Ocular Therapeutix™ Reports Second Quarter 2022 Financial Results and Business Update

August 8, 2022

Interim Data from the U.S.-based Clinical Trial for OTX-TKI for the Treatment of Wet AMD to be Presented at American Academy of Ophthalmology (AAO) in the Third Quarter of 2022

DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg Recorded Quarterly Net Product Revenue of $12.1 Million, Representing Year-Over-Year Growth of 9%

Reiterated DEXTENZA Annual Net Product Revenue Guidance for 2022 between $55 to $60 million, Representing Annual Growth of Approximately 26% to 38%

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

BEDFORD, Mass.--(BUSINESS WIRE)--Aug. 8, 2022-- 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 quarter ended June 30, 2022, and provided updates on its ophthalmology pipeline.

“Through the first half of the year we are making good progress executing on our commercial strategy and developing our strong ophthalmology pipeline,” said Antony Mattessich, President and Chief Executive Officer. “Looking ahead, we plan to announce interim data from the U.S.-based Phase 1 clinical trial of OTX-TKI for the treatment of wet AMD in the third quarter. Wet AMD represents a large market opportunity for a highly differentiated product, and we believe that OTX-TKI has the potential to become a new standard of care in the management of serious retinal diseases. On the commercial front, DEXTENZA achieved net revenue of $12.1 million for the quarter despite staffing challenges at our ASC and HOPD customers that hindered their ability to operate at full capacity. We believe these challenges are transient in nature and that drivers such as the recent recommendation of continued separate payment through 2023 by CMS, bringing new territories online, and the ramp-up of our new office-based salesforce should have a positive impact on DEXTENZA sales over the remainder of 2022 and beyond.”

Recent Business Updates

OTX-TKI Data Expected to be Presented at American Academy of Ophthalmology (AAO) Meeting at the End of September

- The U.S.-based Phase 1 trial continues to progress with all 21 study subjects currently through 24 weeks on study.
- Interim data from the trial are scheduled to be presented by Dilsher Dhoot, MD at the AAO Retina Subspecialty Day, Late Breaking Developments, Part 1 on Friday, September 30th at 3:29 p.m. CT.
- The AAO presentation is anticipated to provide data at 28 weeks for all subjects.

Implemented Organizational Changes to Strengthen the Company’s Alignment Around Its Retina Programs and the Overall Development of its Ophthalmology Pipeline

- Peter K. Kaiser, M.D., a world-renowned ophthalmologist and retinal disease expert, is advising the Company in the newly created role of Chief Medical Advisor, Retina. Dr. Kaiser is advising on clinical development strategies for all retina programs including OTX-TKI. Dr. Kaiser is also advising on pre-clinical development work for Ocular’s gene therapy delivery and complement inhibition development programs. Dr. Kaiser serves in this role on a consulting basis while continuing as Chaney Family Endowed Chair in Ophthalmology Research and Professor of Ophthalmology at the Cleveland Clinic Lerner College of Medicine and Cole Eye Institute.
- Rabia Gurses Ozden, M.D., who previously served as the Company’s Senior Vice President, Clinical Development, has been promoted to the role of Chief Medical Officer to lead the clinical development of the Company’s current and growing ophthalmology pipeline focusing on the front and back of the eye. Dr. Gurses Ozden has more than 15 years of experience in clinical development, clinical operations, and pharmacovigilance in pharmaceutical and medical device development with demonstrated capabilities in global program and project management as well as experience interacting with the FDA, EMA, PMDA, and CFDA for regulatory filings, and new clinical endpoint development.
- Michael Goldstein, M.D., who previously served as Chief Medical Officer, President of Ophthalmology, departed from the Company to pursue additional business interests on June 30, 2022, but is continuing to work with the Company as a consultant in the newly created role of Chief Strategy Advisor, in which capacity he is advising the Company on pipeline development activities.

The U.S. Commercial Uptake of DEXTENZA

- Net product revenue of DEXTENZA® for the quarter was $12.1 million, a 9% increase over the second quarter of 2021.
- The Company is reiterating its guidance of $55 to $60 million in net product revenue for 2022.
- In-market purchases were over 27,000 billable units for the quarter, down approximately 2% quarter over quarter as the Company believes many end customers, primarily ASCs, continued to operate below capacity due to staffing challenges.

The Company has also experienced similar staffing challenges with several open positions within the field force currently unfilled.
- The new, office-based business unit focused on launching DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis is now in place.
- In July, CMS issued its proposed rule for the 2023 Outpatient Prospective Payment System (OPPS) rulemaking cycle recommending that DEXTENZA continue to be separately paid in ASCs through 2023 under the non-opioid pain management supply provision. The final rule regarding the recommendation is anticipated in November 2022. In addition, physician reimbursement for the administration of DEXTENZA remains available under the product's Category 1 CPT code, which became effective January 1, 2022, ensuring more reliable payment to physicians for the administration of DEXTENZA across all payer types and in all settings of care.

Key Pipeline Program Updates

- ***OTX-TKI (axitinib intravitreal implant) for the potential treatment of wet AMD and other retinal diseases.***
  - At the Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting held on May 1-4, 2022 in Denver, the Company presented two posters highlighting recent studies of OTX-TKI in non-human primates: a pharmacokinetic and tolerability study and a six-month GLP toxicology study.
  - Enrollment in the Australia-based Phase 1 clinical trial is closed and Company continues to follow subjects.
- ***OTX-TIC (travoprost intracameral implant) for the treatment of patients with primary open-angle glaucoma or ocular hypertension.***
  - The Company continues to actively enroll its U.S.-based Phase 2 prospective, multi-center, randomized, controlled clinical trial evaluating the safety, tolerability, and efficacy of OTX-TIC for the treatment of patients with primary open-angle glaucoma or ocular hypertension.
  - The Company has designed the Phase 2 trial to evaluate whether OTX-TIC can cause a clinically meaningful decrease in intraocular pressure while preserving endothelial cell health, enabling chronic dosing.
  - The Company received a $2.0 million clinical support payment from AffaMed Therapeutics (AffaMed), under its licensing agreement, in the second quarter of 2022 following the dosing of the first patient in the Phase 2 trial in the first quarter of 2022.
- ***OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease.***
  - Based on the data from the Phase 2 clinical trial, the Company intends to initiate a small trial in the first half of 2023 to evaluate the performance of OTX-DED versus short duration, biodegradable collagen plugs. Specifically, the Company is conducting this trial to explain the magnitude of the placebo effect seen in both the OTX-DED and the OTX-CSI Phase 2 trials in which the vehicle hydrogel placebo insert or placebo comparator remained in the canaliculus longer than anticipated, performing more like an active comparator than a placebo.
  - The Company believes that the data from this trial may inform the selection of a more appropriate placebo comparator for both the OTX-DED and the OTX-CSI programs.
- ***OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease.***
  - Based on the data from the Phase 2 clinical trial, the Company is continuing formulation work to extend the durability of the OTX-CSI insert.
  - The Company's goal is to select the most appropriate formulations to move forward.

Second Quarter Ended June 30, 2022 Financial Results

Net revenue, which includes both gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, and collaboration revenue was $12.3 million for the second quarter and represented an approximately 5% increase over the same period in 2021. Net product revenue of DEXTENZA in the second quarter of 2022 was $12.1 million versus $11.1 million in the comparable quarter of 2021, reflecting a 9% increase. Total net revenue for the second quarter of 2022 also included collaboration revenue of $0.1 million from the Company's licensing agreement with AffaMed.

Research and development expenses for the second quarter were $13.1 million versus $13.9 million for the comparable period in 2021 driven primarily by a reduction in clinical and pre-clinical spending offset by an increase in unallocated personnel costs and other expenses.

Selling and marketing expenses in the quarter were $10.1 million as compared to $8.4 million for the comparable quarter of 2021, due primarily to an increase in professional fees related to trade shows, conferences and advertising.

General and administrative expenses were $7.8 million for the second quarter versus $8.6 million in the comparable quarter of 2021, primarily reflecting a decrease in professional fees.

The Company reported a net loss of $ (18.8) million, or a loss of $ (0.24) and $ (0.25) per share on a basic and diluted basis, respectively, for the second quarter ended June 30, 2022. This compares to a net loss of $(8.5) million, or a loss of $(0.11) per share on a basic basis and $(0.25) per share on a diluted basis. for the comparable period in 2021. Net loss in the second quarter of 2022 was reduced by a $2.8 million non-cash item attributable to a decrease in the fair value of the derivative liability associated with the Company's convertible notes, as the price of its common stock declined during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization were $4.8 million in the second quarter of 2022 versus $4.9 million for the comparable quarter of 2021.

As of August 5, 2022, the Company had 77.0 million shares outstanding.

2022 Financial Guidance

- Total net product revenue in 2022 is expected to be in the range of $55 to $60 million, representing growth of between 26% to 38% over 2021. The growth is anticipated to be primarily driven by sales of DEXTENZA for the treatment of post-surgical inflammation and pain.
- As of June 30, 2022, the Company had $134.5 million in cash and cash equivalents versus $145.4 million at March 31, 2022. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA and anticipated cash outflows from operating expenses, the Company believes that its existing cash and cash equivalents are sufficient to 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 the impacts from the ongoing 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 (800) 715-9871 (U.S.) or (646) 307-1963 (International) to listen to the live conference call. The conference ID number for the live call will be 9296568. A replay of the webcast will be available on the Company's website for 90 days following the live call.

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 and ocular itching associated with allergic conjunctivitis. Ocular Therapeutix's earlier stage development assets include: OTX-TKI (axitinib intravitreal implant), currently in Phase 1 clinical trials for the treatment of wet AMD and other retinal diseases; OTX-TIC (travoprost intracameral implant), currently in a Phase 2 clinical trial for the treatment of primary open-angle glaucoma or ocular hypertension; and 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, both of which have completed 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.

About DEXTENZA

DEXTENZA is FDA approved for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. DEXTENZA is a corticosteroid intracanalicular insert placed in the punctum, a natural opening in the inner portion of the lower eyelid, and into the canaliculus and is designed to deliver dexamethasone to the ocular surface for up to 30 days without preservatives. DEXTENZA resorbs and exits the nasolacrimal system without the need for removal.

Please see full Prescribing and Safety Information at www.DEXTENZA.com.

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 development and regulatory status of the Company's product candidates, such as the Company's development of and prospects for approvability of OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, and OTX-CSI for the chronic treatment of dry eye disease; the Company's plans to advance the development of its product candidates or preclinical programs; the ongoing development of the Company's extended-delivery hydrogel depot technology; the potential utility of any of the Company's product candidates; the size of potential markets for 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; 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 successfully develop and commercialize products for the ophthalmology office setting, 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, whether clinical trial data such as the data reported in this release will be indicative of the results of subsequent 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 meet supply demands, 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 revenues and relevant regulatory authorities' operations, any additional financing needs, the Company's ability to recruit and retain key personnel, 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.

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,	
	2022	2021	2022	2021
Revenue:				
Product revenue, net	$ 12,144	$ 11,718	$ 24,642	$ 19,061
Collaboration revenue	122	—	811	—
Total revenue, net	12,266	11,718	25,453	19,061
Costs and operating expenses:				
Cost of product revenue	1,155	1,096	2,454	1,988
Research and development	13,100	13,859	26,200	24,786
Selling and marketing	10,140	8,391	19,203	16,477
General and administrative	7,787	8,603	15,344	16,268
Total costs and operating expenses	32,182	31,949	63,201	59,519
Loss from operations	(19,916)	(20,231)	(37,748)	(40,458)
Other income:				
Interest income	73	8	89	20
Interest expense	(1,696)	(1,655)	(3,378)	(3,335)
Change in fair value of derivative liability	2,773	13,396	9,731	38,412
Other income (expense), net	—	1	(2)	1
Total other income, net	1,150	11,750	6,440	35,098
Net loss	$ (18,766)	$ (8,481)	$ (31,308)	$ (5,360)
Net loss per share, basic	$ (0.24)	$ (0.11)	$ (0.41)	$ (0.07)
Weighted average common shares outstanding, basic	76,764,296	76,324,367	76,755,028	76,198,384
Net loss per share, diluted	$ (0.25)	$ (0.25)	$ (0.47)	$ (0.51)
Weighted average common shares outstanding, diluted	82,533,528	82,093,599	82,524,260	81,967,616

Ocular Therapeutix, Inc.

Consolidated Balance Sheet
(In thousands, except share and per share data)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 134,539	$ 164,164
Accounts receivable, net	20,482	21,135
Inventory	1,500	1,250
Prepaid expenses and other current assets	3,801	4,751
Total current assets	160,322	191,300
Property and equipment, net	6,680	6,956
Restricted cash	1,764	1,764
Operating lease assets	4,305	4,867
Total assets	$ 173,071	$ 204,887
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,703	$ 4,592
Accrued expenses and other current liabilities	19,450	20,121
Deferred revenue	1,189	—

Operating lease liabilities	1,771	1,624
Total current liabilities	26,113	26,337
Other liabilities:		
Operating lease liabilities, net of current portion	4,999	5,924
Derivative liability	10,461	20,192
Deferred revenue, net of current portion	13,000	13,000
Notes payable, net of discount	25,128	25,000
2026 convertible notes, net	27,567	26,435
Total liabilities	107,268	116,888
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, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 76,910,026 and 76,731,940 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	8	8
Additional paid-in capital	642,907	633,795
Accumulated deficit	(577,112)	(545,804)
Total stockholders' equity	65,803	87,999
Total liabilities and stockholders' equity	$ 173,071	$ 204,887

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