



Ocular Therapeutix™ Reports Fourth Quarter and Full Year 2015 Financial Results

March 10, 2016

PDUFA target action date of July 24, 2016 for the NDA for DEXTENZA™ for the treatment of post-surgical ocular pain; DEXTENZA advancing in late-stage clinical trials in multiple indications

Initiation of Phase 3 clinical program for OTX-TP for the treatment of glaucoma and ocular hypertension expected in 3Q 2016

Conference Call Today at 8:00 am Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 10, 2016-- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the fourth quarter of 2015 and the twelve months ended December 31, 2015.

"With a July 2016 PDUFA date for our lead program and several planned and ongoing late-stage clinical trials across multiple indications, 2016 will be an important year for us in the development of our innovative sustained-release ophthalmic therapies," said Amar Sawhney, Ph.D., President and Chief Executive Officer. "Our approach is designed to offer patients an alternative to eye drop therapy with the benefit of simple one-time administration. We are now preparing for the potential FDA approval of DEXTENZA for the treatment of ocular pain following ophthalmic surgery, and are continuing to enroll patients in our ongoing Phase 3 trials with DEXTENZA for post-surgical ocular inflammation and pain, as well as allergic conjunctivitis, with the goal of broadening DEXTENZA's label. We also plan to initiate the first of two planned Phase 3 trials with OTX-TP for the treatment of glaucoma and ocular hypertension later this year."

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

DEXTENZA for the treatment of post-surgical ocular inflammation and pain

- In December 2015, a New Drug Application (NDA) was accepted for filing by the U.S. Food and Drug Administration (FDA) for DEXTENZA (sustained release dexamethasone), Intracanalicular Depot for the treatment of post-surgical ocular pain.
 - The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of July 24, 2016 for the NDA.
 - The data included in the NDA are from one Phase 2 clinical trial and two Phase 3 clinical trials conducted with DEXTENZA for the treatment of post-surgical ocular inflammation and pain.
 - If the FDA grants marketing approval for DEXTENZA for the treatment of post-surgical ocular pain on the PDUFA action date, the Company expects to launch this product in early 2017.
- A third Phase 3 clinical trial for DEXTENZA for post-surgical ocular inflammation and pain is currently enrolling with 285 patients out of a planned total of 436 patients enrolled as of March 7, 2016.
 - If the Company achieves favorable results in the third Phase 3 trial and subject to approval of the NDA for post-surgical ocular pain by the FDA, the Company intends to submit an NDA supplement for DEXTENZA in the first half of 2017 aiming to broaden its label to include the post-surgical inflammation indication.

DEXTENZA for the treatment of allergic conjunctivitis

- In November 2015, Ocular Therapeutix commenced enrollment in a second Phase 3 clinical trial to evaluate the safety and efficacy of DEXTENZA for the treatment of allergic conjunctivitis.
 - The Company reported topline results of its first Phase 3 allergic conjunctivitis clinical trial in October 2015. The primary endpoint of treatment of ocular itching associated with allergic conjunctivitis was successfully achieved in this trial.
 - If the primary efficacy endpoint for ocular itching is met in the second Phase 3 trial and subject to the approval of the NDA submitted for DEXTENZA for the treatment of post-surgical ocular pain, the Company expects to submit an NDA supplement to the FDA for ocular itching associated with allergic conjunctivitis in the fourth quarter of 2016.

DEXTENZA for the treatment of inflammatory dry eye disease

- In December 2015, Ocular Therapeutix reported encouraging topline results from an exploratory Phase 2 clinical trial designed to evaluate a range of objective and subjective measures (signs and symptoms, respectively) for DEXTENZA for the treatment of inflammatory dry eye disease.
 - The trial showed a statistically significant difference between the DEXTENZA treatment arm and the placebo arm in the efficacy measure of total corneal staining change from baseline at day 30.
 - Supportive efficacy measures of conjunctival staining showed clinically meaningful benefit; improvement in the frequency and severity of symptoms of eye dryness, itchiness, and scratchiness were also seen.
 - This trial was designed to optimize the enrollment of patients based on signs.

- o The Company plans to meet with the FDA to discuss the Phase 2 results and potential Phase 3 clinical trial designs for dry eye-related indications.

OTX-TP (sustained release travoprost) for the treatment of glaucoma and ocular hypertension

- Ocular Therapeutix recently announced its Phase 3 clinical development strategy for OTX-TP for the treatment of glaucoma and ocular hypertension following a meeting with the FDA in the first quarter of 2016.
 - o Ocular Therapeutix intends to commence the first of two planned Phase 3 clinical trials in the third quarter of 2016 after holding an End of Phase 2 meeting with the FDA in the second quarter of 2016.
 - o The Company does not expect a timolol comparator or validation arm will be required in the study design and does not anticipate that eye drops, placebo or active, will be administered in either arm.
 - o The Company expects that the FDA will require that OTX-TP show a statistically superior reduction of intraocular pressure (IOP), compared to placebo, as a primary efficacy endpoint, as well as clinically meaningful reduction of IOP.

Fourth Quarter and Full Year 2015 Financial Results

- As of December 31, 2015, cash, cash equivalents and marketable securities totaled \$105.1 million. Cash used in operating activities was \$8.6 million in the fourth quarter of 2015 and \$33.7 million for the year ended December 31, 2015. There was \$15.6 million in outstanding debt as of December 31, 2015 and no principal payments are due until January 2017. 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 third quarter of 2017.
- Ocular Therapeutix reported a net loss of approximately \$10.6 million, or \$(0.43) per share, for the quarter ended December 31, 2015, compared to a net loss of \$8.0 million, or \$(0.37) per share, for the quarter ended December 31, 2014. The fourth quarter 2015 results include \$1.3 million in non-cash charges for stock-based compensation compared to \$1.0 million in such non-cash charges in the fourth quarter of 2014. The Company reported a net loss of approximately \$39.7 million, or \$(1.71) per share, for the year ended December 31, 2015, compared to a net loss of \$28.7 million, or \$(2.69) per share, for the year ended December 31, 2014. The 2015 results include \$4.6 million in non-cash charges for stock-based compensation compared to \$5.0 million in such non-cash charges in 2014 including a stock grant made in connection with the expansion of the Company's intellectual property rights.
- Total operating expenses for the three and twelve month periods ended December 31, 2015 were \$10.7 million and \$39.9 million, respectively, as compared to \$8.1 million and \$27.9 million for the comparable periods in 2014. Research and development (R&D) expenses for the three and twelve month periods ended December 31, 2015 were \$6.9 million and \$26.6 million, respectively, compared to \$5.1 million and \$18.9 million for the comparable periods in 2014. The increases are primarily related to personnel costs and clinical trials of DEXTENZA and OTX-TP product candidates as well as preclinical development of the Company's anti-VEGF and TKI programs for the treatment of wet age-related macular degeneration and other back of the eye diseases.
- Ocular Therapeutix generated \$0.4 million and \$1.8 million in revenue during the three month and twelve month periods ended December 31, 2015 from product sales of ReSure[®] Sealant and from collaborations with corporate partners.
- As of December 31, 2015, there were approximately 24.8 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 8:00 am Eastern Time to discuss the Company's financial results and provide a general business update.

The live webcast can be accessed by visiting the investor 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 conference call. The conference ID number for the live call will be 60154048. An archive of the webcast will be available until March 24, 2016 on the company's website.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. (NASDAQ: OCUL) is a biopharmaceutical company focused on the development 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[™] (sustained release dexamethasone) Intracanalicular Depot, is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for inflammatory dry eye disease. An NDA for the post-operative ocular pain indication has been accepted for filing by the FDA with a PDUFA date of July 24, 2016. A third Phase 3 clinical trial is being conducted for post-operative ocular inflammation and pain. For glaucoma and ocular hypertension, a Phase 2b clinical trial has been completed with OTX-TP (sustained release travoprost) Intracanalicular Depot, and the first of two OTX-TP Phase 3 clinical trials is expected to be initiated in the third quarter of 2016. Ocular Therapeutix is also evaluating sustained-release injectable anti-VEGF drug 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 statements about 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 post-surgical inflammation and pain, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel depot technology and the advancement of the Company's other product candidates, the potential utility of any of the Company's product candidates, 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, 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.

OCULAR THERAPEUTIX, INC.
STATEMENTS OF OPERATIONS and COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2015	2014	2015	2014
Revenue:				\$
Product revenue	\$ 394	\$ 193	\$ 1,354	460
Collaboration revenue	42	312	396	312
Total revenue:	436	505	1,750	772
Operating expenses:				
Cost of product revenue	92	30	319	91
Research and development	6,886	5,148	26,611	18,880
Selling and marketing	1,143	658	3,852	1,982
General and administrative	2,590	2,216	9,165	6,913
Total operating expenses	10,711	8,052	39,947	27,866
Loss from operations	(10,275)	(7,547)	(38,197)	(27,094)
Other income (expense):				
Interest income	45	—	166	7
Interest expense	(408)	(407)	(1,724)	(1,119)
Other income (expense), net	1	—	7	(442)
Total other expense, net	(362)	(407)	(1,551)	(1,554)
Net loss	(10,637)	(7,954)	(39,748)	(28,648)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(11)
Net loss attributable to common stockholders	\$ (10,637)	\$ (7,954)	\$ (39,748)	\$ (28,659)

Net loss per share attributable to common stockholders, basic and diluted	\$ (0.43)	\$ (0.37)	\$ (1.71)	\$ (2.69)
Weighted average common shares outstanding, basic and diluted	24,732,847	21,289,378	23,244,162	10,652,865
Comprehensive loss:				
Net loss	\$ (10,637)	\$ (7,954)	\$ (39,748)	\$ (28,648)
Other comprehensive loss:				
Unrealized loss on marketable securities	(52)	—	(68)	—
Total other comprehensive loss	(52)	—	(68)	—
Total comprehensive loss	\$ (10,689)	\$ (7,954)	\$ (39,816)	\$ (28,648)

OCULAR THERAPEUTIX, INC.

BALANCE SHEETS

(In thousands, except share and per share data)

	December 31,	
	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,784	\$ 37,393
Marketable securities	74,280	37,435
Accounts receivable	193	329
Inventory	134	133
Prepaid expenses and other current assets	1,592	893
Total current assets	106,983	76,183
Property and equipment, net	3,095	1,782
Restricted cash	228	228
Total assets	\$ 110,306	\$ 78,193
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,957	\$ 1,316
Accrued expenses and deferred rent	3,379	3,016
Deferred revenue	42	188
Notes payable, net of discount, current	—	1,354
Total current liabilities	5378	5,874
Deferred rent, long-term	68	112
Notes payable, net of discount, long-term	15,272	13,511
Total liabilities	20,718	19,497
Commitments and contingencies		
Stockholders' equity:		

Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at December 31, 2015 and 2014; no shares issued or outstanding at December 31, 2015 and 2014	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at December 31, 2015 and December 31, 2014; 24,750,281 and 21,333,507 shares issued and outstanding at December 31, 2015 and 2014, respectively	2	2
Additional paid-in capital	218,830	148,122
Accumulated deficit	(129,176)	(89,428)
Accumulated other comprehensive loss	(68)	—
Total stockholders' equity	89,588	58,696
Total liabilities and stockholders' equity	\$ 110,306	\$ 78,193

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Source: Ocular Therapeutix, Inc.

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