Ocular Therapeutix™ Reports Fourth Quarter and Year End 2020 Financial Results and Business Update

March 11, 2021

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 11, 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 fourth quarter and year ended December 31, 2020 and provided updates on its leading ophthalmology pipeline.

“The fourth quarter marked considerable commercial, clinical and regulatory progress for the Company,” said Antony Mattessich, President and Chief Executive Officer. “Physician interest in DEXTENZA® remains high, and despite the challenging backdrop of COVID, adoption by ASCs and HOPDs continues to drive strong growth in reported sales. In the fourth quarter of 2020, in-market purchases were in excess of 14,000 billable units, representing sequential quarterly growth of greater than 40%. Beyond DEXTENZA, we have a unique pipeline of ophthalmology product candidates that each target indications within multi-billion dollar segments of the ophthalmology market. In 2021 we look forward to initiating multiple Phase 2 programs.”

Recent Business Updates

Presented Interim Data from the Phase 1 Clinical Trial of OTX-TKI (axitinib intravitreal implant) in Patients with Wet Age-Related Macular Degeneration (wet AMD) at Angiogenesis, Exudation, and Degeneration 2021. Interim data from the Phase 1 clinical trial continued to support that the product candidate has been generally well tolerated and observed to have a favorable safety profile, shows preliminary biological activity with a decrease in retinal fluid observed by two months in some subjects in cohorts 2 and 3 and initial durability in several subjects in cohort 2 over six months and in one subject over 13 months. The presentation can be accessed by visiting the Investors section of the Company’s website at investors.ocutx.com.

Presented Interim Data from the Phase 1 Clinical Trial of OTX-TIC (travoprost intracameral implant) in Patients with Primary Open Angle Glaucoma or Ocular Hypertension at the 10th Annual Glaucoma 360 New Horizons Forum. Interim data from the Phase 1 clinical trial from the four fully enrolled cohorts generally showed a mean reduction in intraocular pressure from baseline of 7-11 mm Hg with onset of action as early as two days after insertion and sustained durability of activity of six months or longer with a single implant in many subjects. Overall, no serious ocular adverse events were noted. The presentation can be accessed by visiting the Investors section of the Company’s website at investors.ocutx.com.

Dosed First Patient in Phase 2 Clinical Trial Evaluating OTX-DED (dexamethasone intracanalicular insert). The Phase 2 clinical trial is a U.S.-based, randomized, double-masked, vehicle-controlled, multi-center trial evaluating two different formulations of a new dexamethasone drug product candidate OTX-DED (dexamethasone intracanalicular insert) in approximately 150 subjects with dry eye disease. In accordance with the clinical trial protocol, the subjects are to be followed for approximately two months after randomization. This trial is designed to assess the safety and efficacy of OTX-DED for the short-term treatment of signs and symptoms of dry eye disease by evaluating bulbar conjunctival hyperemia, eye dryness score/frequency of eye dryness using visual analog scale, and total corneal fluorescein staining.

U.S. Commercial Uptake of DEXTENZA. Net product revenue of DEXTENZA® (dexamethasone ophthalmic insert) 0.4mg for the quarter was $6.9 million, a 28% sequential increase over the third quarter of 2020. The Company believes the record quarter of DEXTENZA sales was driven by continued increases in surgical volumes, new account growth, the positive impact of the DEXTENZA rebate program and greater awareness by physicians of procedure reimbursement. Further building on the reimbursement, in November the American Medical Association announced its intention to establish a permanent Category 1 Current Procedure Terminology (CPT) Code, effective January 1, 2022, for the administration of drug-eluting intracanalicular inserts, including DEXTENZA.

Notified of target PDUFA date for DEXTENZA allergic conjunctivitis sNDA. On March 4th, the Company announced the supplemental New Drug Application (sNDA) for DEXTENZA® (dexamethasone ophthalmic insert) 0.4 mg has been accepted for review by the U.S. Food and Drug Administration (FDA). The FDA has set an action date under the Prescription Drug User Fee Act (PDUFA) of October 18, 2021.

Promoted Michael Goldstein, MD, MBA, to President, Ophthalmology and Appointed Rabia Gurses-Ozden, MD as Senior Vice President, Clinical Development. Following his promotion, Dr. Goldstein is maintaining his role as Chief Medical Officer while adding responsibilities for commercial operations in alignment with the overall Company strategy. Dr. Ozden has become responsible for leading the clinical development of Ocular Therapeutix’s current and growing pipeline of indications focusing on the front and back of the eye. The strategic appointments reflect Ocular’s commitment to developing innovative therapies for diseases and conditions of the eye and are expected to play a key role in supporting Ocular’s potential growth.

Received $12 Million Initial Upfront Payment from Recently Signed AffaMed Collaboration. In October, the Company entered into a licensing agreement with AffaMed Therapeutics for rights to develop and commercialize DEXTENZA and OTX-TIC in greater China, South Korea and the ASEAN markets. Beyond the $12 million in upfront payments, the Company has the potential to receive up to an additional $91 million in future aggregate milestones and payments and to receive tiered double-digit royalties on future sales.

Raised an Additional $86.3 Million in Net Proceeds from Equity Offering. In December, the Company raised $86.3 million net in a follow-on equity offering at a public offering price of $21.50 per share. The Company had $228.1 million in cash and cash equivalents as of December 31, 2020.

Key Program Updates

- ***OTX-TKI (axitinib intravitreal implant) for the potential treatment of wet age-related macular degeneration (wet***

AMD) and other retinal diseases.

- The Company filed an exploratory IND (eIND) and received clearance from the FDA to initiate a Phase 1 clinical trial of OTX-TKI in the United States. A planned U.S.-based Phase 1 clinical trial is anticipated to start in mid-2021 and to consist of 20 subjects: 15 dosed with 600 µg plus an anti-VEGF induction injection and 5 dosed with aflibercept every eight weeks.

- ***OTX-TIC (travoprost intracameral implant) for the treatment of patients with primary open angle glaucoma or ocular hypertension.***
  - The Company completed enrollment of all four cohorts of its Phase 1 clinical trial.
  - The Company plans to initiate a randomized, double-masked, active-controlled Phase 2 clinical trial in mid-2021 in the United States with a total of 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 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 hydrogel vehicle insert in approximately 140 subjects for the chronic treatment of dry eye disease.
  - Enrollment in the Phase 2 study has progressed ahead of schedule and topline data is now expected in the fourth quarter of 2021 versus prior guidance of the first half of 2022.
- ***OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease.***
  - The Company dosed the first subject in U.S.-based, randomized, double-masked, vehicle-controlled, multi-center Phase 2 clinical trial in approximately 150 subjects with dry eye disease.
  - Data from the Phase 2 clinical trial is expected in the first half of 2022.

Fourth Quarter and Year Ended December 31, 2020 Financial Results

Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was approximately $7.4 million for the three months ended December 31, 2020, reflecting a 25% sequential increase over the third quarter and a 226% increase over the fourth quarter 2019. Net product revenue of DEXTENZA® in the fourth quarter 2020 was $6.9 million versus $5.4 million in the third quarter 2020 and reflects an approximate 28% sequential increase. Total net product revenue for the fourth quarter of 2020 also includes net product revenue of $0.5 million from ReSure® Sealant. Overall, net product revenue for the year was $17.4 million versus $4.2 million for 2019 and primarily reflects a strong uptake in DEXTENZA sales during the second half of 2020.

Research and development expenses for the fourth quarter were $7.6 million versus $10.1 million for the comparable period in 2019 primarily driven by the reduction in force executed in the fourth quarter of 2019 and reduced clinical trial costs associated with the completion of the Phase 3 DEXTENZA allergic conjunctivitis trial and the Phase 3 OTX-TP trial, offset by increases in the costs associated with the Phase 1 clinical trials of OTX-TKI, OTX-TIC and OTX-CSI as well as the commencement of the Phase 2 clinical trial of OTX-CSI. Overall R&D expenses for the full year decreased $12.4 million to $28.7 million from $41.1 million in 2019, reflecting the trends identified above.

Selling and marketing expenses for the fourth quarter were $6.8 million as compared to $7.1 million for the same quarter in 2019. The modest decrease relates to reduced consulting fees and travel-related costs offset by increased personnel costs. Overall, selling and marketing expenses for the full year increased to $26.6 million from $24.5 million in 2019, driven primarily by increased personnel costs offset by reduced spending on consulting, conferences and related costs.

Finally, general and administrative expenses were $6.6 million for the fourth quarter versus $5.6 million in the comparable quarter of 2019. The increase in expenses stemmed primarily from increased personnel expenses and consulting fees. Overall, G&A expenses for the full year increased $0.8 million to $22.9 million from $22.1 million in 2019, again reflecting primarily increased personnel and consulting fees.

With respect to financial results for the fourth quarter, the Company reported a net loss of $(85.6) million, or a loss of $(1.21) per share on a basic and diluted basis. This compares to a net loss of $(26.0) million, or a loss of $(0.54) per share on a basic and diluted basis for the same period in 2019. As operating expenses were modestly down quarter over quarter, the significant increase in loss was driven almost exclusively by a non-cash charge of $69.5 million related to the change in the fair value of the derivative liability associated with the Company's convertible notes. This change in fair value was due primarily to a 172% increase in the Company's common stock price during the fourth quarter of 2020 as compared to the third quarter of 2020. We expect the change in fair value of the derivative liability to continue to fluctuate until it is settled based on the extent changes occur in the underlying assumptions in calculating fair value including the price of the Company's common stock. The net loss for the fourth quarter also included $2.8 million in non-cash charges for stock-based compensation and depreciation compared to $2.6 million for the same quarter in 2019. Overall, the Company reported a net loss of $(155.6) million or a loss of $(2.56) per share on a basic and diluted basis for the full year ended December 31, 2020 versus a net loss of $(86.4) million or a loss of $(1.91) per share on a basic and diluted basis in 2019.

As of March 2, 2021, the Company had 76.1 million shares outstanding.

As of the full year ended December 31, 2020, the Company had $228.1 million in cash and cash equivalents versus $54.4 million at December 31, 2019. These cash amounts exclude restricted cash of $1.8 million. The cash balance benefited during the fourth quarter from $161.7 million in net proceeds from two follow-on equity offerings, one in October 2020 for $75.4 million in net proceeds and one in December 2020 for $86.3 million in net proceeds. Fourth quarter cash also benefited from proceeds of $12.0 million in upfront payments from the recently announced licensing agreement with AffaMed. For the full year ended December 31, 2020, cash and cash equivalents benefited from total net proceeds from financing activities of $228.0 million, including $48.3 million in net proceeds from a follow-on equity offering in May 2020 and $14.4 million in net proceeds from the sales of common stock under the Company's 2019 Sales Agreement earlier in the year. The May, October and December equity offerings were executed at public offering prices per share of $5.50, $9.75 and $21.50, respectively.

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 December 31, 2020, 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 and expenses associated with the commercialization of DEXTENZA, and the pace of research and clinical development programs, and 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 7189257. An archive of the webcast will be available until May 10, 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 FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery. Ocular Therapeutix has received a PDUFA target action date of October 18, 2021, for an sNDA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional approved indication of DEXTENZA. 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 each of 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 two Phase 2 clinical trials. Also, in collaboration with Regeneron, OTX-AFS (aflibercept suprachoroidal injection) is in pre-clinical development 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 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 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 other financial 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 under transitional pass-through and to maintain the effectiveness of established 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 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 severity and duration of the COVID-19 pandemic including its effect on the Company's and relevant regulatory authorities' operations, any additional financing needs 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019

Revenue:				
Product revenue, net	$ 7,349	$ 2,256	$ 17,403	$ 4,227
Total revenue, net	7,349	2,256	17,403	4,227
Costs and operating expenses:				
Cost of product revenue	680	839	2,083	2,325
Research and development	7,624	10,125	28,694	41,091
Selling and marketing	6,811	7,143	26,614	24,491
General and administrative	6,578	5,551	22,859	22,122
Total costs and operating expenses	21,693	23,657	80,250	90,029
Loss from operations	(14,344)	(21,401)	(62,847)	(85,802)
Other income (expense):				
Interest income	6	213	168	1,229
Interest expense	(1,725)	(1,805)	(6,768)	(6,101)
Change in fair value of derivative liability	(69,549)	(3,024)	(86,189)	4,310
Other income (expense), net	—	—	—	(8)
Total other income (expense), net	(71,268)	(4,616)	(92,789)	(570)
Net loss and comprehensive loss	$ (85,612)	$ (26,017)	$ (155,636)	$ (86,372)
Net loss per share, basic	$ (1.21)	$ (0.54)	$ (2.56)	$ (1.91)
Weighted average common shares outstanding, basic	70,614,333	48,489,846	60,752,225	45,273,231

OCULAR THERAPEUTIX, INC.

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 228,057	$ 54,437
Accounts receivable, net	12,252	2,548
Inventory	1,201	954
Prepaid expenses and other current assets	4,650	2,231
Total current assets	246,160	60,170
Property and equipment, net	8,095	10,151
Restricted cash	1,764	1,764
Operating lease assets	5,844	6,655
Total assets	$ 261,863	$ 78,740
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,709	$ 3,268
Accrued expenses and other current liabilities	14,307	7,635
Operating lease liabilities	1,358	1,126
Notes payable, net of discount, current	8,290	—
Total current liabilities	26,664	12,029
Other liabilities:		
Operating lease liabilities, net of current portion	7,548	8,905
Derivative liability	98,313	12,124
Deferred revenue	12,000	—
Notes payable, net of discount	16,936	25,007
2026 convertible notes, net	24,307	24,305
Total liabilities	185,768	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 December 31, 2020 and December 31, 2019, respectively	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 75,996,732 and 50,333,559 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	8	5
Additional paid-in capital	615,338	379,980
Accumulated deficit	(539,251)	(383,615)

Total stockholders' equity (deficit)	76,095	(3,630)
Total liabilities and stockholders' equity (deficit)	$ 261,863	$ 78,740

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