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): **October 3, 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 October 3, 2023, Ocular Therapeutix, Inc. (the "Company") announced the initiation of its first pivotal clinical trial to evaluate OTX-TKI, the Company's axitinib intravitreal implant, for the treatment of wet age-related macular degeneration ("wet AMD") with the activation of the Company's first clinical trial site in the United States. The Company expects to enroll its first subject in the clinical trial before year-end.

As previously disclosed, the Company has requested a Special Protocol Assessment (the "SPA") from the U.S. Food and Drug Administration (the "FDA") regarding the design of its first pivotal clinical trial of OTX-TKI, which is designed as a superiority trial that will enroll approximately 300 evaluable wet AMD subjects who are treatment naïve in the study eye. The trial is designed to be a multi-center, parallel-group trial that will be run primarily at U.S. sites with subjects randomized to one injection of aflibercept or one implant of OTX-TKI. The safety and efficacy of OTX-TKI will be assessed by measuring best corrected visual acuity and central subfield thickness. While the Company has received this institutional review board approval, the Company does not intend to enroll a subject before the SPA feedback is received from 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, including the timing and design of the Company's pivotal trials of OTX-TKI for the treatment of wet AMD; the Company's plans to advance the development of OTX-TKI; the Company's cash runway and sufficiency of the Company's cash resources; 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, including the conduct of post-approval studies; 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 first pivotal trial of OTX-TKI for the treatment of wet AMD; uncertainties as to the response from the FDA regarding the SPA submission for OTX-TKI, including the risk that the FDA will not agree with the design of the first pivotal trial under the SPA; the risk that even if the FDA agrees with the design of the first pivotal 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; 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: October 3, 2023

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