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

May 5, 2021

DEXTENZA® Achieved Quarterly Record of 16,634 Billable Units Sold to End Customers, Representing Quarterly Sequential Growth of 15%.

BEDFORD, Mass.--(BUSINESS WIRE)--May 5, 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 first quarter of 2021, and provided updates on its strong ophthalmology pipeline.

"Our progress in the first quarter of 2021 was significant," said Antony Mattessich, President and Chief Executive Officer. "Revenue for DEXTENZA® was up over 200% against the prior year period and we achieved record quarterly, in-market sales in excess of 16,000 billable units, representing 15% sequential quarterly growth. Encouragingly, the momentum we saw in the first quarter has continued into the second quarter with estimated sales in excess of 8,000 billable units in April alone. Beyond DEXTENZA, we have made progress in advancing our pipeline of product candidates that continue to show potential to set the standard of care in their respective disease areas. We have had a large presence at this year's ongoing ARVO meeting with seven total presentations highlighting both pre-clinical and clinical updates in our key programs. In 2021 we look forward to continued momentum with DEXTENZA and further development of our pipeline which includes the planned initiation of two Phase 2 programs in wet-AMD and glaucoma and the expected completion of a Phase 2 clinical trial in dry eye disease."

Recent Business Updates

Presented Pre-Clinical and Clinical Data at the 2021 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting. Six company presentations and one presentation from an investigator-initiated trial are being held at the 2021 Association for Research in Vision and Ophthalmology (ARVO) Virtual Meeting this week. Updated interim analyses of Phase 1 data for both OTX-TKI for the treatment of wet age-related macular degeneration (wet AMD) and other retinal diseases and OTX-TIC for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension were presented. Both presentations provided additional data that continue to support the development of products that could become the standard of care in these large markets.

Data are also being presented on the Company's products targeting ocular surface disease including pre-clinical pharmacokinetic data on OTX-CSI for the chronic treatment of dry eye disease and OTX-DED for the short-term treatment of signs and symptoms of dry eye disease. Additionally, we are presenting a post-hoc analysis of data on DEXTENZA® (dexamethasone ophthalmic insert) for the treatment of allergic conjunctivitis. The use of DEXTENZA in allergic conjunctivitis is currently under U.S. Food and Drug Administration (FDA) review with a target action Prescription Drug User Fee Act (PDUFA) date of October 18, 2021. This presentation evaluates the safety of the product candidate across the four clinical trials conducted.

U.S. Commercial Uptake of DEXTENZA. Net product revenue of DEXTENZA® for the quarter was $6.7 million, an approximately 220% increase over the first quarter of 2020. Net sales for the quarter were flat relative to the previous quarter primarily due to variations in distributor inventory levels. DEXTENZA in-market unit volume to surgery centers, which is the best determinant of true underlying demand, achieved a record in the first quarter of 16,634 billable inserts and grew at approximately 15% sequentially over the previous quarter. As previously reported, January and February in-market billable inserts were 4,582 and 4,901, respectively. In-market demand then rebounded strongly in March with sales of billable inserts achieving a record month of 7,151 units.

The Company is also reporting that April in-market, billable units are estimated to have exceeded 8,000 units, setting a new monthly record.

Dosed First Patient in Phase 2 Clinical Trial Evaluating OTX-DED (dexamethasone intracanalicular insert). The Phase 2 clinical trial is a U.S.-based, prospective, randomized, double-masked, vehicle-controlled, multi-center trial evaluating two different formulations of a new dexamethasone drug product candidate OTX-DED in approximately 150 subjects with dry eye disease. 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, the visual analog score of eye dryness and severity, and total corneal fluorescein staining.

Key Program Updates

- ***OTX-TKI (axitinib intravitreal implant) for the potential treatment of wet AMD and other retinal diseases.***
  - The Company filed an exploratory IND (eIND) in November 2020 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.
- ***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 the fourth quarter of 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 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 dosed the first subject in a U.S.-based, prospective, 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.
- ***DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg for the treatment of ocular itching associated with allergic conjunctivitis.***
    - The FDA has set a target action PDUFA date of October 18, 2021.
- ***ReSure® Sealant is designed to prevent wound leaks in corneal incisions following cataract surgery.***
    - The Company has received notification from FDA confirming that the Company has fulfilled all post-approval study requirements for ReSure® Sealant, with a requirement to update the ReSure label reflecting the study results.

First Quarter Ended March 31, 2021 Financial Results

Gross product revenue net of discounts, rebates, and returns, which the Company refers to as total net product revenue, was $7.3 million for the three months ended March 31, 2021, representing a greater than 175% increase over the first quarter of 2020. Net product revenue of DEXTENZA® in the first quarter was $6.7 million versus $2.1 million in the comparable quarter 2020 and reflects an approximate 220% increase. Total net product revenue for the first quarter of 2021 also includes net product revenue of $0.6 million from ReSure® Sealant.

Research and development expenses for the first quarter of 2021 were $10.9 million versus $6.1 million for the comparable period in 2020 primarily driven by increased headcount as well as increased clinical trial costs associated with the ongoing Phase 2 clinical trial for OTX-CSI, the commencement of the Phase 2 clinical trial of OTX-DED and the ongoing Phase 1 clinical trials of OTX-TKI and OTX-TIC.

Selling and marketing expenses in the first quarter of 2021 were $8.1 million as compared to $7.1 million for the same quarter in 2020, primarily reflecting increased personnel costs associated with expansion of the sales force.

General and administrative expenses were $7.7 million for the first quarter of 2021 versus $5.2 million in the comparable quarter of 2020. The increase in expenses stemmed primarily from increased personnel expenses and professional fees.

The Company reported net income of $3.1 million, or a profit of $0.04 per share on a basic basis and a net loss of $(20.8) million, or a loss of $(0.24) per share on a diluted basis in the first quarter of 2021. This compares to a net loss of $(21.5) million, or a loss of $(0.41) per share on a basic and diluted basis for the same period in 2020. As operating expenses increased quarter over quarter, the modest profit was driven by a non-cash gain of $25.0 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 decline in the Company's common stock price during the first quarter of 2021. Non-cash charges for stock-based compensation and depreciation and amortization were $3.7 million in the first quarter of 2021 versus $2.4 million for the same quarter in 2020.

As of May 1, 2021, the Company had 76.3 million shares outstanding.

As of March 31, 2021, the Company had $209.4 million in cash and cash equivalents versus $228.1 million at December 31, 2020. Based on 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 March 31, 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 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 3944056. An archive of the webcast will be available until August 5, 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 target action date under the Prescription Drug User Fee Act, commonly known as PDUFA, of October 18, 2021, for a supplemental new drug application 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 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 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, 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, in-market sales and other financial and operational metrics of DEXTENZA; 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 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, 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 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.

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue:		
Product revenue, net	$ 7,342	$ 2,609
Total revenue, net	7,342	2,609
Costs and operating expenses:		
Cost of product revenue	892	819
Research and development	10,927	6,098
Selling and marketing	8,086	7,130
General and administrative	7,665	5,176
Total costs and operating expenses	27,570	19,223
Loss from operations	(20,228)	(16,614)
Other income (expense):		
Interest income	12	139
Interest expense	(1,679)	(1,633)
Change in fair value of derivative liability	25,016	(3,404)
Total other income (expense), net	23,349	(4,898)
Net income (loss) attributable to common stockholders	$ 3,121	$ (21,512)
Net income (loss) per share, basic	$ 0.04	$ (0.41)
Weighted average common shares outstanding, basic	76,071,017	51,900,882
Net income (loss) per share, diluted	$ (0.24)	$ (0.41)
Weighted average common shares outstanding, diluted	87,245,706	51,900,882

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Consolidated Balance Sheets

(In thousands, except share and per share data)
(unaudited)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 209,378	$ 228,057
Accounts receivable, net	13,631	12,252
Inventory	1,123	1,201
Prepaid expenses and other current assets	4,000	4,650
Total current assets	228,132	246,160
Property and equipment, net	7,527	8,095
Restricted cash	1,764	1,764
Operating lease assets	5,617	5,844
Total assets	$ 243,040	$ 261,863
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,152	$ 2,709
Accrued expenses and other current liabilities	13,574	14,307
Operating lease liabilities	1,421	1,358
Notes payable, net of discount, current	8,290	8,290
Total current liabilities	27,437	26,664
Other liabilities:		
Operating lease liabilities, net of current portion	7,169	7,548
Derivative liability	73,297	98,313
Deferred revenue	12,000	12,000
Notes payable, net of discount	14,907	16,936
2026 convertible notes, net	24,822	24,307
Total liabilities	159,632	185,768
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 76,236,710 and 75,996,732 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	8	8
Additional paid-in capital	619,530	615,338
Accumulated deficit	(536,130)	(539,251)
Total stockholders' equity	83,408	76,095
Total liabilities and stockholders' equity	$ 243,040	$ 261,863

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