
**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): January 23, 2017

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))
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Item 8.01 Other Events.

On January 23, 2017, Ocular Therapeutix, Inc. (the “Company”) announced that it had resubmitted a new drug application (an “NDA”) to the U.S. Food and Drug Administration (the “FDA”) for DEXTENZA™ (dexamethasone insert) 0.4 mg for the treatment of ocular pain occurring after ophthalmic surgery. As previously disclosed, the resubmission was in response to a Complete Response Letter received from the FDA in July 2016, which referenced items pertaining to deficiencies in the Company’s manufacturing process and controls identified during a pre-NDA approval inspection of the Company’s manufacturing facility performed by the FDA New England District Office in February 2016 that were documented on FDA Form 483.

The Company’s resubmission of the NDA included a letter from the New England District Office accepting that the Company’s responses satisfactorily addressed the remaining corrective actions in the Form 483 and manufacturing records from three recently completed commercial batches of DEXTENZA. Adequate resolution of the Form 483 manufacturing deficiencies with the 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 Company’s NDA and determine whether a re-inspection of our manufacturing facility is needed within 30 days of the NDA resubmission date. The Company expects that a decision by the FDA to conduct a re-inspection of the Company’s manufacturing facility 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 needed, 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 FDA’s response to the resubmitted 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 Company’s collaboration with Regeneron Pharmaceuticals, Inc., 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: January 23, 2017

By: /s/ W. Bradford Smith

W. Bradford Smith

Chief Financial Officer