daily release of the drug and is designed to improve synchronization of axitinib drug depletion with hydrogel bioresorption.

Cautionary Note on Forward Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans, and prospects for the Company, including the development and regulatory status of the Company’s product candidates, including the timing, design, and enrollment of the Company’s pivotal trials of AXPAXLI (also called OTX-TKI) for the treatment of wet AMD; the Company’s plans to advance the development of AXPAXLI; and other statements containing the words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “goal,” “may,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company’s preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the timing and costs involved in commercializing DEXTENZA or any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of DEXTENZA or any product or product candidate that receives regulatory approval; the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA; the initiation, design, timing, conduct and outcomes of clinical trials, including the SOL trial; the risk that the FDA will not agree with the Company’s interpretation of the written agreement under the SPA; the risk that even though the FDA has agreed with the overall design of the SOL trial, the FDA may not agree that the data generated by the SOL trial supports potential marketing approval; uncertainty as to whether the data from earlier clinical trials will be predictive of the data of later clinical trials, particularly later clinical trials that have a different design or utilize a different formulation than the earlier trials; availability of data from clinical trials and expectations for regulatory submissions and approvals; the Company’s scientific approach and general development progress; uncertainties inherent in estimating the Company’s cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; Company’s existing indebtedness and the ability of the Company’s creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; the Company’s ability to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all; and other factors discussed in the “Risk Factors” section contained in the Company’s quarterly and annual reports on file with the Securities and Exchange Commission. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company’s views as of the date of this Current Report on Form 8-K. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the Company’s views as of any date subsequent to the date of this Current Report on Form 8-K.

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.

OCULAR THERAPEUTIX, INC.

Date: January 25, 2024

By: /s/ Donald Notman

Donald Notman
Chief Financial Officer
