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): **September 12, 2023**

OCULAR THERAPEUTIX, INC.
(Exact Name of Company as Specified in Charter)

Delaware	**001-36554**	**20-5560161**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 September 12, 2023, Ocular Therapeutix, Inc. (the "Company") submitted a request for a Special Protocol Assessment (the "SPA") to the U.S. Food and Drug Administration (the "FDA") to determine whether the protocol for the first of the Company's two planned OTX-TKI pivotal trials in wet age-related macular degeneration ("wet AMD") adequately addresses scientific and regulatory requirements for a clinical trial that could support marketing approval. The Company currently expects that, subject to FDA comments to the protocol under the SPA, this trial will be a prospective, multi-center, randomized, parallel-group trial run primarily at U.S. sites. The proposed protocol for the trial contemplates a superiority trial comparing a single implant of OTX-TKI to a single injection of aflibercept and assessing the safety and efficacy of OTX-TKI in subjects with wet AMD by measuring best corrected visual acuity and central subfield thickness. The Company plans to enroll approximately 300 evaluable wet AMD subjects who are treatment naïve in the study eye in the clinical trial. The Company designed this trial based on extensive discussions with key opinion leaders, and the Company believes its proposed clinical trial protocol is consistent with previous discussions with the FDA and the current draft guidelines for the development of products for the treatment of wet AMD as promulgated by the FDA.

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, such as the Company's development of and the timing of planned pivotal clinical trials for OTX-TKI for the treatment of wet AMD; the Company's plans to advance the development of OTX-TKI; 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, uncertainties as to the initiation, timing, conduct and outcomes of clinical trials; the risk that the FDA will not agree with the design of the planned pivotal trial under the SPA; the risk that even if the FDA agrees with the design of the trial under the SPA, the FDA will not agree that the data generated by the trial could support 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 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; the sufficiency of cash resources; 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: September 13, 2023

By: /s/ Donald Notman
Donald Notman
Chief Financial Officer