Ocular Therapeutix™ Reports Third Quarter 2016 Financial Results and Provides Corporate Update

November 9, 2016

Preparing to Resubmit NDA for DEXTENZA™ for the Treatment of Ocular Pain Occurring After Ophthalmic Surgery to FDA by the End of 2016

Began Enrollment in First Phase 3 Clinical Trial with OTX-TP (Sustained Release Travoprost) for the Treatment of Glaucoma and Ocular Hypertension

Entered Into Strategic Collaboration with Regeneron to Develop Sustained Release Formulation of Aflibercept for the Treatment of Wet AMD and Other Serious Retinal Diseases

Conference Call Today at 8:30 am Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Nov. 9, 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 third quarter ended September 30, 2016 and provided a general business update.

"Following productive discussions with the FDA, we are preparing for the resubmission of our NDA for DEXTENZA™ for post-surgical ocular pain by the end of the year," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "We are also pleased to have commenced patient enrollment in our first Phase 3 clinical trial with OTX-TP for the treatment of glaucoma and ocular hypertension. We believe that this is the first Phase 3 clinical trial to be conducted with a non-invasive, sustained release drug candidate for the treatment of glaucoma, and our goal is to address the major issue of low patient compliance rates associated with currently approved topical therapies. Further, we are excited to have entered into a strategic collaboration with Regeneron to develop a potential first-in-class sustained release protein-based anti-VEGF hydrogel injection for the treatment of wet AMD and other serious retinal diseases."

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

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

- Ocular Therapeutix expects to resubmit its New Drug Application (NDA) for DEXTENZA (dexamethasone insert) 0.4 mg, for intracanalicular use in the treatment of ocular pain occurring after ophthalmic surgery by the end of 2016.
    - Ocular Therapeutix continues to build its commercial organization and infrastructure in preparation for the earliest possible launch of DEXTENZA.
    - The Company recently appointed Andy Hurley to the newly created position of chief commercial officer. Mr. Hurley has over two decades of sales, marketing, market access and commercial operations experience across the pharmaceutical industry and will be responsible for leading Ocular's commercial organization, focusing on effective execution of the DEXTENZA launch and potential future product launches.
- Ocular Therapeutix expects topline results from its third Phase 3 clinical trial for DEXTENZA for post-surgical ocular inflammation and pain to be available in the fourth quarter of 2016.
    - If the Company obtains favorable results from this 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 to broaden the label to include a post-surgical inflammation indication.
- At the recent Ocular Surgery News (OSN) 2016 annual meeting in New York City, Ocular Therapeutix reported positive results from a patient-reported outcomes survey of patients who were administered DEXTENZA. The survey population consists of patients from the first two Phase 3 trials with DEXTENZA for the treatment of post-surgical ocular inflammation and pain. In the trial, the majority of participants preferred DEXTENZA over eye drops:
    - 100% of participants stated the DEXTENZA insert was comfortable;
    - 96% rated their overall experience with DEXTENZA as convenient or very convenient;
    - 88% of participants stated that if they were to undergo cataract surgery again, they would request DEXTENZA; and
    - 84% of participants stated they were willing to pay more for DEXTENZA than eye drops.

DEXTENZA for the treatment of allergic conjunctivitis

- The Company plans to conduct a non-significant risk (NSR) study to confirm the effect on efficacy of the placebo insert used in previous studies compared with a rapidly absorbing placebo insert. Pending 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 (sustained release travoprost) for the treatment of glaucoma and ocular hypertension

- Ocular Therapeutix has commenced enrollment in the first of two planned Phase 3 clinical trials for OTX-TP (sustained release travoprost) for the treatment of glaucoma and ocular hypertension.

    - The U.S.-based, prospective, multicenter, randomized, parallel-arm, placebo-controlled study is expected to enroll approximately 550 patients with open angle glaucoma or ocular hypertension at 50 clinical sites.
    - Importantly, the Phase 3 study design does not include a timolol comparator or validation arm, and does not have active or placebo eye drops administered in either arm. The comparator arm utilizes a non-drug eluting hydrogel-based intracanalicular insert.
    - 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 2, 6 and 12 weeks following insertion.
- The Company's most recent results from ongoing NSR investigational device exemption (IDE) human clinical studies using the non-drug eluting version of the OTX-TP insert demonstrate significantly improved retention rates.

Sustained release intravitreal depots for the treatment of serious retinal diseases

- The Company entered into a strategic collaboration, option and license agreement with Regeneron Pharmaceuticals for the development of a sustained release formulation of aflibercept, the vascular endothelial growth factor (VEGF) trap for the treatment of wet age-related macular degeneration (wet AMD) and other serious retinal diseases.
    - Regeneron's market share leading aflibercept is currently approved by the FDA for certain indications under the brand name EYLEA®.
    - Under the terms of the agreement, Regeneron has the option to obtain an exclusive license to use Ocular Therapeutix's hydrogel-based technology for the development and commercialization of a sustained release formulation of aflibercept and other biologics targeting VEGF for ophthalmic indications.
    - Upon the exercise of the option, Ocular Therapeutix would receive a payment of $10 million from Regeneron and would be eligible to receive up to a total of $305 million in milestone payments, including the option exercise payment, for a sustained release version of aflibercept as well as tiered high single-digit to low-to-mid teen-digit royalties on potential future net sales.
- The Company has demonstrated up to 6 months of sustained release of a few different anti-VEGF drugs using its hydrogel-based drug delivery technology with a good safety profile in preclinical studies completed to date.
- Ocular Therapeutix retains all rights to develop its sustained-release hydrogel-based drug delivery platform with all other non-VEGF targeting compounds as well as with small molecule pharmaceuticals, including tyrosine-kinase inhibitors (TKIs), for other retinal diseases.
- The Company also demonstrated minimal inflammatory response *in vivo* through 26 weeks with both its anti-VEGF protein and TKI depots currently in development.

Third Quarter 2016 Financial Results

- As of September 30, 2016, cash, cash equivalents and marketable securities totaled $75.7 million excluding $1.7 million in restricted cash. Cash used in operating activities was $7.3 million in the third quarter of 2016, compared to $9.7 million for the third quarter of 2015. The decrease in cash position in the third quarter of 2016 was $8.1 million. There was $15.6 million in outstanding debt as of September 30, 2016 and principal payments are due starting January 2017 over a 36-month period. 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 fourth quarter of 2017.
- Ocular Therapeutix reported a net loss of approximately $9.6 million, or $(0.39) per share, for the quarter ended September 30, 2016, compared to a net loss of $11.5 million, or $(0.47) per share, for the quarter ended September 30, 2015. The third quarter 2016 results include $1.4 million in non-cash charges for stock-based compensation compared to $1.2 million in such non-cash charges in the third quarter of 2015.
- Total costs and operating expenses for the quarter ended September 30, 2016 were $9.7 million, as compared to $11.6 million for the quarter ended September 30, 2015. Research and development (R&D) expenses for the quarter ended September 30, 2016 were $5.7 million, compared to $8.3 million for the quarter ended September 30, 2015. The decrease in R&D expenses is primarily due to lower clinical trial costs. The patient enrollment phase of the third Phase 3 trial of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery was completed in the second quarter of 2016 and the first of two planned Phase 3 trials of OTX-TP for the treatment of glaucoma and ocular hypertension was initiated late in the third quarter of 2016 with the majority of costs expected to be incurred in future quarters. The decrease in R&D expenses was partially offset by an increase in sales and marketing expenses as we prepare for the potential launch of DEXTENZA for ocular pain indication subject to FDA approval of our NDA.
- As of September 30, 2016, there were approximately 24.9 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 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 8389302. An archive of the webcast will be available until November 23, 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 has submitted an NDA for post-surgical pain for its lead product candidate, DEXTENZA™ (dexamethasone insert), which is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis. 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. For additional information about the Company, please visit www.ocutx.com.

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 resubmission of the NDA, 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 depot 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)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenue:				
Product revenue	$ 477	$ 388	$ 1,334	$ 960
Collaboration revenue	—	41	42	354
Total revenue:	477	429	1,376	1,314
Costs and operating expenses:				
Cost of product revenue	112	91	316	227
Research and development	5,686	8,263	19,737	19,725
Selling and marketing	1,294	798	4,175	2,709
General and administrative	2,623	2,451	8,002	6,575

Total costs and operating expenses	9,715	11,603	32,230	29,236
Loss from operations	(9,238)	(11,174)	(30,854)	(27,922)
Other income (expense):				
Interest income	69	53	236	121
Interest expense	(426)	(406)	(1,262)	(1,316)
Other income (expense), net	(1)	3	(1)	6
Total other expense, net	(358)	(350)	(1,027)	(1,189)
Net loss	(9,596)	(11,524)	(31,881)	(29,111)
Net loss per share, basic and diluted	$ (0.39)	$ (0.47)	$ (1.29)	$ (1.28)
Weighted average common shares outstanding, basic and diluted	24,853,880	24,713,597	24,792,087	22,757,646
Comprehensive loss:				
Net loss	$ (9,596)	$ (11,524)	$ (31,881)	$ (29,111)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	(5)	(8)	73	(16)
Total other comprehensive income (loss)	(5)	(8)	73	(16)
Total comprehensive loss	$ (9,601)	$ (11,532)	$ (31,808)	$ (29,127)

Ocular Therapeutix, Inc.

Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	September 30, 2016	**December 31, 2015**
Assets		
Current assets:		
Cash and cash equivalents	$ 52,234	$ 30,784
Marketable securities	23,513	74,280
Accounts receivable	243	193
Inventory	126	134
Prepaid expenses and other current assets	708	1,592
Total current assets	76,824	106,983
Property and equipment, net	3,795	3,095
Restricted cash	1,728	228
Total assets	$ 82,347	$ 110,306
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,680	$ 1,957
Accrued expenses and deferred rent	2,791	3,379

Deferred revenue	—	42
Notes payable, net of discount, current	3,772	—
Total current liabilities	8,243	5,378
Deferred rent, long-term	32	68
Notes payable, net of discount, long-term	11,778	15,272
Total liabilities	20,053	20,718
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at September 30, 2016 and December 31, 2015, no shares issued or outstanding at September 30, 2016 and December 31, 2015	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at September 30, 2016 and December 31, 2015, 24,879,887 and 24,750,281 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	2	2
Additional paid-in capital	223,344	218,830
Accumulated deficit	(161,057)	(129,176)
Accumulated other comprehensive income (loss)	5	(68)
Total stockholders' equity	62,294	89,588
Total liabilities and stockholders' equity	$ 82,347	$ 110,306

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Source: Ocular Therapeutix, Inc.

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