

**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): **July 6, 2020**

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 (see General Instruction A.2. below):

- 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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.

OTX-TKI Clinical Trial Update

On May 14, 2020, Ocular Therapeutix, Inc. (the “Company”) disclosed the receipt of interim data regarding its ongoing Phase 1 clinical trial of OTX-TKI, a hydrogel implant incorporating axitinib, a small molecule tyrosine kinase inhibitor, delivered by intravitreal injection for the potential treatment of wet age-related macular degeneration (AMD) and other retinal diseases. The Phase 1 clinical trial is a multi-center, open-label, dose-escalation study in Australia designed to evaluate the safety, biological activity, durability and tolerability of OTX-TKI. At the time of the prior disclosure, two cohorts of six subjects each had been enrolled, a lower dose cohort of 200 µg and a higher dose cohort of 400 µg. The Company also amended the trial protocol to provide for a third cohort of subjects to receive a higher dose of 600 µg.

The Company previously disclosed that, as of May 13, 2020, the first two patients in the second (400 µg) cohort had shown a clinically meaningful reduction in intraretinal and/or subretinal fluid out to six months with a single implant. The Company has now received further information from the clinical trial site in Australia where these two patients are being treated. Specifically, the clinical trial site has reported to the Company that one of these two patients showing a clinically meaningful reduction in intraretinal and/or subretinal fluid was treated with anti-VEGF medication at a site visit at month 4.5 (in mid-March 2020) and at month 6 (in early May 2020). The patient who was treated with anti-VEGF medication at the visits at month 4.5 and month 6 exhibited a clinically meaningful reduction in intraretinal fluid out to 4.5 months with a single OTX-TKI implant before treatment with anti-VEGF medication. However, because of the use of anti-VEGF medication beginning with the 4.5 month visit, the Company is not able to appropriately evaluate durability of treatment with OTX-TKI in this patient beyond 4.5 months.

The clinical trial protocol and/or guidelines for completing electronic case report forms for the trial provide that (1) anti-VEGF medication may be administered at the investigator’s discretion based on consideration of predefined, specified criteria relating to a loss of visual acuity or increase in retinal fluid, (2) the clinical trial site should notify a medical monitor within three days of treatment with anti-VEGF medication, (3) administration of anti-VEGF medication should be entered into the clinical trial database in a timely manner and (4) a follow-up visit should occur within seven to ten days after administration of anti-VEGF medication to determine the effect of treatment. However, based on information made available to the Company, none of these elements of the clinical trial protocol or electronic case report form guidelines were followed at the clinical trial site with respect to treatment of this particular patient with anti-VEGF medication after insertion of the OTX-TKI implant. In particular, the patient was treated with anti-VEGF medication despite not meeting the predefined criteria relating to loss of visual acuity or increase in retinal fluid and the administration of anti-VEGF medication at the month 4.5 visit and at the month 6 visit was not entered into the clinical trial database until after a subsequent visit at month 7.5 in mid-June 2020. As a result, this information was not available to or known by the Company in connection with its prior disclosures. It is the Company’s understanding that at the time of and following the 4.5 month visit in mid-March 2020, the clinical and research operations of the trial site were being adversely impacted by the effects of the COVID-19 pandemic.

This Phase 1 trial is continuing, and the Company intends to present more complete data for the first two cohorts when available at a future medical conference. As previously planned, the third 600 µg cohort of the trial was initiated, with the first patient in this cohort being enrolled. The Company also plans to file an application by the end of 2020 to initiate clinical development of OTX-TKI in the United States for patients with wet age-related macular degeneration, diabetic macular edema (DME) and retinal vein occlusion (RVO). Based on trial data currently available to the Company, OTX-TKI continues to be generally well tolerated and has been observed to have a favorable safety profile, with no ocular serious adverse events to date.

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 commercialization of DEXTENZA[®], ReSure[®] Sealant, or any of the Company's product candidates; the commercial launch of, and effectiveness of reimbursement codes for, DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of DEXTENZA for additional indications including allergic conjunctivitis, OTX-CSI for the treatment of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-IVT as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the ongoing development of the Company's extended-delivery hydrogel depot technology; the potential utility of any of the Company's product candidates; the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, including any potential future payments thereunder; the expected impact of the COVID-19 pandemic on the Company and its operations; the 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 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, ReSure Sealant or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of DEXTENZA, ReSure Sealant or any product candidate that receives regulatory approval, the ability to maintain reimbursement codes for DEXTENZA, the initiation, timing and conduct of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the Company's ability to generate its projected net product revenue on the timeline expected, if at all, the sufficiency of cash resources, the Company's existing indebtedness, the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default, the outcome of the Company's ongoing legal proceedings, the severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, the need for additional financing or other actions 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 report. 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 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: July 6, 2020

By: /s/ Donald Notman

Donald Notman
Chief Financial Officer
