



Ocular Therapeutix™ Reports First Quarter 2020 Financial Results and Business Update

May 8, 2020

Presented Interim Clinical Data for OTX-TKI Showing Favorable Safety Profile, Tolerability, Durability and Early Biological Activity

Announced Positive Phase 3 Clinical Trial for DEXTENZA in Allergic Conjunctivitis; Plan to File sNDA with the U.S. Food and Drug Administration by the End of 2020

First Quarter DEXTENZA® Net Product Revenue of \$2.1 million, a 31% Sequential Increase Compared with Fourth Quarter of 2019

BEDFORD, Mass.--(BUSINESS WIRE)--May 8, 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 financial results for the first quarter ended March 31, 2020 and provided a business update.

"The outlook for Ocular continues to brighten," said Antony Mattessich, President and CEO. "As our development programs continue to perform in the clinic, changes in the regulatory and competitive landscapes give us even more confidence in our future. Successes in our clinical programs have us tracking toward target product profiles that could set the standard of care in disease areas like wet AMD, glaucoma, dry eye, and post-operative pain and inflammation while changes in the external environment make us more confident in the regulatory pathways and potential market acceptability of our programs. Similarly, concern over infection risk brought on by the COVID pandemic has sparked increased interest in truly "hands free" products like DEXTENZA that can replace 70 eye drops with a single physician-administered bioresorbable insert. As we see surgery centers and hospitals starting to schedule ophthalmic surgeries again, we are excited about our prospects of not only regaining but accelerating the momentum we saw through the middle of March for DEXTENZA."

COVID-19 Update

- In March 2020, the Company enacted a mandatory "work from home" policy for employees and continues to comply with national and local guidelines.
- The Company has provided training for its staff in safety precautions and supplied personal protective equipment to ensure employee and customer safety as ambulatory surgery centers begin reopening.
- The Company believes there has been limited impact from COVID-19 to date on its ongoing clinical programs. Enrollment in the Phase 1 clinical trial of OTX-TIC in patients with primary open angle glaucoma or ocular hypertension has recently slowed but the Company believes enrollment in Cohort 4 will not be materially impacted and currently anticipates enrollment to pick up as ophthalmology practices begin to resume normal operations.
- The global COVID-19 pandemic has impacted recent DEXTENZA sales trends. Restrictions on cataract surgeries due to the pandemic significantly reduced our sales in late March. Despite recent elective surgery restrictions being lifted in certain geographies, the Company anticipates current guidelines and recommendations from the global health authorities will significantly impact revenue in the second quarter.

Key Program Updates

OTX-TKI (tyrosine kinase inhibitor intravitreal implant containing axitinib)

OTX-TKI is a bioresorbable, hydrogel implant incorporating axitinib, a small molecule tyrosine kinase inhibitor with anti-angiogenic properties for the potential treatment of wet age-related macular degeneration (wet AMD) and other retinal diseases. The Company is currently running a Phase 1, prospective, multi-center, open-label, dose escalation clinical trial intended to evaluate the safety, durability, tolerability, and biological activity of OTX-TKI for the treatment of wet AMD. Two cohorts of six subjects each have been enrolled, a lower-dose cohort of 200 ug and a higher-dose cohort of 400 ug.

- Interim data were presented by Robert Avery, MD, a member of the Phase 1 Data Safety Monitoring Committee, at the 8th Annual Vit Buckle Society Meeting on April 20, 2020.
- The first two patients in the second, or higher-dose, cohort have shown a clinically meaningful reduction in intraretinal and/or subretinal fluid out to four and half months with a single implant. Other patients in the second cohort continue to be evaluated and have yet to reach this timepoint. As is typical of such early stage trials, visual acuity has not shown consistent improvement across the cohort.
- If the durability and safety of OTX-TKI are confirmed in larger trials out to the four and half month time point or beyond, the Company believes that this product candidate, if approved, would have the potential to become a new standard of treatment for wet AMD.
- 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.
- The Company completed a protocol amendment in April 2020 to enroll a third cohort of patients to be dosed at 600 ug and

anticipates commencing enrollment of the third cohort by the middle of the year.

OTX-TIC (intracameral travoprost implant)

OTX-TIC is a long-acting travoprost intracameral implant for the treatment of patients with primary open angle glaucoma or ocular hypertension. The Company is currently enrolling a Phase 1, prospective, multi-center, open-label, dose escalation clinical trial which is intended to evaluate the safety, biological activity, durability, and tolerability of OTX-TIC for the reduction of elevated intraocular pressure (IOP) in patients with primary open angle glaucoma or ocular hypertension.

- 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 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 is completed. Enrollment in the fourth cohort has been initiated but, due to COVID-19, is experiencing temporary delays. The Company believes enrollment will pick-up as ophthalmic offices open back up for non-emergent patients by the end of the second quarter. Long-term evaluation remains ongoing in the first two cohorts.
- The Company believes there is an established clinical and regulatory pathway for OTX-TIC.

DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg

DEXTENZA is an FDA-approved corticosteroid indicated for the treatment of ocular inflammation and pain following ophthalmic surgery.

- **U.S. Commercial Launch of DEXTENZA.** The Company reported net product revenue of DEXTENZA® in the first quarter ended March 31, 2020 of \$2.1 million versus \$1.6 million in the fourth quarter ended December 31, 2019, a 31% sequential increase. 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 stoppage of elective surgical procedures at ambulatory surgery centers and hospitals. Despite recent elective surgery restrictions being lifted in certain geographies, the Company anticipates current guidelines and recommendations from the global health authorities will significantly impact revenue in the second quarter.
- **DEXTENZA in Allergic Conjunctivitis.** The Company announced positive topline results from its Phase 3 clinical trial to evaluate the safety and efficacy of DEXTENZA® for the treatment of ocular itching associated with allergic conjunctivitis (AC).
 - DEXTENZA-treated subjects demonstrated a statistically significant difference in ocular itching scores ($p < 0.0001$) compared to vehicle-treated subjects at all three pre-specified time points of 3 minutes, 5 minutes and 7 minutes on Day 8 (afternoon).
 - Upon the completion of the analysis of the Phase 3 data, the Company plans to request a meeting with the FDA and intends to submit an sNDA by the end of 2020.
 - The potential expansion of DEXTENZA with an office-setting indication highlights the versatility of the product and the opportunity for the Company's technology to potentially be used in other ocular surface diseases.
- **DEXTENZA for use in other ocular surface indications.** Third-party clinical investigators have initiated nine trials to study the use of DEXTENZA in cataract surgery and other potential indications. The first trial to fully enroll is a study comparing DEXTENZA to current standard of care, prednisolone acetate, for patients who have undergone LASIK surgery. The remaining eight trials are all currently enrolling and treated patients are being followed.

OTX-CSI (cyclosporine intracanalicular insert)

The Company has recently initiated a Phase 1, open label, single center clinical trial in the United States to evaluate the safety, biological activity, durability, and tolerability of OTX-CSI for the treatment of dry eye disease. We expect to dose the first subject in the second quarter of 2020. The Company believes that the well-known efficacy of cyclosporine combined with the punctal occlusion of an intracanalicular insert could represent an attractive product if proven to be safe and efficacious.

First Quarter Ended March 31, 2020 Financial Results

- Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was \$2.6 million for the three months ended March 31, 2020. Net product revenue of DEXTENZA® and ReSure® Sealant in the first quarter were \$2.1 million and \$0.5 million respectively. Total net product revenue of \$2.6 million for the quarter compares to \$0.5 million for the same quarter in 2019, as DEXTENZA sales did not begin until late in the second quarter of 2019.
- Research and development expenses for the first quarter were \$6.1 million versus \$11.3 million for the comparable period in 2019 and primarily reflect a decrease in personnel and unallocated costs due the organizational restructuring announced

in November 2019.

- Selling and marketing expenses for the first quarter were \$7.1 million as compared to \$3.3 million for the same quarter in 2019. This increase relates almost entirely to support of the commercial launch of DEXTENZA, driven primarily by the full impact of the hiring of new members of the commercial team including Key Account Managers, Field Reimbursement Managers and Medical Sales Liaisons beginning in the second quarter of 2019.
- Finally, general and administrative expenses were \$5.2 million for the first quarter of 2020 versus \$5.4 million in the comparable quarter of 2019. The decrease in expenses for the quarter stemmed primarily from decreased professional costs.
- The Company reported a net loss of \$(21.5) million, or a loss of \$(0.41) per share on a basic and diluted basis for the first quarter of 2020. This compares to a net loss of \$(17.1) million, or a loss of \$(0.41) per share on a basic and \$(0.45) per share on a diluted basis, for the same period in 2019. The net loss for the first quarter included \$2.3 million in non-cash charges for stock-based compensation and depreciation compared to \$2.5 million for the same quarter in 2019. In addition, the net loss for the quarter, includes a non-cash charge of \$3.4 million related to the change in the fair value of the derivative liability associated with the Company's convertible notes as compared to a gain of \$3.2 million in the same period in 2019.
- As of May 1, 2020, the Company had approximately 53.4 million shares outstanding.
- As of the March 31, 2020, the Company had \$48.2 million in cash and cash equivalents versus \$54.4 million at year end 2019. These cash amounts exclude restricted cash of \$1.8 million. The cash balance benefited during the first quarter from \$12.7 million in net proceeds generated from the sale of common stock under the Company's 2019 Sales Agreement with Jefferies LLC. For the period from March 31 to May 7, 2020, the Company has sold additional common stock under the 2019 Sales Agreement generating net proceeds of \$1.7 million; approximately \$1.3 million of common stock remains available to be sold under the 2019 Sales Agreement.
- Based on current plans including 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, as of March 31, 2020, together with the second quarter 2020 net proceeds through May 7th from sales of common stock pursuant to its 2019 Sales Agreement highlighted previously, will enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements into the first quarter of 2021. This cash guidance is subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic, 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, and other aspects of the Company's business.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 am Eastern Time to review the Company's financial results and provide a general business update. The live webcast can be accessed by visiting the Investors section of the Company's website at investors.ocutx.com. Please connect at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (844) 464-3934 (U.S.) or (765) 507-2620 (International) to listen to the live conference call. The conference ID number for the live call will be 2083975. An archive of the webcast will be available until August 6, 2020 on the Company's website.

About DEXTENZA® (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.

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®, is FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery. Ocular Therapeutix has recently completed a Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis and intends to file an sNDA by the end of 2020. 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-CSI, an intracanalicular insert for the treatment of dry eye disease, 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® 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®, 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-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-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; 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 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 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.

Ocular Therapeutix, Inc. Consolidated Statements of Operations and Comprehensive Loss (In thousands, except share and per share data) (Unaudited)

	Three Months Ended March 31,	
	2020	2019
Revenue:		
Product revenue, net	\$ 2,609	\$ 492
Total revenue, net	2,609	492
Costs and operating expenses:		
Cost of product revenue	819	128
Research and development	6,098	11,317
Selling and marketing	7,130	3,347
General and administrative	5,176	5,358
Total costs and operating expenses	19,223	20,150
Loss from operations	(16,614)	(19,658)
Other income (expense):		
Interest income	139	329
Interest expense	(1,633)	(1,018)
Change in fair value of derivative liability	(3,404)	3,223
Total other income (expense), net	(4,898)	2,534

Net loss and comprehensive loss	\$ (21,512)	\$ (17,124)
Net loss per share, basic	\$ (0.41)	\$ (0.41)
Weighted average common shares outstanding, basic	51,900,882	42,251,292
Net loss per share, diluted	\$ (0.41)	\$ (0.45)
Weighted average common shares outstanding, diluted	51,900,882	44,174,369

OCULAR THERAPEUTIX, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 48,152	\$ 54,437
Accounts receivable, net	3,429	2,548
Inventory	1,107	954
Prepaid expenses and other current assets	2,465	2,231
Total current assets	55,153	60,170
Property and equipment, net	9,473	10,151
Restricted cash	1,764	1,764
Operating lease assets	6,467	6,655
Total assets	\$ 72,857	\$ 78,740
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 2,839	\$ 3,268
Accrued expenses and other current liabilities	5,018	7,635
Operating lease liabilities	1,181	1,126
Notes payable, net of discount, current	2,074	—
Total current liabilities	11,112	12,029
Operating lease liabilities, net of current portion	8,590	8,905
Derivative liability	15,528	12,124
Notes payable, net of discount	22,987	25,007
2026 convertible notes, net	25,299	24,305
Total liabilities	83,516	82,370
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2020 and December 31, 2019, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized and 53,037,703 and 50,333,559 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	5	5
Additional paid-in capital	394,463	379,980
Accumulated deficit	(405,127)	(383,615)
Total stockholders' deficit	(10,659)	(3,630)
Total liabilities and stockholders' deficit	\$ 72,857	\$ 78,740

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200508005111/en/): <https://www.businesswire.com/news/home/20200508005111/en/>

Investors

Ocular Therapeutix
Donald Notman
Chief Financial Officer
dnotman@ocutx.com
or
Westwicke, an ICR Company
Chris Brinzey, 339-970-2843
Managing Director

chris.brinzey@westwicke.com

Media

Ocular Therapeutix

Scott Corning

Senior Vice President, Commercial

scorning@ocutx.com

Source: Ocular Therapeutix