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): **May 20, 2019**

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.)

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 (*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:

Title of each class	Trading Symbol(s)	Name of exchange on which registered
Common Stock, $0.0001 par value per share	**OCUL**	**The Nasdaq Global Select 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 May 20, 2019, Ocular Therapeutix, Inc. (the "Company") announced topline results from the first pivotal Phase 3 clinical trial of OTX-TP, an intracanalicular insert that delivers a preservative-free formulation of the drug travoprost for the reduction of intraocular pressure ("IOP") in patients with primary open-angle glaucoma or ocular hypertension. OTX-TP is designed to lower IOP for up to 90 days and to address the poor adherence associated with chronic, daily eye drop regimens, the current standard of care.

The Phase 3 randomized, double blind, placebo-controlled clinical trial was conducted across more than 50 sites and enrolled 554 subjects with open-angle glaucoma or ocular hypertension in the full analysis set ("FAS") population. The trial's primary efficacy endpoint was to demonstrate a statistically superior mean reduction of IOP from baseline for OTX-TP treated subjects compared with placebo insert treated subjects at nine different time points, three diurnal time points (8 a.m., 10 a.m., and 4 p.m.) at each of 2, 6, and 12 weeks following insertion. Topline results show that the trial did not achieve its primary endpoint of statistically significant superiority in mean reduction of IOP compared with placebo at all nine time points. OTX-TP treated subjects did have a greater reduction in IOP from baseline relative to placebo insert at all nine time points, and these differences were statistically significant (p value < 0.05) for eight of the nine time points (see Table 1 below). The reductions from baseline for OTX-TP treated subjects in this trial ranged from 3.27-5.72 millimeters of mercury (mm Hg) across the nine time points with higher levels of intraocular pressure reduction seen at the earlier time points in this trial.

Table 1: Reduction in Intraocular Pressure (Change from Baseline)

Diurnal Time Points	2 Week mm Hg			6 Week mm Hg			12 Week mm Hg		
	OTX-TP	Vehicle	p-value	OTX-TP	Vehicle	p-value	OTX-TP	Vehicle	p-value
8:00 AM	-5.72	-3.88	<.0001	-4.81	-4.01	0.0181	-3.91	-3.52	0.2521
10:00 AM	-4.92	-3.16	<.0001	-4.03	-3.23	0.0077	-3.34	-2.63	0.0234
4:00 PM	-5.22	-3.18	<.0001	-4.16	-3.14	0.0004	-3.27	-2.60	0.0310

FAS Population (OTX-TP=343 subjects, Vehicle=211 subjects) ***Least Squares (LS) Means***

OTX-TP was generally well tolerated and no ocular serious adverse events were observed. The most common ocular adverse events seen in the study eye were dacryocanaliculitis (approximately 7% in OTX-TP vs. 3% in placebo) and lacrimal structure disorder (approximately 6% in OTX-TP vs. 4% in placebo).

The Company plans to continue its review of the topline data and expects to discuss the data with the U.S. Food and Drug Administration before it determines the next steps in its clinical development plans for OTX-TP.

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, including the anticipated commercial launch of, and receipt of reimbursement codes for, DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's regulatory submissions for and the timing and conduct of, or implications of results from, clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and the prospects for the approvability of, and discussions with regulatory authorities regarding, DEXTENZA for post-surgical ocular inflammation or any other indications, OTX-TP for the treatment of primary open-angle glaucoma and ocular hypertension, 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 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, those related to 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 obtain 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 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 and 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 filing. 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 filing.

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: May 20, 2019

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