

**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): **September 24, 2019**

**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 (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>
<b>Common Stock, \$0.0001 par value per share</b>	<b>OCUL</b>	<b>The Nasdaq Global Select Market</b>

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        x

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.        x

**Item 8.01. Other Events.**

On September 24, 2019, Ocular Therapeutix, Inc. (the “Company”) announced that it had dosed the first patients in its Phase 3 clinical trial of DEXTENZA® for the treatment of symptoms of allergic conjunctivitis (“AC”).

The Phase 3 clinical trial is a U.S.-based, multi-center, 1:1 randomized, double-masked, placebo-controlled trial that intends to enroll approximately 80 subjects, testing the safety and efficacy of DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg versus a placebo vehicle punctum plug using the Ophthalmic Research Associates’ modified Conjunctival Allergen Challenge (Ora-Cac®) Model for the treatment of ocular itching associated with AC. The trial is designed to assess the effect of DEXTENZA compared with a placebo on allergic reactions using a series of successive allergen challenges over a 30-day period. The primary efficacy endpoint being evaluated in the study is ocular itching following insertion of DEXTENZA at multiple time points during the 30-day period. DEXTENZA is administered by a physician as a bioresorbable intracanalicular insert and designed for drug release to the ocular surface for up to 30 days.

This trial represents the third Phase 3 clinical trial in AC conducted by the Company and, if successful, the Company plans to submit a supplemental New Drug Application to the U.S. Food and Drug Administration (“FDA”) for ocular itching associated with AC. Topline data from this trial are anticipated in the first half of 2020.

**About DEXTENZA® (dexamethasone ophthalmic insert) 0.4mg**

DEXTENZA is an FDA-approved corticosteroid indicated for the treatment of ocular inflammation and pain following ophthalmic surgery. DEXTENZA is inserted into the lower lacrimal punctum into the canaliculus by the physician following ophthalmic surgery. A single DEXTENZA releases a 0.4mg dose of dexamethasone for up to 30 days following insertion. DEXTENZA is preservative free, resorbable and does not require removal. Saline irrigation or manual expression can be performed to remove the insert, if necessary.

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections. 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. Intraocular pressure should be monitored during the course of the treatment. Corticosteroids may suppress the host response to, and increase the hazard for and severity of, secondary bacterial, viral, or fungal infections. The use of steroids after cataract surgery may delay wound healing and increase the incidence of bleb formation.

The most commonly reported ocular adverse reactions that occurred in patients treated with DEXTENZA were anterior chamber inflammation including iritis and iridocyclitis (10%) and elevations in intraocular pressure (6%). The most common non-ocular adverse reaction was headache (1%).

**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: September 24, 2019

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