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

November 7, 2022

Announced Positive Interim Data from the U.S.-based Phase 1 Clinical Trial of OTX-TKI for the Treatment of Wet AMD at the American Academy of Ophthalmology (AAO) 2022 Annual Meeting

Initiation of OTX-TKI Phase 1 Clinical Trial for the treatment of Diabetic Retinopathy Planned for Q1 of 2023 and Phase 2/3 Clinical Trial for the treatment of Wet AMD Planned for Q3 of 2023

DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg Recorded Quarterly Net Product Revenue of $11.9 Million

Revised DEXTENZA Annual Net Product Revenue Guidance for 2022 to be between $48 to $52 million, Representing Annual Growth of Approximately 10% to 20%

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

BEDFORD, Mass--(BUSINESS WIRE)--Nov. 7, 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 September 30, 2022, and provided updates on its ophthalmology pipeline.

“We presented arguably the most important clinical data in the Company’s history at this year’s AAO meeting” commented Antony Mattessich, President and CEO. “In the 7-month data from our U.S.-based Phase 1 clinical trial of a 600 µg, single implant OTX-TKI for the treatment of controlled wet AMD, 80% and 73% of subjects were rescue-free up to 6 and 7 months, respectively. In addition to our goal of moving OTX-TKI into a Phase 2/3 trial for the treatment of wet AMD in Q3 of 2023, we also plan to initiate a Phase 1 trial for the treatment of diabetic retinopathy (DR) in Q1 of 2023. Pending good results, and subject to a follow-up meeting with the FDA, we believe we could be in position to initiate our first Phase 3 trial of OTX-TKI for the treatment of DR in Q1 of 2024. On the commercial front, DEXTENZA achieved net revenue of $11.9 million for the quarter despite the continued staffing challenges that we have observed 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 recent staffing of our sales force at targeted levels and bringing new sales territories online should have a near and long term positive impact on DEXTENZA sales.”

Business Updates

OTX-TKI (axitinib intravitreal implant) for the potential treatment of wet AMD, diabetic retinopathy and other retinal diseases.

- Presented positive interim 7-month data from U.S.-based Phase 1 trial of OTX-TKI for the treatment of Wet AMD at the AAO 2022 Annual Meeting. Data was presented using a data cut-off date of August 24, 2022.
  - Interim data showed a single OTX-TKI implant was generally well tolerated with no drug-related ocular or systemic serious adverse events (SAEs). There were no reported adverse events such as elevated IOP, retinal detachment, retinal vasculitis, or implant migration into the anterior chamber observed in the OTX-TKI arm. There was one SAE of acute endophthalmitis in the OTX-TKI arm which occurred following a mandated aflibercept injection at Month 1.
  - Subjects treated with a single OTX-TKI implant demonstrated stable and sustained best corrected visual acuity (BCVA) (mean change from baseline of -1.3 letters) and central subfield foveal thickness (CSFT) (mean change from baseline of +9.2 µm) at 7 months, which was comparable with the aflibercept arm dosed every 8 weeks (mean change from BVCA baseline of -1 letter; mean change from CSFT baseline of +0.4 µm).
  - 80% of subjects in the OTX-TKI arm were rescue-free up to 6 months and 73% of subjects in the OTX-TKI arm were rescue-free up to 7 months.
  - The Company intends to present 10-month data at the upcoming Angiogenesis, Exudation, and Degeneration 2023 Meeting at 8:10 am on Saturday, February 11th, 2023 and plans to follow subjects at least until their respective one-year anniversaries of initial dosing, in accordance with the clinical trial protocol.
  - The Company plans to meet with the FDA in early 2023 to discuss potential future clinical trial requirements with the goal of initiating a Phase 2/3 clinical trial for the treatment of wet AMD in Q3 of 2023.
- The Company intends to initiate a U.S.-based Phase 1 clinical trial for the treatment of DR in Q1 of 2023.
  - The US Phase 1 trial is planned to be conducted under an existing eIND across approximately 10 sites and is designed to include approximately 20 patients randomized to either a 600 µg OTX-TKI single implant containing axitinib or sham control.
  - Pending good data results from the Phase 1, and subject to a follow-up meeting with the FDA, the Company believes it could be well positioned to initiate its first Phase 3 pivotal trial for the treatment of DR in Q1 of 2024.

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 repeat dosing.
- The Company plans to provide a topline data release in Q4 of 2023.

Dry Eye Programs moving forward in a measured manner with a collaborative study of OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease.

- The Company intends to initiate a collaborative clinical trial in the first half of 2023 to evaluate the performance of OTX-DED versus fast-dissolving collagen plugs and no inserts at all. Specifically, the Company plans to conduct this trial to explain the magnitude of the placebo effect seen in both the OTX-DED and the OTX-CSI (cyclosporine intracanalicular insert for the chronic treatment of dry eye disease) Phase 2 trials in which the vehicle hydrogel placebo insert remained in the canaliculus longer than anticipated, performing more like an active comparator than a placebo comparator.
- The Company plans to use the results of the collaborative study to inform the next steps for both OTX-DED and OTX-CSI.

DEXTENZA (dexamethasone ophthalmic insert) 0.4mg is FDA approved for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis.

- Net product revenue of DEXTENZA for the quarter was $11.9 million, in line with the third quarter of 2021 and down approximately 2% sequentially quarter-over-quarter.
- In-market purchases were over 26,000 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.
- In light of this performance, the Company is revising its guidance to $48 to $52 million in net product revenue for 2022.
- The Company presented multiple posters on the real-world safety, demographic and clinical characteristics of DEXTENZA using the Academy's IRIS® Registry at the AAO 2022 Annual Meeting.
- On November 1, 2022, the Centers for Medicare and Medicaid Services (CMS) issued the calendar year 2023 hospital outpatient prospective payment system (OPPS) rule, confirming that DEXTENZA, as anticipated, will be separately payable in ambulatory surgery centers under the non-opioid supply provision for CY 2023.

Third Quarter Ended September 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 $12.0 million for the third quarter of 2022 and represented an approximately 2% decrease over the same period in 2021. DEXTENZA net product revenue was $11.9 million for the third quarter of 2022, flat to the comparable quarter of 2021 and down approximately 2% on a sequential quarterly basis. Net revenue in the third quarter of 2022 also included $0.1 million in collaboration revenue associated with the Company's work with AffaMed. Net product revenue in the third quarter of 2021, included $0.3 million attributable to sales of ReSure Sealant.

Research and development expenses for the third quarter of 2022 were $13.7 million versus $12.7 million for the comparable period in 2021 driven primarily by an increase in personnel and a higher level of preclinical development activity.

Selling and marketing expenses in the third quarter of 2022 were $10.2 million as compared to $9.6 million for the comparable quarter of 2021, reflecting primarily an increase in field force personnel.

General and administrative expenses were $8.5 million for the third quarter of 2022 versus $8.1 million in the comparable quarter of 2021, primarily due to an increase in personnel related costs, including stock-based compensation.

The Company reported a net loss for the third quarter of 2022 of $(24.2) million, or a loss of $(0.31) per share on a basic and diluted basis, compared to net income of $2.7 million, or net income of $0.03 per share on a basic basis and a loss of $(0.23) per share on a diluted basis for the same period in 2021. Net loss in the third quarter of 2022 included a $1.1 million non-cash item attributable to an increase in the fair value of the derivative liability associated with the Company's convertible notes, as the price of its common stock increased during the quarter. Non-cash charges for stock-based compensation and depreciation and amortization were $4.7 million in the third quarter of 2022 versus $4.4 million for the same quarter in 2021.

As of November 4, 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 $48 to $52 million, representing growth of between 10% to 20% over 2021. The growth is anticipated to be driven by sales of DEXTENZA for the treatment of post-surgical inflammation and pain.
- As of September 30, 2022, the Company had $121.0 million in cash and cash equivalents versus $134.5 million at June 30, 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. A live audio webcast will be available at www.ocutx.com. Interested parties may also register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 and diabetic retinopathy, 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 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 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.

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

	Three Months Ended	Nine Months Ended

	September 30,		September 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue, net	$ 11,913	$ 12,153	$ 36,555	$ 31,214
Collaboration revenue	52	—	864	—
Total revenue, net	11,965	12,153	37,419	31,214
Costs and operating expenses:				
Cost of product revenue	1,073	1,310	3,528	3,298
Research and development	13,719	12,719	39,919	37,505
Selling and marketing	10,186	9,576	29,390	26,054
General and administrative	8,531	8,077	23,875	24,345
Total costs and operating expenses	33,509	31,682	96,712	91,202
Loss from operations	(21,544)	(19,529)	(59,293)	(59,988)
Other income (expense):				
Interest income	285	7	375	27
Interest expense	(1,797)	(1,658)	(5,175)	(4,991)
Change in fair value of derivative liability	(1,133)	23,837	8,598	62,249
Other income (expense), net	1	—	(1)	—
Total other income (expense), net	(2,644)	22,186	3,797	57,285
Net (loss) income	$ (24,188)	$ 2,657	$ (55,496)	$ (2,703)
Net (loss) income per share, basic	$ (0.31)	$ 0.03	$ (0.72)	$ (0.04)
Weighted average common shares outstanding, basic	76,975,839	76,552,060	76,829,434	76,317,563
Net (loss) income per share, diluted	$ (0.31)	$ (0.23)	$ (0.73)	$ (0.75)
Weighted average common shares outstanding, diluted	76,975,839	85,446,886	82,598,666	82,086,795

Ocular Therapeutix, Inc.

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 120,950	$ 164,164
Accounts receivable, net	19,802	21,135
Inventory	1,545	1,250
Prepaid expenses and other current assets	3,318	4,751
Total current assets	145,615	191,300
Property and equipment, net	7,196	6,956
Restricted cash	1,764	1,764
Operating lease assets	4,004	4,867
Total assets	$ 158,579	$ 204,887
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,308	$ 4,592
Accrued expenses and other current liabilities	21,614	20,121
Deferred revenue	603	—
Operating lease liabilities	1,744	1,624
Total current liabilities	29,269	26,337
Other liabilities:		
Operating lease liabilities, net of current portion	4,610	5,924
Derivative liability	11,594	20,192
Deferred revenue, net of current portion	13,533	13,000
Notes payable, net of discount	25,192	25,000
2026 convertible notes, net	28,152	26,435
Total liabilities	112,350	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 September 30, 2022 and December 31, 2021, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 77,010,385 and 76,731,940 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	8	8
Additional paid-in capital	647,521	633,795
Accumulated deficit	(601,300)	(545,804)
Total stockholders' equity	46,229	87,999
Total liabilities and stockholders' equity	$ 158,579	$ 204,887

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