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 3, 2018**

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))

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 December 3, 2018, Ocular Therapeutix, Inc. (the "Company") announced the U.S. Food and Drug Administration ("FDA") has approved its New Drug Application ("NDA") for DEXTENZA®. DEXTENZA (dexamethasone ophthalmic insert) 0.4mg is for intracanalicular use for the treatment of ocular pain following ophthalmic surgery.

DEXTENZA® Label

DEXTENZA (dexamethasone ophthalmic insert) is a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery.

DEXTENZA is a preservative-free ophthalmic insert that is inserted in the lower lacrimal punctum and into the canaliculus. A single DEXTENZA releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion.

DEXTENZA is resorbable and does not require removal. Saline irrigation or manual expression can be performed to remove the insert if necessary. DEXTENZA is intended for single-use only.

DEXTENZA was studied in two randomized, multicenter, double-masked, parallel group, vehicle-controlled Phase 3 clinical trials, with patients receiving DEXTENZA or its vehicle immediately upon completion of cataract surgery. In Study 1, 80% of DEXTENZA-treated patients (n=164) were pain-free at Day 8 compared to 43% of vehicle-treated patients (n=83) ($p<0.0001$). In Study 2, 77% of DEXTENZA-treated patients (n=161) were pain-free at Day 8 compared to 59% of vehicle-treated patients (n=80) ($p=0.025$).

Safety was assessed from the two Phase 3 clinical trials and a Phase 2 clinical trial. Overall, 351 subjects were exposed to DEXTENZA. The most common ocular adverse reactions in subjects treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (9%), increased intraocular pressure (5%), reduced visual acuity (2%), eye pain (1%), cystoid macular edema (1%), corneal edema (1%), and conjunctival hyperemia (1%). The most common non-ocular adverse event was headache (1%).

DEXTENZA® Important Safety Information

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella; mycobacterial infections; fungal diseases of the eye; and dacryocystitis.

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma and intraocular pressure should be monitored during treatment.

Corticosteroids may suppress the host response and thus increase the hazard for secondary ocular infections. In acute purulent conditions, steroids may mask infection and enhance existing infection.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).

Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate.

Use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

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 ReSure Sealant, DEXTENZA® or any of the Company's product candidates, 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 approvability of 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 Company's post-approval studies of ReSure® Sealant and the Company's expectations regarding its appeal of the warning letter regarding ReSure Sealant; 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 ReSure Sealant, DEXTENZA or any product candidate that receives regulatory approval, including the conduct of post-approval studies, the ability to retain regulatory approval of ReSure Sealant, DEXTENZA or any product candidate that receives regulatory approval, 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 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 press release represent the Company's views as of the date of this release. 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. 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 release.

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 3, 2018

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