Ocular Therapeutix™ Reports Third Quarter 2015 Financial Results

November 10, 2015

Advances in Clinical Programs Include NDA Submission for DEXTENZA™ (sustained release dexamethasone, 0.4mg) for the Treatment of Post-Surgical Ocular Pain

Results Reported for Phase 3 Allergic Conjunctivitis and Phase 2b Glaucoma Programs

Conference Call Today at 5:00 pm Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Nov. 10, 2015-- 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, 2015.

"Our product development programs advanced meaningfully during the third quarter with an NDA submission to the Food and Drug Administration for our lead product candidate, DEXTENZA for a post-surgical ocular pain indication, as well as the reporting of clinical trial results of DEXTENZA in our Phase 3 allergic conjunctivitis program and our Phase 2b glaucoma program," said Amar Sawhney, Ph.D., President and Chief Executive Officer. "We are pleased by the productivity of our research and clinical teams, who are dedicated to developing sustained-release ophthalmic therapies with proprietary tailored hydrogels that offer preservative-free, one-time administration or once in every few months therapy with potentially greater compliance and better patient outcomes."

Clinical and Corporate Updates during the Third Quarter and Anticipated Near-Term Milestones for Key Development Programs

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

- An NDA for DEXTENZA for a post-surgical ocular pain indication was submitted in September 2015.
- A third Phase 3 clinical trial for DEXTENZA for post-surgical ocular inflammation and pain was initiated in October 2015.
- Subject to obtaining favorable results in the third Phase 3 trial and approval of the NDA for post-surgical ocular pain by the FDA, the Company intends to submit an NDA supplement for DEXTENZA in the second half of 2016 aiming to broaden its label to include the post-surgical inflammation indication.

DEXTENZA for the treatment of allergic conjunctivitis and inflammatory dry eye disease

- DEXTENZA successfully met the primary endpoint for the treatment of ocular itching associated with allergic conjunctivitis in a first Phase 3 clinical trial. There was a statistically significant difference ($p<0.0001$) in the mean scores between the DEXTENZA treatment group and the placebo group for ocular itching at all three time points measured on day 7 post-insertion of the drug product or placebo. The difference in the scores for ocular itching between the DEXTENZA group and the placebo group was greater than 0.5 units at all time points on day 7 post-insertion and was greater than 1 unit at a majority of the time points on day 7 post-insertion, in each case as measured on a five-point scale. The other primary endpoint of conjunctival redness was not met. Though this endpoint has typically been included in Phase 3 trials for allergic conjunctivitis, most drugs currently marketed for the treatment of allergic conjunctivitis are indicated for ocular itching only.
- Since the FDA typically requires two Phase 3 trials to support each ophthalmic indication, the Company plans to initiate a second Phase 3 clinical trial before the end of 2015. If the primary endpoint for ocular itching is met in this second Phase 3 trial, the Company plans to seek approval from the FDA for DEXTENZA for this indication. The Phase 3 trial was conducted by Ora, Inc. using their proprietary modified Ora-CAC® (Conjunctival Allergen Challenge) model. This model was developed by Ora to assess the longer therapeutic effect of a one-time administered sustained release drug product. Ora has conducted many of the clinical trials for ophthalmic drugs that have been approved by the FDA.
- DEXTENZA is also being investigated in an exploratory Phase 2 clinical trial for the treatment of inflammatory dry eye disease. Topline results are expected by year-end 2015. This study was not powered for statistical significance but was designed to explore which signs or symptoms would be appropriate to include in the design of a future clinical study that can evaluate efficacy of DEXTENZA or other molecules in a sustained release product as a potential therapy for dry eye disease.

OTX-TP (sustained release travoprost) product candidate for the treatment of glaucoma

- Topline results from a Phase 2b clinical trial were announced for the Company's OTX-TP product candidate for the treatment of glaucoma and ocular hypertension, showing clinically meaningful intraocular pressure (IOP) reduction out to day 90 and improvement in depot retention. Based on safety results available to date, patients in the trial treated with OTX-TP did not experience any hyperemia-related adverse events, which is a common side effect caused by currently

marketed topical glaucoma products.

- The Phase 2b trial was designed to further assist in the Phase 3 clinical study design including estimating treatment effect relative to timolol, determining the duration of effect up to 3 months, and assessing patients' ability to self-assess the presence of the drug product.
- In the Phase 2b trial, OTX-TP achieved consistent IOP lowering with the same drug release rate as in the Phase 2a clinical trial of OTX-TP. The duration of effect as measured by the clinically meaningful reduction of IOP was in the 4.5 to 5.7 mmHg range, observed at 8 am out to 90 days. The comparator timolol arm lowered IOP in the 6.4 to 7.6 mmHg range. This difference between the two arms could be due to the presence of the placebo plug which enables longer retention of timolol drops on the ocular surface.
- Prior to initiating its Phase 3 clinical program for OTX-TP in glaucoma, the Company plans to conduct further studies to determine the effect of the placebo depot, incorporate findings from non-significant risk studies to its product design and discuss alternative clinical trial designs, more representative of real world use, with the FDA. At day 60, which was the primary efficacy measure, in the intent-to-treat (ITT) population the OTX-TP group had an IOP lowering effect of 4.8 mmHg, compared with IOP lowering of 6.4 mmHg for the timolol arm. At day 90, which was a secondary efficacy measure, the OTX-TP group had an IOP lowering effect of 5.2 mmHg, compared with an IOP lowering effect of 7.3 mmHg in the timolol arm.
- In a post-hoc analysis that used the longer washout baseline and excluded approximately 10% of patients who were on more than one IOP lowering medication prior to the study, the difference between the groups was observed to have been narrowed at day 60; 5.3 mmHg for OTX-TP group compared to 6.2 mmHg for timolol group.
- In summary, the Phase 2b glaucoma trial was designed to assist the Company in its Phase 3 clinical design. The Company continues to believe that a sustained release therapy for the treatment of glaucoma has the potential to significantly improve patient compliance, one of the most challenging issues with existing eye drop therapies. After examining the results of the post-hoc analysis, the Company will likely continue to focus on a 90-day product, especially since a clinically relevant IOP lowering effect through day 90 was observed. The Company expects the commencement of a Phase 3 program of OTX-TP in the second half of 2016 versus prior guidance of the first half of 2016.

American Academy of Ophthalmology (AAO) and Ophthalmology Innovation Summit (OIS) Meetings

- Amar Sawhney, Ph.D., Chairman, President and Chief Executive Officer of Ocular Therapeutix will be presenting at the Ophthalmic Innovation Symposium (OIS) meeting on November 12, 2015 in Las Vegas. At the AAO meeting to be held in Las Vegas from November 14-17, 2015, the Company will have several presentations highlighting DEXTENZA and the ReSure® Sealant.

Expansion and Strengthening of the Board of Directors

The Company strengthened its Board of Directors with two appointments:

- Jeffrey S. Heier, M.D., a prominent retinal specialist at Ophthalmology Consultants of Boston and a leading retinal clinical researcher of new treatments for diseases of the back of the eye, including macular degeneration, diabetic macular edema, and venous occlusive disease; and
- James O'Shea, who has substantial experience in successfully managing commercial stage pharmaceutical and biotechnology companies. Jim was the President and Chief Operating Officer at Sepracor, Inc., where he led the launch and commercialization of Xepenex® and Lunesta®. He also served as Vice Chairman at Sepracor and was the Senior Vice President of Sales & Marketing at Zeneca.

Third Quarter 2015 Financial Results

- As of September 30, 2015, cash and cash equivalents and marketable securities totaled $113.6 million. Cash used in operating activities was $9.7 million and $25.1 million for the three and nine month periods ended September 30, 2015, respectively. There was $15.0 million in outstanding debt as of September 30, 2015.
- Ocular Therapeutix reported a net loss of approximately $11.5 million, or $(0.47) per share, for the quarter ended September 30, 2015, compared to a net loss of $7.3 million, or $(0.48) per share, for the quarter ended September 30, 2014. The third quarter 2015 results include $1.2 million in non-cash charges for stock-based compensation compared to $0.6 million in the third quarter of 2014.
- Total operating expenses for the quarter ended September 30, 2015 were $11.6 million as compared to $6.9 million for the quarter ended September 30, 2014. Research and development (R&D) expenses for the quarter ended September 30, 2015 were $8.3 million, compared to $4.5 million for the quarter ended September 30, 2014. The increase is 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 in revenue during the three months ended September 30, 2015 from product sales of ReSure® Sealant and from collaborations with corporate partners.

- As of October 31, 2015, there were approximately 24.7 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 5:00 pm 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 71925202**.** An archive of the webcast will be available until November 24, 2015 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 candidates are in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and Phase 2 clinical development for glaucoma and inflammatory dry eye disease. The Company 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 of the Company's product candidates, such as the Company's plans for regulatory submissions and the design and conduct of a third clinical trial of DEXTENZA™ for post-surgical inflammation and pain, the timing and conduct of the Company's additional development work and clinical trials of OTX-TP for the treatment of glaucoma and ocular hypertension, the timing and conduct of a second Phase 3 clinical trial of DEXTENZA for the treatment of allergic conjunctivitis and the Company's exploratory Phase 2 clinical trial of DEXTENZA for the treatment of inflammatory dry eye disease, the ongoing development of the Company's sustained release hydrogel depot technology, the advancement of the Company's other product candidates, the potential utility of any of the Company's product candidates 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)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	**2014**	**2015**	**2014**
Revenue:				
Product revenue	$ 388	$ 143	$ 960	$ 267
Collaboration revenue	41	—	354	—
Total revenue:	429	143	1,314	267
Operating expenses:				
Cost of product revenue	91	32	227	61
Research and development	8,263	4,482	19,725	13,732
Selling and marketing	798	479	2,709	1,324
General and administrative	2,451	1,926	6,575	4,697
Total operating expenses	11,603	6,919	29,236	19,814

Loss from operations	(11,174)	(6,776)	(27,922)	(19,547)
Other income (expense):				
Interest income	53	5	121	7
Interest expense	(406)	(412)	(1,316)	(712)
Other income (expense), net	3	(111)	6	(442)
Total other expense, net	(350)	(518)	(1,189)	(1,147)
Net loss	(11,524)	(7,294)	(29,111)	(20,694)
Accretion of redeemable convertible preferred stock to redemption value	—	—	—	(11)
Net loss attributable to common stockholders	$ (11,524)	$ (7,294)	$ (29,111)	$ (20,705)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.47)	$ (0.48)	$ (1.28)	$ (2.93)
Weighted average common shares outstanding, basic and diluted	24,713,597	15,165,612	22,757,646	7,068,399
Comprehensive loss:				
Net loss	$ (11,524)	$ (7,294)	$ (29,111)	$ (20,694)
Other comprehensive loss:				
Unrealized loss on marketable securities	(8)	—	(16)	—
Total other comprehensive loss	(8)	—	(16)	—
Total comprehensive loss	$ (11,532)	$ (7,294)	$ (29,127)	$ (20,694)

OCULAR THERAPEUTIX, INC.
BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 41,198	$ 37,393
Marketable securities	72,445	37,435
Accounts receivable	189	329
Inventory	147	133
Prepaid expenses and other current assets	1,919	893
Total current assets	115,898	76,183
Property and equipment, net	3,193	1,782
Restricted cash	228	228
Total assets	$ 119,319	$ 78,193
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,624	$ 1,316
Accrued expenses	3,591	3,016
Deferred revenue	83	188
Notes payable, net of discount, current	5,883	1,354

Total current liabilities	11,181	5,874
Deferred rent, long-term	81	112
Notes payable, net of discount, long-term	9,249	13,511
Total liabilities	20,511	19,497
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 authorized at September 30, 2015 and December 31, 2014; no shares issued or outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at September 30, 2015 and December 31, 2014; 24,730,061 and 21,333,507 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	2	2
Additional paid-in capital	217,361	148,122
Accumulated deficit	(118,539)	(89,428)
Accumulated other comprehensive loss	(16)	—
Total stockholders' equity	98,808	58,696
Total liabilities and stockholders' equity	$ 119,319	$ 78,193

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