Ocular Therapeutix™ Reports Second Quarter 2021 Financial Results and Business Update

August 9, 2021

DEXTENZA® Recorded Net Quarterly Sales of $11.1 Million, Representing Quarterly Sequential Growth of Approximately 65%

Initiated First Clinical Trial in the U.S. to Assess a Single OTX-TKI Implant Containing a 600µg Dose of Axitinib for the Treatment of Wet Age-Related Macular Degeneration

Conference Call to Discuss Second Quarter Results to be Held at 4:30 p.m. ET

BEDFORD, Mass.--(BUSINESS WIRE)--Aug. 9, 2021-- 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 reported financial results for the second quarter of 2021, and provided updates on its ophthalmology pipeline.

"It has been a productive quarter for Ocular as we work to build a leading ophthalmology company," said Antony Mattessich, President and Chief Executive Officer. "Net product revenue for DEXTENZA® was up nearly 700% against the prior year period and we achieved record quarterly in-market sales of nearly 25,000 billable units, representing a 50% sequential increase over the first quarter. Beyond DEXTENZA, we made significant progress in advancing our pipeline of product candidates, dosing the first patient in our U.S.-based trial of OTX-TKI, and completing a research agreement with Mosaic Biosciences targeting dry-AMD that further builds our product pipeline. In the second half of 2021, we look forward to continued momentum with DEXTENZA, including a PDUFA date in allergic conjunctivitis in October, and further development of our pipeline which includes the expected completion of our Phase 2 clinical trial with OTX-CSI, our cyclosporine-containing intracanalicular insert for the chronic treatment of dry eye disease."

Recent Business Updates

First Patient Dosed in U.S.-based Clinical Trial Evaluating OTX-TKI (axitinib intravitreal implant) for the Treatment of Wet AMD. The Phase 1 clinical trial in the U.S. is a prospective, randomized, controlled, multi-center trial evaluating a single OTX-TKI implant containing a 600 µg dose of axitinib with an anti-VEGF induction injection, compared with a 2 mg dose of aflibercept administered every 8 weeks in subjects previously treated with anti-VEGF therapy. This is the first clinical trial utilizing the Company's single dose, 600 µg implant. This trial is designed to assess the safety, tolerability, and biological activity of OTX-TKI for the treatment of wet AMD and is being conducted under an exploratory IND, at five sites with a total of 20 randomized subjects: 15 subjects being treated with a single OTX-TKI implant with an anti-VEGF induction injection, and 5 subjects being treated at eight-week intervals with a dose of aflibercept. OTX-TKI has the potential to be a novel sustained release administration of axitinib, with six months or longer durability, which includes a potential new mechanism of action for the treatment for patients with wet AMD and other retinal diseases.

U.S. Commercial Uptake of DEXTENZA. Net product revenue of DEXTENZA® for the quarter was $11.1 million, a nearly 700% increase over the second quarter 2020, and an approximately 65% sequential increase over the first quarter of 2021. DEXTENZA in-market unit volume to surgery centers was a record of nearly 25,000 billable inserts, an approximately 50% sequential increase over the previous quarter. The Company believes this growth reflects strong end-user demand for DEXTENZA driven by an increase in cataract procedure volumes and market share gains. June 2021 in-market unit sales set a monthly record of 9,779 billable inserts as cataract volumes continued to increase through the second quarter of 2021 after a slowing of procedures earlier in the year as result of regional COVID surges. As previously reported, April and May in-market unit sales were 8,025 billable inserts and 7,186 billable inserts, respectively.

DEXTENZA Pass-Through Payment Status Recommended for Extension Through the End of 2022. CMS, in its CY 2022 Outpatient Prospective Payment System (OPPS) proposed rule on July 19, 2021, recommended that pass-through status of DEXTENZA be extended six months through the end of 2022. The Company expects that, if finalized, this decision would move any negotiation between the Company and CMS on DEXTENZA's post-pass-through payment status into the next rulemaking cycle, a year from now. The Company continues to believe there are a number of pathways whereby it can continue to provide patient access to DEXTENZA in ASCs and HOPDs beyond the pass-through period and expects to be working actively in advance of the 2023 rulemaking cycle.

New Medicare Physician Fee Schedule Proposed for Insertion of DEXTENZA. The Medicare Physician Fee Schedule proposed rule was also issued in July. The proposed rule indicated that the Company's CPT procedural code, 0356T for the Insertion of a drug-eluting implant into the lacrimal canaliculus, continues to be on track to convert to a Category 1 code in January of 2022 with a proposed procedure payment of $31.91 in the facility and $37.61 in the physician's office for unilateral insertion. The Company is pleased with the prospect of the Category 1 code conversion for the procedure since Category 1 CPT codes typically benefit from broader coverage and payment among all types of payers. However, the Company intends to use the formal comment period to actively pursue higher potential payment rates that it believes are well justified.

Presented Clinical Data at the 2021 American Society of Cataract and Refractive Surgery (ASCRS) Meeting. Eight company presentations and five presentations from investigator-initiated trials were presented at the 2021 ASCRS Meeting on July 23-27th. Data was presented on multiple programs advancing in clinic as well as DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg for intracanalicular use and ReSure® Sealant. The data being presented continue to support the use of DEXTENZA to treat post-operative ocular inflammation and pain and the ability to research the use of our proprietary hydrogel technology to potentially address the unmet needs in the ophthalmic space, specifically in glaucoma, dry eye disease and allergic conjunctivitis. Posters for the Company-sponsored presentations can be accessed on the corporate website.

Regeneron Collaboration to Develop a Sustained-Release Formulation of Aflibercept for the Treatment of Wet AMD and other Serious Retinal Diseases Terminated. Regeneron has terminated its collaboration with the Company. The collaboration with Regeneron was initially formed in 2016, and later amended in 2020 to focus on the research and development of an extended-delivery formulation of aflibercept to be delivered to the suprachoroidal space for the treatment of retinal diseases. Ocular is now free to potentially pursue discovery work in this area on its own or with a

partner.

Key Program Updates

- ***OTX-TKI (axitinib intravitreal implant) for the potential treatment of wet AMD and other retinal diseases.***
  - The Company dosed the first subject in the U.S.-based Phase 1 clinical trial evaluating a single OTX-TKI implant containing a 600 µg dose of axitinib compared to aflibercept administered every 8 weeks in subjects previously treated with anti-VEGF therapy.
- ***OTX-TIC (travoprost intracameral implant) for the treatment of patients with primary open-angle glaucoma or ocular hypertension.***
  - Following supportive data from a U.S.-based Phase 1 study, the Company is targeting the initiation of a randomized, double-masked, active-controlled Phase 2 clinical trial in the fourth quarter of 2021 in the United States.
  - The clinical trial will enroll approximately 105 subjects to evaluate two different formulations of OTX-TIC versus a control arm receiving Durysta™.
- ***OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease.***
  - The Company has completed enrollment of a U.S.-based Phase 2, randomized, double-masked, multi-center clinical trial to evaluate the safety, efficacy, durability, and tolerability of two different formulations of OTX-CSI versus hydrogel vehicle insert.
  - Top-line data from the Phase 2 clinical trial are expected in the fourth quarter of 2021.
- ***OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease.***
  - The Company is enrolling a U.S.-based, prospective, randomized, double-masked, vehicle-controlled, multi-center Phase 2 clinical trial in approximately 150 subjects with dry eye disease.
  - Enrollment has been faster than anticipated and data from the Phase 2 clinical trial is now expected in the first quarter of 2022 versus prior guidance of the first half of 2022.
- ***DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg for the treatment of ocular itching associated with allergic conjunctivitis.***
  - The FDA has set a PDUFA target action date of October 18, 2021.

Second Quarter Ended June 30, 2021 Financial Results

Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was $11.7 million and represented a 631% increase over the same period in 2020. Net product revenue of DEXTENZA® in the second quarter was $11.1 million versus $1.4 million in the comparable quarter 2020, reflecting a nearly seven times increase. Total net product revenue for the second quarter also includes net product revenue of $0.6 million from ReSure® Sealant, compared with $0.2 million from ReSure Sealant in the comparable quarter 2020.

Research and development expenses for the second quarter were $13.9 million versus $8.0 million for the comparable period in 2020 primarily driven by increased headcount as well as increased clinical trial costs associated with the initiation of the US-based Phase 1 trial of OTX-TKI as well as the ongoing Phase 2 clinical trials for OTX-CSI and OTX-DED, the ongoing Phase 1 clinical trial of OTX-TKI in Australia and the Phase 3 pediatric clinical trial of DEXTENZA in accordance with the FDA's post-approval requirements.

Selling and marketing expenses in the quarter were $8.4 million as compared to $6.2 million for the same quarter in 2020, reflecting increased personnel costs associated with expansion of our field force.

Finally, general and administrative expenses were $8.6 million for the second quarter versus $5.1 million in the comparable quarter of 2020. The increase in expenses stemmed primarily from increased personnel expenses and professional fees.

With respect to the financial results for the second quarter, the Company reported a net loss of $8.5 million, or $(0.11) per share on a basic and $(0.25) per share on a diluted basis. This compares to a net loss of $36.6 million, or $(0.64) per share on a basic and diluted basis for the same period in 2020. The decreased loss was due primarily from a $30.4 million net change in the fair value of the derivative liability associated with our convertible note driven by a decrease in the price of our common stock during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization was $4.9 million in the second quarter versus $2.5 million for the same quarter in 2020.

As of August 4, 2021, the Company had 76.6 million shares outstanding.

As of June 30, 2021, the Company had $191.9 million in cash and cash equivalents versus $209.4 million at March 31, 2021. Based on our current plans and related estimates of anticipated cash inflows from DEXTENZA and ReSure product sales and cash outflows from operating expenses, the Company believes that existing cash and cash equivalents, as of June 30, 2021, will enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements through 2023. This cash guidance is subject to a number of assumptions including those related to the severity and duration of the COVID-19 pandemic, the revenues, expenses and reimbursement associated with DEXTENZA, and the pace of research and clinical development programs, among other aspects of the business.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 4:30 pm 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 3436758. An archive of the webcast will be available until November 9, 2021 on the Company's website.

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 an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery. Ocular Therapeutix has received a target action date under the Prescription Drug User Fee Act, commonly known as PDUFA, of October 18, 2021, for a supplemental new drug application for DEXTENZA to include an additional indication for the treatment of ocular itching associated with allergic conjunctivitis. Ocular Therapeutix's earlier stage development assets currently in Phase 1 clinical trials include OTX-TKI (axitinib intravitreal implant) for the treatment of wet AMD and other retinal diseases and OTX-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension. Ocular Therapeutix is currently evaluating OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease in Phase 2 clinical trials. Ocular Therapeutix's first product, ReSure® Sealant, is an FDA-approved device to prevent wound leaks in 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 conduct of post-approval studies of and compliance with related labeling requirements for DEXTENZA and ReSure Sealant; 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 the PDUFA target action date scheduled for October 18, 2021 for allergic conjunctivitis, OTX-CSI for the chronic treatment of dry eye disease, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, and OTX-TKI 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 operations of Company collaborations, including any potential future costs or payments thereunder; projected net product revenue, in-market sales and other financial and operational metrics of DEXTENZA and ReSure Sealant; potential market sizes for indications targeted by the Company's product candidates, if approved; 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 preclinical and 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 and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA, the initiation, timing, conduct and outcomes of clinical trials, availability of data from clinical trials and expectations for regulatory submissions and approvals, the Company's ability to enter into and perform its obligations under collaborations and the performance of its collaborators under such collaborations, 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 in-market 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 severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, any additional financing needs 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 press 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, whether as a result of new information, future events or otherwise, 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 press release.

Ocular Therapeutix, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue, net	$ 11,718	$ 1,569	$ 19,061	$ 4,178
Total revenue, net	11,718	1,569	19,061	4,178
Costs and operating expenses:				
Cost of product revenue	1,096	134	1,988	953
Research and development	13,859	8,021	24,786	14,119
Selling and marketing	8,391	6,153	16,477	13,283
General and administrative	8,603	5,145	16,268	10,321

Total costs and operating expenses	31,949	19,453	59,519	38,676
Loss from operations	(20,231)	(17,884)	(40,458)	(34,498)
Other income (expense):				
Interest income	8	17	20	156
Interest expense	(1,655)	(1,694)	(3,335)	(3,327)
Change in fair value of derivative liability	13,396	(17,007)	38,412	(20,411)
Other income (expense), net	1	—	1	—
Total other income (expense), net	11,750	(18,684)	35,098	(23,582)
Net loss	$ (8,481)	$ (36,568)	$ (5,360)	$ (58,080)
Net loss per share, basic	$ (0.11)	$ (0.64)	$ (0.07)	$ (1.06)
Weighted average common shares outstanding, basic	76,324,367	57,368,292	76,198,384	54,634,572
Net loss per share, diluted	$ (0.25)	$ (0.64)	$ (0.51)	$ (1.06)
Weighted average common shares outstanding, diluted	82,093,599	57,368,292	81,967,616	54,634,572

Ocular Therapeutix, Inc.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 191,860	$ 228,057
Accounts receivable, net	18,734	12,252
Inventory	1,112	1,201
Prepaid expenses and other current assets	4,817	4,650
Total current assets	216,523	246,160
Property and equipment, net	7,042	8,095
Restricted cash	1,764	1,764
Operating lease assets	5,378	5,844
Total assets	$ 230,707	$ 261,863
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,881	$ 2,709
Accrued expenses and other current liabilities	16,182	14,307
Operating lease liabilities	1,487	1,358
Notes payable, net of discount, current	—	8,290
Total current liabilities	21,550	26,664
Other liabilities:		
Operating lease liabilities, net of current portion	6,770	7,548
Derivative liability	59,901	98,313
Deferred revenue	12,000	12,000
Notes payable, net of discount	24,891	16,936
2026 convertible notes, net	25,348	24,307
Total liabilities	150,460	185,768
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at June 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 76,454,597 and 75,996,732 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	8	8
Additional paid-in capital	624,850	615,338
Accumulated deficit	(544,611)	(539,251)
Total stockholders' equity	80,247	76,095
Total liabilities and stockholders' equity	$ 230,707	$ 261,863

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