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): **October 13, 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").

Resolution of ReSure Sealant Warning Letter

On September 8, 2020, we reported that we received a close-out letter from the U.S. Food and Drug Administration (the "FDA"), dated September 2, 2020, regarding a warning letter, dated October 18, 2018, previously issued to us in connection with a post-approval study for our ReSure® Sealant product. Such warning letter was based on the observed inability to conduct a post-approval study evaluating endophthalmitis rates following ReSure use in a post-approval Device Exposure Registry study required under 21 CFR 814.82(a)(2) as a condition within the premarket approval application. Following our appeal of the warning letter and subsequent discussions with agency staff, we have come to an agreement with the FDA to conduct a retrospective study looking at sites with access to ReSure compared to those without access to ReSure using the American Academy of Ophthalmology's Iris Registry data base. If we complete the proposed retrospective study in accordance with our agreement with the FDA, we believe that the FDA will deem our obligations to conduct post-approval studies related to ReSure Sealant to have been satisfied.

Initiation of DEXTENZA Phase 3 Pediatric Clinical Trial

On September 10, 2020, we announced that we had dosed the first pediatric patients in a Phase 3 clinical trial evaluating DEXTENZA for the treatment of post-surgical ocular inflammation and pain in children following cataract surgery. The Phase 3 clinical trial is a U.S.-based, randomized, multicenter clinical trial in which we intend to enroll approximately 60 subjects. The clinical trial is designed to evaluate the safety and biological activity of DEXTENZA® compared to an active control, prednisolone acetate suspension eye drops, for the treatment of inflammation and pain following ocular surgery for pediatric cataract in children between zero and three years of age. The primary endpoint is the absence of pain at day eight post-treatment as measured by a FLACC (Face, Legs, Activity, Cry, Consolability) score of zero. This planned clinical trial is a post-approval requirement of the FDA in accordance with the Pediatric Research Equity Act of 2003, in connection with the FDA's prior approval of DEXTENZA for the treatment of inflammation and pain following ophthalmic surgery in adults.

Initiation of OTX-CSI Phase 2 Clinical Trial; Announcement of OTX-CSI Phase 1 Data

On September 29, 2020, we announced that we had dosed the first patients in a Phase 2 clinical trial designed to assess the safety, tolerability and durability and to evaluate the efficacy of OTX-CSI in the treatment of dry eye disease. The Phase 2 clinical trial is a U.S.-based, randomized, masked, multi-center trial evaluating two different formulations of OTX-CSI with vehicle insert in approximately 105 subjects who are to be followed for a period of 16 weeks. Endpoints include tear production as measured by the Schirmer test; signs of dry eye disease as measured by corneal fluorescein staining; and symptoms of dry eye disease as measured by the visual analog scale ("VAS") eye dryness severity score and the VAS dry eye frequency score. We anticipate receiving topline data from this Phase 2 clinical trial in the first half of 2022.

On October 8, 2020, we also announced that we had received topline data from our Phase 1 clinical trial evaluating OTX-CSI in the treatment of dry eye disease. The Phase 1 clinical trial is a U.S.-based, open-label, single-center trial designed to evaluate safety, tolerability and durability of OTX-CSI and to assess biological activity by measuring signs and symptoms of dry eye disease in five subjects (10 eyes) over approximately four months. All subjects completed the 16-week study period with no drop-outs. There were no serious adverse effects reported. The inserts were observed to be well-tolerated, and there were no adverse events of stinging, irritation, blurred vision or tearing reported or observed.

Tear production as measured by the Schirmer's test improved from a mean value of 4.2 mm at baseline to 8.2 mm at Week 12. One of five subjects (20%) had a greater than 10 mm increase from baseline in Schirmer's score at Week 12. Subjects saw an improvement in signs of dry eye disease as measured by corneal total fluorescein staining (a mean value of 6.7 at baseline, improved to a mean value of 2.7 at Week 12, on a scale of 0 to 15). Further, subjects saw an improvement in symptoms of dry eye disease as measured by the VAS eye dryness severity score (a mean value of 51 at baseline, improved to a mean value of 33 at Week 12, on a scale of 0 to 100) and the VAS dry eye frequency score (a mean value of 51 at baseline, improved to a mean value of 31 at Week 12, on a scale of 0 to 100). The onset of action of OTX-CSI was seen as early as two weeks for both signs and symptoms of dry eye disease and was observed to continue over the 16 week study period.

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 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-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 seven-and-one-half months with a single implant. That patient has now shown a clinically meaningful fluid reduction out to nine months. In addition, the treatment continues to be observed to have a favorable safety profile and be generally well-tolerated.

We intend to initiate a Phase 2 clinical trial for OTX-TKI in Australia in mid-2021.

Update on Intellectual Property Matters Related to our Intracanalicular Inserts

As previously reported, a third party has claimed that our intracanalicular insert product DEXTENZA infringes three of its patents relating to intracanalicular inserts. In connection with one such patent, we and such third party entered into a settlement agreement in 2019, without financial consideration, pursuant to which each party agreed to a limited covenant not to sue regarding alleged infringement by DEXTENZA. We initiated administrative proceedings through the Patent Trial and Appeals Board (the "PTAB"), with respect to the other two of such third party's patents. The United States Patent and Trademark Office (the "USPTO") decided to proceed with the administrative proceeding related to one of these two patents, while declining to do so for the other. In June 2020, the PTAB, after an *inter partes* review, determined that we had proven by a preponderance of the evidence that all claims of such patent at issue held by such third party were invalid; the third party has appealed this decision. We believe that DEXTENZA does not infringe the claims of the remaining patent and that, if and to the extent it were asserted against DEXTENZA, such patent would be subject to a claim of invalidity.

We have become aware that the USPTO has recently allowed a patent application filed by this third party related to intracanalicular inserts containing dexamethasone. If, upon issuance of this patent application as a patent, it were asserted against DEXTENZA or other of our product candidates, we believe such patent would be subject to a claim of invalidity.

Additional information regarding risks relating to our intellectual property is included in the "Risk Factors" section of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, including under the heading "Risks Relating to Our Intellectual Property—Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business."

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 treatment of episodic dry eye disease, OTX-CSI for the treatment of dry eye disease, 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-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 and 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: October 13, 2020

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