

**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): **April 13, 2020**

**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.)

**24 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>
Common Stock, \$0.0001 par value per share	OCUL	The Nasdaq Global Select 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 2.02. Results of Operations and Financial Condition.**

On April 13, 2020, Ocular Therapeutix, Inc. (the “Company”) issued a press release (the “Release”) to provide a business update and report on its response to the COVID-19 pandemic. A copy of the Release is included as Exhibit 99.1 hereto and is incorporated by reference herein.

Although the Company is currently in the process of finalizing its financial results for the quarter ended March 31, 2020, the Company disclosed in the Release that it expects to report cash and cash equivalents of approximately \$48.2 million as of March 31, 2020, and approximately \$2.6 million of total net product revenue, approximately \$2.1 million of net product revenue for DEXTENZA<sup>®</sup>, and approximately \$0.5 million of net product revenue for ReSure Sealant, in each case for the quarter ended March 31, 2020. The estimated cash and cash equivalents and net product revenue figures are based on preliminary and unaudited information and management’s estimates as of the date of this Current Report on Form 8-K and are subject to completion of the Company’s financial closing procedures. The Company’s independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the estimated cash and cash equivalents and total net product revenue figures.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, shall be deemed to be “filed” and not “furnished” under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall be deemed to be incorporated by reference in applicable filings under the Securities Act of 1933, as amended, or the Exchange Act.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits:

99.1      [Press Release of the Company, dated April 13, 2020.](#)

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**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: April 13, 2020

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

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## Ocular Therapeutix™ Provides Business Update and Response to COVID-19 Global Pandemic

BEDFORD, Mass. —(BUSINESS WIRE)—April 13, 2020—Ocular Therapeutix™, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today announced its response to the COVID-19 pandemic and related impact on Ocular Therapeutix's business operations.

“In the midst of the global COVID-19 pandemic, our first priority is for the safety and well-being of our employees, patients, clinical collaborators and customers,” said Antony Mattessich, President and Chief Executive Officer. “While we are doing everything in our power to respond appropriately to the current crisis, we are also preparing Ocular Therapeutix and our community of stakeholders to thrive in the future. The Company is well positioned despite the challenging economic conditions.

- Our clinical programs remain on track:
  - o The first two subjects in the higher-dose cohort of our OTX-TKI (axitinib intravitreal implant) Phase I clinical trial have reached the four-and-a-half-month time point and are continuing to show clinically meaningful reductions in intraretinal and/or subretinal fluid with a single implant. If the durability of OTX-TKI is confirmed in larger trials out to this time point or beyond, we believe that it would have the potential to become a new standard of treatment for wet AMD;
  - o Our Phase 3 trial of DEXTENZA® for the treatment of ocular itching associated with allergic conjunctivitis (AC) is expected to read out this quarter and, if successful, we plan to file an sNDA application for this indication;
  - o The first three cohorts of our Phase 1 program for OTX-TIC (travoprost intracameral implant) are fully enrolled and we look forward to providing updates on the results of those patients in the near future; and
  - o OTX-CSI (cyclosporine intracanalicular insert) is set to enter the clinic in the middle of 2020, continuing our development of a treatment for dry eye disease.
- On the revenue side, despite a marked slow-down in cataract and other ophthalmic surgical procedures beginning in the second week of March due to COVID-19, we were able to record DEXTENZA net product revenue in Q1 of an estimated \$2.1 million, representing growth of 31% over Q4 2019; and
- Moving forward, while we anticipate substantial continued weakness in cataract volumes throughout Q2, we expect that with variable expense reductions and a rebound in cataract volumes in Q3, our cash runway should extend into Q1 2021, consistent with our prior guidance.”

### Clinical and Pipeline Update

**OTX-TKI (axitinib intravitreal implant):** OTX-TKI is a bioresorbable, hydrogel implant incorporating axitinib, a small molecule tyrosine kinase inhibitor with anti-angiogenic properties delivered by intravitreal injection to the posterior segment of the eye for the potential treatment of wet age-related macular degeneration (wet AMD) and other retinal diseases. Two cohorts of six subjects each, a lower dose cohort of 200 µg and a higher dose cohort of 400 µg have been enrolled in a Phase 1 clinical trial.

- As of early April 2020, the first two patients in the second or higher-dose cohort have now shown a clinically meaningful reduction in intraretinal and/or subretinal fluid out to four-and-a-half months with a single implant. Other patients in the second cohort are still being followed and have not reached these timepoints yet. As is typical of such early stage trials, visual acuity has not shown consistent improvement across the cohort.
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- Data from both cohorts continue to demonstrate that OTX-TKI has been generally well tolerated and is observed to have a favorable safety profile, with no ocular serious adverse events to date.
- Interim data will be presented by Robert Avery, MD a member of the Phase 1 Data Safety Monitoring Committee, at the 8<sup>th</sup> Annual Vit-Buckle Society meeting on April 20, 2020.

**OTX-TIC (travoprost intracameral implant):** OTX-TIC is a long-acting travoprost intracameral implant in development for the treatment of patients with primary open angle glaucoma or ocular hypertension. The Company presented interim Phase 1 data on OTX-TIC at the Glaucoma 360 Conference held in San Francisco, CA in February 2020 from the first two cohorts enrolled.

- Data from the first two fully enrolled cohorts (cohort 1 = 5 patients, cohort 2 = 4 patients) continue to indicate a clinically meaningful reduction in mean IOP values in patients receiving OTX-TIC.
- The data also continue to show that the mean intraocular pressure (IOP) values remained lowered from baseline through and beyond the six-month study period in many patients and, in one patient, over 18 months.
- Enrollment in the third patient cohort has been completed. Enrollment in the fourth cohort continues, while long-term evaluation remains ongoing in the first two cohorts.

**OTX-CSI (cyclosporine intracanalicular insert):** The Company recently filed an IND and intends to begin a Phase 1 clinical trial for the treatment of dry eye disease in the middle of 2020.

**DEXTENZA (dexamethasone ophthalmic insert) for use in other ocular surface indications:**

- The Company has completed enrollment in a pivotal Phase 3 clinical trial of DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis and continues to expect to release topline results from this trial in the second quarter of 2020. Subject to obtaining favorable results in this clinical trial, the Company plans to submit an NDA supplement to the FDA for the treatment of ocular itching associated with allergic conjunctivitis as DEXTENZA's first non-surgical indication.
- Third-party clinical investigators have initiated nine trials to study the use of DEXTENZA in cataract surgery and in indications beyond cataract surgery. The first trial to fully enroll is a study comparing DEXTENZA to current standard of care, prednisolone acetate, for patients having undergone LASIK surgery. The remaining eight trials are all currently enrolling and treated patients are being followed.

#### **First Quarter Financial Update and 2020 Outlook**

Due to the economic slowdown, preliminary first quarter 2020 total net product revenue is expected to be approximately \$2.6 million, approximately 13% ahead of fourth quarter 2019 total net product revenue (although less than the Company's prior guidance of \$3.0 million to \$3.2 million). First quarter 2020 revenue was negatively impacted by a rapid deceleration of DEXTENZA orders in the second half of March due to COVID-19 and restrictions placed on elective surgical procedures at ambulatory surgery centers and hospitals. Preliminary DEXTENZA net product revenue is estimated to have grown approximately 31% to \$2.1 million for the first quarter 2020 over fourth quarter 2019 net product revenue of \$1.6 million (although less than the Company's prior guidance of \$2.4 million to \$2.6 million). Preliminary ReSure<sup>®</sup> Sealant net product revenue for the first quarter 2020 is estimated to be approximately \$0.5 million. While it is difficult to predict the extent or duration of the impact of the global COVID-19 pandemic on future financial results, March trends have intensified into April and the Company anticipates current guidelines and recommendations from the global health authorities, including the delay of elective surgeries, will significantly impact revenue in the second quarter. The Company is not providing revenue guidance for the remainder of 2020. Although some of the postponed cataract surgeries are expected to be recaptured in the second half of the year, overall volume is expected to be down since ambulatory surgery centers will be re-hiring staff and some patients may be hesitant to return immediately after surgery centers resume business.

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## **Business Update**

The Company will continue to adhere to the guidelines and safety measures that are applicable including stay at home policies and the reporting of only essential personnel for business continuity in order to ensure the safety of its employees, customers and investigators and their staff. The Company is also contributing to the fight against COVID-19 through donations of personal protective equipment to local health care providers.

The Company remains focused on managing expenses and evaluating ways to maximize operating efficiencies while preserving short and long-term growth opportunities. Subject to the completion of its financial closing procedures, the Company currently estimates that as of March 31, 2020, it had approximately \$48.2 million in cash and cash equivalents. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA and ReSure Sealant product sales and cash outflows from operating expenses, the Company believes that existing cash and cash equivalents, together with second quarter net proceeds from sales of common stock pursuant to its 2019 Sales Agreement with Jefferies LLC, will enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements into the first quarter of 2021, consistent with prior guidance. This cash guidance is subject to various assumptions including an expected rebound in cataract surgeries beginning in the third quarter, and other assumptions related to revenues and expenses associated with the commercialization of DEXTENZA, variable expense reductions and the pace of research and clinical development programs as well as other aspects of the Company's business.

In addition, the Company has applied for a low interest loan through the Paycheck Protection Program under the Coronavirus Aid, Relief and Economic Security (CARES) Act. Subject to certain conditions, some or all of such loans may qualify for forgiveness.

The Company is currently in the process of finalizing its financial results for first quarter 2020. The above estimates of net product revenue and cash balance are based on preliminary information and management estimates, subject to the completion of the Company's financial closing procedures.

## **About DEXTENZA<sup>®</sup> (dexamethasone ophthalmic insert) 0.4 mg**

DEXTENZA is an FDA-approved corticosteroid indicated for the treatment of ocular inflammation and pain following ophthalmic surgery. DEXTENZA is inserted in the lower lacrimal punctum and into the canaliculus by the physician following ophthalmic surgery. A single DEXTENZA releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion. DEXTENZA is preservative free, resorbable and does not require removal.

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.

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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%).

### **About Ocular Therapeutix, Inc.**

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel-based formulation technology. Ocular Therapeutix's first commercial drug product, DEXTENZA<sup>®</sup>, is FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery. Ocular Therapeutix is conducting a Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis. OTX-TP (intracanalicular travoprost insert) is an intracanalicular insert in clinical development for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension. The Company's earlier stage development assets include OTX-TIC, an extended-delivery intracameral travoprost implant for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension, as well as sustained release intravitreal implants for the treatment of retinal diseases. These intravitreal implants include OTX-TKI, containing the tyrosine kinase inhibitor (TKI) axitinib, and, in collaboration with Regeneron, OTX-IVT, an extended-delivery protein-based anti-vascular endothelial growth factor (VEGF) trap. Ocular Therapeutix's first product, ReSure<sup>®</sup> Sealant, is FDA-approved to seal corneal incisions following cataract surgery.

### **Forward Looking Statements**

Any statements in this press release about future expectations, plans, and prospects for the Company, including the commercialization of DEXTENZA<sup>®</sup>, ReSure Sealant, or any of the Company's product candidates; the commercial launch of, and effectiveness of reimbursement codes for, 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-TP for the treatment of primary open-angle glaucoma and ocular hypertension, 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-IVT 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 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 or estimated net product revenue; the expected impact of the COVID-19 pandemic on the company and its operations; estimated cash balance; 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 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, 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 press release represent the Company's views as of the date of this release. 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 release.

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**Investors**

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