
**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): **December 5, 2025**

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.)

15 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.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements of Ocular Therapeutix, Inc. (the “Company”) regarding future expectations, plans, and prospects for the Company; statements regarding the development and regulatory status of the Company’s product candidate AXPAXLI (also known as OTX-TKI), including the Company’s intentions, assuming the data are positive, to submit a new drug application for AXPAXLI based on year 1 data from the Company’s SOL-1 Phase 3 clinical trial of AXPAXLI for the treatment of wet age-related macular degeneration; statements regarding the timing of the availability of data from the SOL-1 trial; and other statements containing the words “anticipate”, “believe”, “estimate”, “expect”, “intend”, “designed”, “goal”, “may”, “might”, “plan”, “predict”, “project”, “target”, “potential”, “will”, “would”, “could”, “should”, “continue”, and similar expressions, all of which 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 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 regarding the initiation, design, timing, conduct and outcomes of ongoing and planned clinical trials, including the Company’s SOL-1 trial, SOL-R trial, planned SOL-X trial, HELIOS-2 trial, and HELIOS-3 trial; the risk that the U.S. Food and Drug Administration (“FDA”) will not agree with the Company’s interpretation of the written agreements under the Special Protocol Assessments for AXPAXLI, including for the SOL-1 trial; uncertainty as to whether the FDA will accept a new drug application for AXPAXLI on the basis of a single pivotal clinical trial; the risk that even though the FDA has agreed with the overall design of the SOL-1 trial, the FDA may not find that the data generated by the trial and submitted by the Company, even if positive, is sufficient to demonstrate the safety and efficacy of AXPAXLI to the degree necessary to support marketing approval for wet age-related macular degeneration; the risk that the FDA might not agree to the Company’s design, protocol, and statistical analysis plan of any of its clinical trials for which the Company has not obtained a Special Protocol Assessment; the risk that the Company and the FDA may not agree on the registrational pathway for any of its product candidates, including AXPAXLI; uncertainty as to whether the Company will be able to timely satisfy the FDA’s other requirements for regulatory approval of AXPAXLI, even if the Company can satisfy the FDA’s clinical requirements to demonstrate safety and efficacy; uncertainty as to what restrictions, if any, may be imposed on the label for AXPAXLI, if approved, pending the receipt of additional clinical data or otherwise; 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, whether preliminary or interim data from a clinical trial (including masked safety or masked rescue data from the Company’s SOL-1 trial or SOL-R trial) will be predictive of final data from such trial, or whether data from a clinical trial assessing a product candidate for one indication will be predictive of results in other indications; uncertainty as to the Company’s ability to retain regulatory approval of any product or product candidate that receives regulatory approval; uncertainty as to whether data from the Company’s SOL-X trial will demonstrate clinically meaningful, long-term benefits; uncertainties regarding the potential commercial advantages and/or position of the Company’s product candidates; 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; the 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; 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 may 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.

Item 8.01 Other Events.

The U.S. Food and Drug Administration (“FDA”) has historically required two adequate and well-controlled clinical trials to demonstrate the safety and efficacy of ophthalmic product candidates, in particular for larger indications such as wet age-related macular degeneration (“wet AMD”). Following recent public statements from FDA leadership, as well as the Company’s interactions with the FDA’s Division of Ophthalmology subsequent to these statements, and assuming the data are positive, the Company now intends to submit a new drug application for its product candidate AXPAXLI (also known as OTX-TKI) for the treatment of wet AMD based on year 1 data from the Company’s SOL-1 Phase 3 clinical trial, without waiting for additional clinical data from SOL-1, SOL-R or other clinical trials. The Company plans to engage with the FDA with respect to the regulatory pathway for AXPALI and will provide additional updates. The Company expects to report top-line data from year 1 of the SOL-1 clinical trial during the first quarter of 2026.

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: December 5, 2025

By: /s/ Donald Notman

Donald Notman

Chief Financial Officer and Chief Operating Officer
