

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 14, 2016

**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.)

34 Crosby Drive, Suite 105  
Bedford, MA 01730  
(Address of Principal Executive Offices) (Zip Code)

Company's telephone number, including area code: (781) 357-4000

(Former Name or Former Address, if Changed Since Last Report)

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))

## Item 8.01 Other Events.

As previously disclosed, in November 2016, Ocular Therapeutix, Inc. (the “Company”) received notice from the New England District Office of the U.S. Food and Drug Administration (the “FDA”) accepting that the Company’s responses satisfactorily addressed the remaining corrective actions in a Form 483 originally issued by the FDA in February 2016 relating to deficiencies in the Company’s manufacturing process and controls for its product candidate DEXTENZA.

Following a meeting with the FDA in October 2016 and receipt of the notice from the FDA’s New England District Office in November 2016 closing out the remaining Form 483 issues, the Company has continued to prepare for a resubmission to the New Drug Application (“NDA”) for DEXTENZA for the treatment of post-surgical ocular pain that the Company previously filed in September 2015. The Company received a Complete Response Letter from the FDA regarding the NDA for DEXTENZA in July 2016. The Company’s plan is to include manufacturing records from recently completed commercial batches of DEXTENZA in the NDA resubmission. The NDA resubmission is expected early in the first quarter of 2017 following the completion of testing of these commercial batches.

Adequate resolution of the Form 483 manufacturing deficiencies with the FDA’s New England District Office is a prerequisite to the approval of the NDA for DEXTENZA, although the final decision as to the adequacy of the Company’s manufacturing processes is made by the FDA’s Center for Drug Evaluation and Research, with input from the Office of Process and Facilities, as part of the NDA review process. The Company anticipates that the FDA will classify the resubmission of the NDA and determine whether a re-inspection of the Company’s manufacturing facility is needed within 30 days of the NDA resubmission date. The Company expects that, if the FDA makes a decision to conduct a re-inspection of the manufacturing facility, such a decision would result in a classification of the resubmission to the NDA as a class 2, or major review, and would take up to six months to complete. If no re-inspection is required, the Company expects the FDA to classify the NDA resubmission as a class 1, or minor review, and take up to two months to complete.

## Forward Looking Statements

Any statements in this filing about future expectations, plans and prospects for the Company, including the development and regulatory status of the Company’s product candidates, such as the Company’s expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for the treatment of post-surgical ocular inflammation and pain, including our expectations regarding the NDA filed with the FDA and the resubmission of the NDA, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of inflammatory dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company’s sustained release hydrogel depot technology, the potential utility of any of the Company’s product candidates, potential commercialization of the Company’s product candidates, the potential benefits and future operation of the collaboration with Regeneron, 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 or any product candidate that receives regulatory approval, the initiation 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 and need for additional financing or other actions and other factors discussed in the “Risk Factors” section contained in the Company’s reports on file with the Securities and Exchange Commission, including the Risk Factors filed on Form 8-K on November 30, 2016. In addition, the forward-looking statements included in this report represent the Company’s views as of the date hereof. 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 hereof.

**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 14, 2016

By: /s/ W. Bradford Smith

W. Bradford Smith

Chief Financial Officer