



## Ocular Therapeutix™ Reports Fourth Quarter and Full Year 2016 Financial Results

March 10, 2017

*PDUFA Target Action Date of July 19, 2017 for the DEXTENZA™ NDA for the Treatment of Ocular Pain Occurring After Ophthalmic Surgery*

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

*Completed \$25 Million Follow-on Public Offering*

*Conference Call Today at 8:30 am Eastern Time*

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 10, 2017-- Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative drug products using its proprietary hydrogel platform technology for the treatment of diseases and conditions of the eye, today announced financial results for the fourth quarter of 2016 and the twelve months ended December 31, 2016.

"We continue to execute our diversification strategy as we seek to improve the standard of care across many ophthalmic indications using our proprietary hydrogel platform technology," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "With the July 19<sup>th</sup> PDUFA date for DEXTENZA fast approaching, pre-commercialization activities are well underway as DEXTENZA has the potential to become the first approved non-invasive extended release drug product that can provide a full post-operative course of therapy following ocular surgery with a single administration."

Dr. Sawhney continued, "We also continue to make substantial progress across our additional drug product development programs targeting common causes of blindness such as glaucoma and wet AMD. Together, our programs comprise a potential market opportunity of more than \$11 billion in the United States. We look forward to the further advancement of these product candidates towards potential commercialization."

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

#### **DEXTENZA™**

- In February 2017, the U.S. Food and Drug Administration (FDA) accepted the Company's New Drug Application (NDA) resubmission for DEXTENZA (dexamethasone insert) 0.4 mg for intracanalicular use, for the treatment of ocular pain occurring after ophthalmic surgery and established a target action date under the Prescription Drug User Fee Act (PDUFA) of July 19, 2017.
- In November 2016, Ocular Therapeutix announced positive topline results from its most recent Phase 3 clinical trial of DEXTENZA for the treatment of post-surgical ocular inflammation and pain.
  - The trial successfully met its two primary efficacy endpoints for inflammation and pain, achieving statistically significant differences between the treatment group and the placebo group for the absence of inflammatory cells on day 14, and the absence of pain on day 8, respectively.
  - Secondary efficacy endpoints for the trial included differences in the absence of anterior chamber (AC) flare, absence of AC cells, and ocular pain. As previously reported, all of these secondary endpoints were met with statistical significance at all time points, with the exception of the endpoint for the absence of AC cells at day 2.
  - Approximately 46% of patients in the DEXTENZA treatment group were shown to have an absence of AC flare at day 4 after insertion, which the Company believes provides further support of the early onset anti-inflammatory effect of DEXTENZA.
  - The Company has completed the full safety assessment for this Phase 3 clinical trial. DEXTENZA has exhibited a favorable safety profile and has been well tolerated in all clinical trials, regardless of indication.
  - 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 inflammation.
- DEXTENZA is also in Phase 3 clinical development for the treatment of allergic conjunctivitis. The Company is planning to initiate a non-significant risk device study in the middle of 2017 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 the first of two planned Phase 3 clinical trials for OTX-TP (travoprost insert) for the treatment of glaucoma and ocular hypertension.
  - The Phase 3 trial design includes a treatment group receiving OTX-TP and a placebo group receiving a non-drug eluting version of the Company's hydrogel platform technology based intracanalicular insert.

- Importantly, there is no timolol comparator or validation arm and no active or placebo eye drops being administered in either arm.
- The primary efficacy endpoint is statistically superior reduction of intraocular pressure (IOP) from baseline with OTX-TP compared to placebo at three diurnal time points (8am, 10am, 4pm) at intervals of 2, 6 and 12 weeks following insertion.
- 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®.
  - Ocular Therapeutix has demonstrated up to 6 months of sustained release of several anti-VEGF drugs using its hydrogel platform technology, with a good safety profile, in preclinical studies completed to date.
- In parallel, Ocular Therapeutix continues to advance its proprietary hydrogel platform technology for intravitreal drug delivery with tyrosine-kinase inhibitors (TKIs).
  - The Company expects to enter Phase 1 clinical testing with its TKI depots in the second half of 2017.

#### **Fourth Quarter and Full Year 2016 Financial Results**

- In January 2017, Ocular Therapeutix completed a registered underwritten public offering of \$25 million of shares of its common stock pursuant to a shelf registration statement that was previously filed with and declared effective by the Securities and Exchange Commission.
- As of December 31, 2016, cash, cash equivalents and marketable securities totaled \$68.1 million. Cash used in operating activities was \$7.6 million in the fourth quarter of 2016 and \$34.0 million for the year ended December 31, 2016.
- There was \$15.6 million in outstanding debt as of December 31, 2016. 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 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. The Company expects that cash, cash equivalents and marketable securities will be sufficient to fund operating expenses, debt service obligations and capital expenditures into 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.
- Ocular Therapeutix reported a net loss of approximately \$(12.8) million, or \$(0.52) per share, for the quarter ended December 31, 2016, compared to a net loss of \$(10.6) million, or \$(0.43) per share, for the quarter ended December 31, 2015. The fourth quarter 2016 results include \$1.7 million in non-cash charges for stock-based compensation compared to \$1.3 million in such non-cash charges in the fourth quarter of 2015. The Company reported a net loss of approximately \$(44.7) million, or \$(1.80) per share, for the year ended December 31, 2016, compared to a net loss of \$(39.7) million, or \$(1.71) per share, for the year ended December 31, 2015. The 2016 results include \$6.0 million in non-cash charges for stock-based compensation compared to \$4.6 million in such non-cash charges in 2015.
- Total costs and operating expenses for the three and twelve month periods ended December 31, 2016 were \$13.0 million and \$45.2 million, respectively, as compared to \$10.7 million and \$39.9 million for the comparable periods in 2015. Research and development (R&D) expenses for the three and twelve month periods ended December 31, 2016 were \$7.3 million and \$27.1 million, respectively, compared to \$6.9 million and \$26.6 million for the comparable periods in 2015. The Company continues to advance the clinical and preclinical development of its hydrogel platform technology and its portfolio of drug product candidates.
- Ocular Therapeutix generated \$0.5 million and \$1.9 million in revenue during the three month and twelve month periods ended December 31, 2016 from product sales of ReSure® Sealant and from collaborations with corporate partners.
- As of December 31, 2016, there were approximately 25.0 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 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](http://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 77324558.

An archive of the webcast will be available until March 24, 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) has completed Phase 3 clinical development for ocular pain and inflammation following ophthalmic surgery. The FDA has accepted the Company's NDA resubmission for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery for filing and has established a target PDUFA date of July 19, 2017. Ocular Therapeutix is also pursuing additional indications for DEXTENZA. 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 resubmission of the NDA filed with the FDA and potential FDA approval, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of inflammatory dry eye disease and OTX-TP for the treatment of glaucoma and ocular hypertension, the ongoing development of the Company's sustained release hydrogel platform 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, 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.

## OCULAR THERAPEUTIX, INC.

### STATEMENTS OF OPERATIONS and COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2016	2015	2016	2015
Revenue:				
Product revenue	\$ 511	\$ 394	\$ 1,845	\$ 1,354
Collaboration revenue	—	42	42	396
Total revenue:	511	436	1,887	1,750
Costs and operating expenses:				
Cost of product revenue	127	92	443	319
Research and development	7,328	6,886	27,065	26,611
Selling and marketing	2,526	1,143	6,701	3,852
General and administrative	3,002	2,590	11,004	9,165
Total costs and operating expenses	12,983	10,711	45,213	39,947

Loss from operations	(12,472 )	(10,275 )	(43,326 )	(38,197 )
Other income (expense):				
Interest income	68	45	304	166
Interest expense	(418 )	(408 )	(1,680 )	(1,724 )
Other income (expense), net	—	1	(1 )	7
Total other expense, net	(350 )	(362 )	(1,377 )	(1,551 )
Net loss attributable to common stockholders	\$ (12,822 )	\$ (10,637 )	\$ (44,703 )	\$ (39,748 )
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.52 )	\$ (0.43 )	\$ (1.80 )	\$ (1.71 )
Weighted average common shares outstanding, basic and diluted	24,888,602	24,732,847	24,816,348	23,244,162
Comprehensive loss:				
Net loss	\$ (12,822 )	\$ (10,637 )	\$ (44,703 )	\$ (39,748 )
Other comprehensive (loss) gain:				
Unrealized (loss) gain on marketable securities	(10 )	(52 )	63	(68 )
Total other comprehensive (loss) gain	(10 )	(52 )	63	(68 )
Total comprehensive loss	\$ (12,832 )	\$ (10,689 )	\$ (44,640 )	\$ (39,816 )

## BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2016	2015
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 32,936	\$ 30,784
Marketable securities	35,209	74,280
Accounts receivable	250	193
Inventory	113	134
Prepaid expenses and other current assets	1,390	1,592
Total current assets	69,898	106,983
Property and equipment, net	3,313	3,095
Restricted cash	1,728	228
Total assets	\$ 74,939	\$ 110,306
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,116	\$ 1,957
Accrued expenses and deferred rent	4,635	3,379
Deferred revenue	—	42
Notes payable, net of discount, current	1,549	—
Total current liabilities	8,300	5,378
Deferred rent, long-term	537	68
Notes payable, net of discount, long-term	14,094	15,272

Total liabilities	22,931	20,718
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized at December 31, 2016 and 2015; no shares issued or outstanding at December 31, 2016 and 2015	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at December 31, 2016 and 2015; 25,024,100 and 24,750,281 shares issued and outstanding at December 31, 2016 and 2015, respectively	3	2
Additional paid-in capital	225,889	218,830
Accumulated deficit	(173,879)	(129,176)
Accumulated other comprehensive loss	(5)	(68)
Total stockholders' equity	52,008	89,588
Total liabilities and stockholders' equity	\$ 74,939	\$ 110,306

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Source: Ocular Therapeutix, Inc.

#### Investors

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