Ocular Therapeutix™ Reports First Quarter 2017 Financial Results

May 5, 2017

PDUFA Target Action Date of July 19, 2017 for the DEXTENZA™ NDA for the Treatment of Ocular Pain Following Ophthalmic Surgery; Commercial Launch Preparation Activities Underway

Enrollment Continues in First Phase 3 Clinical Trial of OTX-TP (travoprost insert) for the Treatment of Glaucoma and Ocular Hypertension

Conference Call Today at 8:30 am Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--May 5, 2017-- Ocular Therapeutix, Inc. (NASDAQ: OCUL), a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the first quarter ended March 31, 2017.

“This is an important time for Ocular Therapeutix as we approach the PDUFA target action date for our lead product candidate, DEXTENZA, for the treatment of ocular pain following ophthalmic surgery,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “Should DEXTENZA be approved, its commercial launch will enable our transition into a fully-integrated, commercial-stage, revenue-generating company. DEXTENZA has now been extensively studied for the treatment of post-surgical ocular pain and inflammation in over 550 clinical trial participants. If approved, we believe DEXTENZA will address the compliance issues associated with steroid eyedrops and serve as an attractive alternative for both patients and ophthalmologists.”

Recent Highlights and Anticipated Near-Term Milestones for Key Development Programs

DEXTENZA™

- A New Drug Application (NDA) for DEXTENZA (dexamethasone insert) 0.4mg for intracanalicular use is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of ocular pain following ophthalmic surgery. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of July 19, 2017 for a decision regarding the potential approval of DEXTENZA. Following a re-inspection of manufacturing operations by the FDA which was completed earlier this week, Ocular Therapeutix received an FDA Form 483 containing inspectional observations focused on procedures for manufacturing processes and analytical testing, related to manufacture of drug product for commercial production. The Company plans to evaluate and respond to the FDA within 15 days with corrective action plans to complete the inspection process. Adequate resolution of the outstanding Form 483 inspectional observations is a prerequisite to the approval of the NDA for DEXTENZA.
    - Subject to the approval of the NDA for post-surgical ocular pain by the FDA, Ocular Therapeutix intends to submit an NDA supplement for DEXTENZA to broaden its label to include an indication for post-surgical ocular inflammation.
- Ocular Therapeutix plans to present additional data from its most recent Phase 3 study evaluating the efficacy and safety of DEXTENZA for the treatment of ocular pain and inflammation following cataract surgery, at the upcoming American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting, being held today through Tuesday, May 9, in Los Angeles, CA.
    - Additional presentations will be made at the meeting regarding recent positive results of a patient experience study of DEXTENZA as well as the importance of the assessment of ocular pain.
- In addition, DEXTENZA is in Phase 3 clinical development for the treatment of allergic conjunctivitis. In May 2017, the Company initiated a non-significant risk device study to confirm the effect on efficacy of the placebo insert used in previous studies compared with a rapidly resorbing placebo insert.
    - Subject to favorable results from this study, the Company plans to conduct an additional Phase 3 clinical trial to further evaluate DEXTENZA for the treatment of allergic conjunctivitis.

OTX-TP (travoprost insert)

- Ocular Therapeutix continues to enroll patients in its first Phase 3 clinical trial for OTX-TP (travoprost insert) for the treatment of glaucoma and ocular hypertension.
- The Company plans to commence its second Phase 3 clinical trial with OTX-TP for the treatment of glaucoma and ocular hypertension in the second half of 2017.
- If approved, OTX-TP may potentially become the first non-invasive, sustained release therapy for the treatment of glaucoma.

Sustained release intravitreal depots for the treatment of serious retinal diseases

- In partnership with Regeneron Pharmaceuticals, Ocular Therapeutix continues to advance the development of an extended release hydrogel-based formulation of Regeneron's protein-based anti-vascular endothelial growth factor (VEGF) trap, aflibercept, for the treatment of wet age-related macular degeneration (wet AMD) and other serious retinal diseases.
    - Regeneron's aflibercept is currently approved by the FDA for certain indications under the brand name EYLEA®.
- In parallel, Ocular Therapeutix continues to advance the development of its proprietary hydrogel platform technology for intravitreal drug delivery with tyrosine-kinase inhibitors (TKIs).
    - Ocular Therapeutix plans to present efficacy, tolerability and pharmacokinetics data with its OTX-TKI product candidate at the upcoming Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting, being held May 7-11, in Baltimore, MD.
    - The Company expects to enter Phase 1 clinical testing with OTX-TKI in the second half of 2017.

First Quarter 2017 Financial Results

- As of March 31, 2017, cash, cash equivalents and marketable securities totaled $80.4 million. This includes the net proceeds from a recently completed registered underwritten public offering of $23.3 million of shares of common stock pursuant to a shelf registration statement that was previously filed with and declared effective by the Securities and Exchange Commission. Cash used in operating activities was $14.6 million in the first quarter of 2017, compared to $9.3 million for the first quarter of 2016. The Company expects that cash, cash equivalents and marketable securities will be sufficient to fund operating expenses, debt service obligations and capital expenditures through the second quarter of 2018. The Company will need to obtain additional capital to support the planned commercial launch of DEXTENZA, subject to FDA approval.
- There was $18.0 million in outstanding debt as of March 31, 2017. In March 2017, the Company amended the terms of its existing credit facility to increase the total commitment to $38.0 million, including $18.0 million funded at closing, which was used primarily to pay-off outstanding balances as of the closing date, and options on two additional tranches of $10.0 million, the availability of each of which is based on the achievement of regulatory and commercial milestones. The interest-only payment period was extended through February 1, 2018, with provisions to further extend the interest-only period based on the achievement of certain regulatory and commercial milestones.
- Ocular Therapeutix reported a net loss of approximately $(16.0) million, or $(0.58) per share, for the quarter ended March 31, 2017, compared to a net loss of $(10.8) million, or $(0.44) per share, for the quarter ended March 31, 2016. The first quarter 2017 results include $2.0 million in non-cash charges for stock-based compensation and depreciation compared to $1.6 million in such non-cash charges in the first quarter of 2016.
- Total costs and operating expenses for the quarter ended March 31, 2017 were $16.1 million, as compared to $11.0 million for the quarter ended March 31, 2016. Research and development (R&D) expenses for the quarter ended March 31, 2017 were $6.7 million, compared to $7.1 million for the quarter ended March 31, 2016. The Company continues to advance the clinical and preclinical development of its hydrogel platform technology and its portfolio of drug product candidates. Selling and marketing expenses for the quarter ended March 31, 2017 were $6.0 million, compared to $1.4 million for the quarter ended March 31, 2016. The 2017 increase represents the costs of pre-commercial activities in preparation for the planned commercial launch of DEXTENZA, subject to FDA approval.
- Ocular Therapeutix generated $0.5 million in revenue during the three-month period ended March 31, 2017 from product sales of ReSure® Sealant.
- As of March 31, 2017, there were approximately 28.9 million shares issued and outstanding.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 am 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 13632485. An archive of the webcast will be available until May 19, 2017 on the Company's website.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary hydrogel platform technology. Ocular Therapeutix's lead product candidate, DEXTENZA™ (dexamethasone insert) 0.4 mg for intracanalicular use, has completed Phase 3 clinical development for the treatment of ocular pain and inflammation following ophthalmic surgery. The FDA has accepted the Company's NDA resubmission for DEXTENZA for the treatment of ocular pain following ophthalmic surgery and has established a target PDUFA action date of July 19, 2017. If its NDA is approved, the Company will submit an NDA supplement for ocular inflammation. OTX-TP (travoprost insert) is in Phase 3 clinical development for glaucoma and ocular hypertension. Ocular Therapeutix is also evaluating injectable drug delivery depots for back-of-the-eye diseases. Ocular Therapeutix's first product, ReSure® Sealant, is FDA-approved 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 development and regulatory status of the Company's product candidates, such as the Company's expectations and plans regarding regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA™ for the treatment of post-surgical ocular inflammation and pain, including our expectations regarding the NDA

filed with the FDA and the FDA's response to the resubmitted NDA and the potential impact of the re-inspection of manufacturing operations, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel technology, the potential utility of any of the Company's product candidates, potential commercialization of the Company's product candidates, the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, including any potential future payments thereunder, 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, those related to the timing and costs involved in commercializing ReSure® Sealant or any product candidate that receives regulatory approval, the initiation 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 sufficiency of cash resources and 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 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. 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 release.

Statements of Operations and Comprehensive Loss

(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended March 31,	
	2017	**2016**
Revenue:		
Product revenue	$ 475	$ 416
Collaboration revenue	—	42
Total revenue	475	458
Costs and operating expenses:		
Cost of product revenue	115	99
Research and development	6,729	7,073
Selling and marketing	6,027	1,389
General and administrative	3,276	2,406
Total costs and operating expenses	16,147	10,967
Loss from operations	(15,672)	(10,509)
Other income (expense):		
Interest income	92	87
Interest expense	(443)	(418)
Total other expense, net	(351)	(331)
Net loss	$ (16,023)	$ (10,840)
Net loss per share, basic and diluted	$ (0.58)	$ (0.44)
Weighted average common shares outstanding, basic and diluted	27,643,746	24,751,682
Comprehensive loss:		
Net loss	$ (16,023)	$ (10,840)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	(4)	68
Total other comprehensive income (loss)	(4)	68
Total comprehensive loss	$ (16,027)	$ (10,772)

Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	March 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 54,682	$ 32,936
Marketable securities	25,697	35,209
Accounts receivable	244	250
Inventory	96	113
Prepaid expenses and other current assets	2,557	1,390
Total current assets	83,276	69,898
Property and equipment, net	5,693	3,313
Restricted cash	1,728	1,728
Total assets	$ 90,697	$ 74,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,754	$ 2,116
Accrued expenses and deferred rent	4,005	4,635
Notes payable, net of discount, current	897	1,549
Total current liabilities	8,656	8,300
Deferred rent, long-term	1,315	537
Notes payable, net of discount, long-term	16,821	14,094
Total liabilities	26,792	22,931
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at March 31, 2017 and December 31, 2016; no shares issued or outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at March 31, 2017 and December 31, 2016; 28,934,454 and 25,024,100 shares issued and outstanding at March 31, 2017 and December 31, 2016, respectively	3	3
Additional paid-in capital	253,813	225,889
Accumulated deficit	(189,902)	(173,879)
Accumulated other comprehensive loss	(9)	(5)
Total stockholders' equity	63,905	52,008
Total liabilities and stockholders' equity	$ 90,697	$ 74,939

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