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, 2020**

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.)

24 Crosby Drive
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))

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 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.

Below are recent corporate updates for Ocular Therapeutix, Inc. (the "Company," "we," "us," or "our").

Update on DEXTENZA Unit Sales

We primarily derive our product revenues from the sale of DEXTENZA® in the United States to a network of specialty distributors, who then resell DEXTENZA to ambulatory surgical centers ("ASCs") and hospital outpatient departments ("HOPDs"). We refer to these resales from the specialty distributors to the ASCs and HOPDs as in-market unit sales.

In-market unit sales were 4,198 billable inserts for October 2020 and 4,327 billable inserts for November 2020.

Update on Ongoing OTX-TKI Phase 1 Clinical Trial

We are conducting a multi-center, open-label, dose-escalation Phase 1 clinical trial in Australia designed to evaluate the safety, biological activity, durability and tolerability of our product candidate OTX-TKI. OTX-TKI is a hydrogel implant incorporating axitinib, a small molecule tyrosine kinase inhibitor, and is designed to be delivered by intravitreal injection for the potential treatment of wet age-related macular degeneration ("wet AMD"), and other retinal diseases. Two cohorts of our Phase 1 clinical trial have been enrolled, a lower dose cohort of 200 µg with six subjects and a higher dose cohort of 400 µg with seven subjects. We are currently enrolling a third cohort of twelve subjects, split between parallel arms of six subjects each. Subjects in the first arm of the third cohort will receive a dose of 600 µg, and subjects in the second arm will receive a 400 µg dose combined with an anti-vascular endothelial growth factor ("VEGF") induction injection.

We previously announced that a patient in the second (400 µg) cohort had shown a clinically meaningful reduction in intraretinal and/or subretinal fluid, as indicated by a decrease in the central subfoveal thickness measured by optical coherence tomography, out to nine months with a single implant. That patient has now shown a clinically meaningful fluid reduction out to eleven months. Additionally, we had previously disclosed that the first patient in the third (600 µg) cohort had shown a clinically meaningful fluid reduction out to three months. That patient has now shown a clinically meaningful fluid reduction out to four-and-a-half months.

We plan to initiate a Phase 2 clinical trial in Australia in mid-2021. We also filed an exploratory IND application for the clinical evaluation of OTX-TKI in the United States in November 2020 and plan to initiate a Phase 1 clinical trial under this IND to evaluate a 600 µg dose and a novel injector in mid-2021.

Update on Ongoing OTX-TIC Phase 1 Clinical Trial

We are conducting a multi-center, open-label, dose-escalation, proof of concept Phase 1 clinical trial to evaluate the safety, biological activity, durability and tolerability of our product candidate OTX-TIC compared to topical travoprost eye drops in patients with primary open-angle glaucoma or ocular hypertension. OTX-TIC is a bioresorbable hydrogel implant incorporating travoprost that is designed to be administered by a physician as an intracameral injection with an initial target duration of drug release of four to six months. The clinical trial is comprised of four cohorts of five patients each: a low-dose cohort receiving a 15 µg dose of drug; a higher-dose cohort receiving a 26 µg dose of drug; a cohort receiving a 15 µg dose of drug through a faster-degrading implant; and a cohort receiving a different formulation of drug in a smaller implant.

Previously, we announced that we had completed enrollment of the first three cohorts but that enrollment in the final cohort, evaluating the smaller implant, had slowed due to the COVID-19 pandemic. We have now completed enrollment for this fourth cohort. We expect to provide topline data for the third and fourth cohorts in the middle of 2021 and anticipate providing an interim update at a medical conference in the first quarter of 2021. We continue to expect to commence a Phase 2 clinical trial in the middle of 2021.

Update on Planned OTX-DED Phase 2 Clinical Trial

We previously reported that we intended to file an IND application in 2020 to evaluate our product candidate OTX-DED for the short-treatment of the signs and symptoms of dry eye disease. OTX-DED incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient into a hydrogel, drug-eluting, preservative-free intracanalicular insert. While OTX-DED incorporates the same active drug as DEXTENZA, it includes a lower dose of the drug that is delivered via a smaller insert.

We have submitted a Phase 2-enabling IND application and, if our IND application is cleared, plan to initiate a Phase 2 clinical trial in the first quarter of 2021.

Cautionary Note on 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; the commercial launch of, and effectiveness of reimbursement codes for, DEXTENZA; the conduct of post-approval studies of DEXTENZA; the development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of DEXTENZA for additional indications including allergic conjunctivitis, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-CSI for the chronic treatment of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-AFS 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 size of potential markets for our product candidates; 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; projected net product revenue, unit sales and other financial and operational metrics of DEXTENZA; the expected impact of the COVID-19 pandemic on the Company and its operations; 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, 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 maintain 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 Company's ability to generate its projected net product revenue and unit sales on the timeline expected, if at all, 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, the severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, the 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 Current Report on Form 8-K. 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 Current Report on Form 8-K.

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, 2020

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