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

November 5, 2020

October Financing Raised $75.2 Million in Proceeds Net of Fees

DEXTENZA® Net Product Revenue in Third Quarter of $5.4 Million, a 280% Increase from the Prior Quarter

Reported Topline Phase 1 Results and Recently Initiated Phase 2 Clinical Trial of OTX-CSI for the Chronic Treatment of Dry Eye Disease

Announced License Agreement and Collaboration for DEXTENZA and OTX-TIC in Select Asian Countries

BEDFORD, Mass.--(BUSINESS WIRE)--Nov. 5, 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 quarter ended September 30, 2020 and provided a business update.

"It has been a productive quarter for Ocular Therapeutix with a number of key developments that we believe will drive significant long-term value," said Antony Mattessich, President and CEO. "DEXTENZA ®s momentum continues as a result of key initiatives implemented earlier in the year and exemplified by a robust 280% increase over the prior quarter. This momentum has continued into the fourth quarter with nearly 4,200 billable inserts sold to ASCs and HOPDs in the month of October. Within our pipeline, we have four clinical-stage programs that are each highly differentiated ophthalmology specialty products in markets where current annual global sales are estimated to exceed $20 billion. Each of these programs address the key unmet need in the indication it is targeting. With an improved cash position following the completion of a successful financing in October and the recently concluded license agreement with AffaMed Therapeutics, we believe we are now in a position to fund each of these four planned programs through its respective read-out of Phase 2 clinical trial data to capture the full potential benefit of the Phase 2 value inflection."

Recent Business Updates

Reported the American Medical Association (AMA) has established a permanent Category I Current Procedural Terminology (CPT) procedure code for 0356T for the administration of drug-eluting intracanalicular inserts, including DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg, effective January 1, 2022. The current professional fee for CPT code 0356T is expected to remain eligible to be paid per the established local fee schedule, where available, until the newly issued CPT Category I code goes into effect on January 1, 2022.

Completed common stock financing in late October. The Company raised $75.2 million, net of fees, from a public offering of common stock in mid-October that augments cash and cash equivalents of $70.6 million as of September 30, 2020. The Company believes it now has adequate resources to fund its four planned Phase 2 programs.

Announced License Agreement and Collaboration for DEXTENZA and OTX-TIC in Select Asian Countries. The Company announced a license agreement and a collaboration with AffaMed Therapeutics for the development and commercialization of DEXTENZA® and OTX-TIC in Greater China, South Korea, and the ASEAN markets. Under the terms of the agreement, Ocular Therapeutix is entitled to receive an upfront payment of $12 million and is eligible to receive development, regulatory and commercial milestone payments and clinical development support payments of up to $91 million in the aggregate, as well as royalties from future product sales. Royalties are tiered and range from a low-teen to low-twenties percentage.

Key Program Updates

OTX-TKI (axitinib intravitreal implant): 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 conducting a Phase 1, prospective, multi-center, open-label, dose-escalation clinical trial in Australia intended to evaluate the safety, durability, tolerability, and biological activity of OTX-TKI for the treatment of wet AMD.
- Two cohorts of our Phase 1 clinical trial have been enrolled, a lower-dose cohort of 200 µg with six subjects and a higher-dose cohort of 400 µg with seven subjects. We are currently enrolling a third cohort of twelve subjects, split between parallel arms of six subjects each. Subjects in the first arm of the third cohort will receive a dose of 600 µg, and subjects in the second arm will receive a 400 µg dose combined with an anti-VEGF induction injection. The Company plans to provide a clinical update at the American Academy of Ophthalmology meeting next week.
- The Company plans to file an exploratory IND by the end of 2020 to initiate clinical development of OTX-TKI in the U.S. and to initiate a Phase 2 clinical trial in Australia by mid-2021.

OTX-TIC (travoprost intracameral 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 conducting 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 in patients with primary open angle glaucoma or ocular hypertension.
- The Company has completed the first two cohorts, has fully enrolled the third cohort to assess the impact of a faster degrading implant with the same therapeutic dose as administered in cohort one, and is enrolling a fourth cohort to assess

an additional formulation with a smaller implant of OTX-TIC.
- The Company plans to initiate a Phase 2 clinical trial for OTX-TIC in mid-2021.

OTX-CSI (cyclosporine intracanalicular insert): OTX-CSI is a long-acting, preservative-free cyclosporine intracanalicular insert for the chronic treatment of dry eye disease.

- The Company announced topline results for its Phase 1, U.S.-based, open label, single-center clinical trial intended to evaluate safety, tolerability, durability, and biological activity on October 8, 2020. All subjects completed the 16-week study period with no drop-outs or reported serious adverse effects. Early signs of biological activity were observed including increased tear production and improvements in the signs of dry eye as measured by corneal fluorescein staining and symptoms of dry eye as measured by eye dryness severity and frequency scores using the visual analog scale.
- The Company has initiated a Phase 2, randomized, masked, multi-center trial to evaluate the safety, efficacy, durability, and tolerability of two different formulations of OTX-CSI versus vehicle insert in approximately 105 subjects for the chronic treatment of dry eye disease. The Company expects topline results in the first half of 2022.

OTX-DED (dexamethasone intracanalicular insert): OTX-DED incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient into a hydrogel, drug-eluting, preservative-free intracanalicular insert. OTX-DED is designed to release dexamethasone over a period of two-to-three weeks for the short-term treatment of the signs and symptoms of dry eye disease.

- The Company remains on track to file a Phase 2-enabling IND by the end of 2020 and, if cleared, initiate a Phase 2 trial in the first quarter of 2021.

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 third quarter ended September 30, 2020 of $5.4 million, a 280% sequential increase over the prior quarter. Revenue reflects a record quarter of DEXTENZA in-market sales as Ambulatory Surgery Centers (ASCs) and Hospital Outpatient Departments (HOPDs) purchased nearly 10,000 billable inserts during the period. The increases observed in the third quarter of 2020 build upon the momentum seen in the prior quarter starting in May and reflect continued increases in surgical volumes as ASCs and HOPDs strive to return to pre-COVID shutdown volumes.
- Three Medicare Administrative Contractors (MACs) covering approximately 50% of all Medicare beneficiaries have now published physician fee schedules for the reimbursement of procedure code 0356T for the administration of drug-eluting intracanalicular inserts, including DEXTENZA. In addition, three of the remaining four MACs have retired their non-coverage policies for 0356T.
- On November 4, 2020, the Company announced that the American Medical Association (AMA) CPT Editorial Panel has accepted the addition of a permanent Category I CPT procedure code to replace the currently available Category III CPT code (0356T) for the administration of drug-eluting intracanalicular inserts, including DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg, effective January 1, 2022.
- The Company remains on track to submit an sNDA for DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis by the end of 2020.

Third Quarter Ended September 30, 2020 Financial Results

Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was $5.9 million for the third quarter as compared to $1.6 million in the second quarter. Net product revenue of DEXTENZA was $5.4 million in the third quarter versus $1.4 million in the second quarter. The Company believes the significant increase of over 280% quarter-over-quarter was driven by the continued re-opening of ACSs and HOPDs as well as the impact of the DEXTENZA rebate program and the more recent physician payment of the procedure CPT code 0356T by some of the MACs. Net product revenue of ReSure® Sealant in the third quarter was $0.5 million versus $0.2 million in the second quarter.

Research and development expenses for the third quarter were $7.0 million versus $10.2 million for the comparable period in 2019 and primarily reflect a decrease in personnel and other unallocated costs due the organizational restructuring announced in November 2019.

Selling and Marketing expenses for the third quarter were $6.5 million versus $6.8 million for the comparable period in 2019, stemming primarily from a decrease in travel, consulting, marketing and conference expenses as a result of the COVID-related slowdown offset somewhat by increased personnel expenses.

General and Administrative expenses were $6.0 million in the third quarter versus $6.2 million in the comparable period in 2019, reflecting a decrease in personnel expenses offset by an increase in professional costs.

The Company reported a net loss of $(11.9) million, or a loss of $(0.19) per share on a basic basis and $(0.21) on a diluted basis for the third quarter. This compares to a net loss of $(18.8) million, or a loss of $(0.40) per share on a basic basis and $(0.45) on a diluted basis, for the same period in 2019. The net loss for the third quarter included $2.6 million in non-cash charges for stock-based compensation and depreciation compared to $3.8 million for the same quarter in 2019. In addition, the net loss for the third quarter includes a non-cash gain of $3.8 million related to the change in the fair value of the derivative liability associated with our convertible notes.

As of November 1, 2020, the Company had approximately 71.4 million shares outstanding.

As of September 30, 2020, the Company had $70.6 million in cash and cash equivalents versus $84.3 million at the end of the second quarter of 2020. The cash at the end of the quarter does not include incremental cash of $75.2 million net of offering discounts, commissions and estimated expenses that was raised in a follow-on public offering of common stock that was completed in October of 2020 and the anticipated proceeds of $12 million in upfront payments from the recently announced licensing agreement with AffaMed.

Based on current plans and 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 September 30, 2020 in combination with the net proceeds from the recent equity offering, enables the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements into 2023. This cash guidance is subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic and other assumptions related to revenues and expenses associated with the commercialization of DEXTENZA, and the pace and expense of our research and clinical development programs, as well as 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 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 8255125. An archive of the webcast will be available until December 20, 2020 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 FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery. Ocular Therapeutix recently completed a Phase 3 clinical trial evaluating DEXTENZA 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-TIC (travoprost intracameral implant) for the reduction of intraocular pressure in patients with primary open-angle glaucoma and ocular hypertension and OTX-TKI (axitinib intravitreal implant) for the treatment of wet AMD and other retinal diseases. Ocular Therapeutix is currently evaluating OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease in a Phase 2 clinical trial. Also, Ocular Therapeutix is currently developing OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease and, in collaboration with Regeneron, OTX-AFS (aflibercept suprachoroidal injection) as an extended-delivery formulation of aflibercept for the treatment of retinal diseases. Ocular Therapeutix's first product, ReSure® Sealant, is an FDA-approved device 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 conduct of post-approval studies of 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-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-CSI for the chronic treatment of dry eye disease, 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 OTX-AFS 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 size of potential markets for our product candidates; 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 net product revenue and unit sales and other financial and operational metrics of DEXTENZA; 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 and unit 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 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 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 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue:				
Product revenue, net	$ 5,876	$ 829	$ 10,054	$ 1,971
Total revenue, net	5,876	829	10,054	1,971
Costs and operating expenses:				
Cost of product revenue	450	806	1,403	1,486
Research and development	6,951	10,235	21,070	30,966
Selling and marketing	6,520	6,777	19,803	17,349
General and administrative	5,961	6,155	16,282	16,571
Total costs and operating expenses	19,882	23,973	58,558	66,372
Loss from operations	(14,006)	(23,144)	(48,504)	(64,401)
Other income (expense):				
Interest income	6	308	162	1,016
Interest expense	(1,715)	(1,651)	(5,042)	(4,296)
Change in fair value of derivative liability	3,771	5,717	(16,640)	7,334
Other income (expense), net	—	(8)	—	(8)
Total other income (expense), net	2,062	4,366	(21,520)	4,046
Net loss and comprehensive loss	$ (11,944)	$ (18,778)	$ (70,024)	$ (60,355)
Net loss per share, basic	$ (0.19)	$ (0.40)	$ (1.22)	$ (1.37)
Weighted average common shares outstanding, basic	62,992,558	46,944,536	57,440,885	44,052,470
Net loss per share, diluted	$ (0.21)	$ (0.45)	$ (1.22)	$ (1.37)
Weighted average common shares outstanding, diluted	68,761,790	52,713,768	57,440,885	44,052,470

Ocular Therapeutix, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 70,642	$ 54,437
Accounts receivable, net	7,779	2,548
Inventory	1,154	954
Prepaid expenses and other current assets	2,328	2,231
Total current assets	81,903	60,170
Property and equipment, net	8,490	10,151
Restricted cash	1,764	1,764
Operating lease assets	6,062	6,655
Total assets	$ 98,219	$ 78,740
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,238	$ 3,268
Accrued expenses and other current liabilities	12,165	7,635
Operating lease liabilities	1,297	1,126
Notes payable, net of discount, current	6,206	—
Total current liabilities	22,906	12,029
Operating lease liabilities, net of current portion	7,909	8,905
Derivative liability	28,764	12,124
Notes payable, net of discount	18,964	25,007
2026 convertible notes, net	23,802	24,305
Total liabilities	102,345	82,370
Commitments and contingencies		
Stockholders' equity (deficit):		

Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 63,070,980 and 50,333,559 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	6	5
Additional paid-in capital	449,507	379,980
Accumulated deficit	(453,639)	(383,615)
Total stockholders' deficit	(4,126)	(3,630)
Total liabilities and stockholders' equity (deficit)	$ 98,219	$ 78,740

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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, Inc.