Ocular Therapeutix™ Reports Third Quarter 2017 Financial Results and Provides Corporate Update

November 7, 2017

Conference Call Today at 5:00pm Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Nov. 7, 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 third quarter ended September 30, 2017, and provided a corporate update.

"In addition to refining our manufacturing process for DEXTENZA™, we are also working diligently on a continuous improvement plan that will bring our manufacturing unit into compliance with GMP standards. We believe the completion of this work is essential for the timely resubmission of the DEXTENZA™ New Drug Application, as well as for the advancement of our other pipeline products," said Antony Mattessich, President and Chief Executive Officer. "During the quarter, we also continued to strengthen our senior leadership team with the appointments of Dr. Mike Goldstein as Chief Medical Officer and Donald Notman as Chief Financial Officer. As we advance our portfolio of hydrogel-based drug product candidates towards key inflection points, we also continue to explore additional opportunities to maximize the value of our proprietary hydrogel-based formulation technology and further enable our transition into a fully-integrated biopharmaceutical company."

Recent Updates and Anticipated Near-Term Milestones

DEXTENZA™ (dexamethasone insert) *for the treatment of post-surgical ocular inflammation and pain*

- Following a January 2017 New Drug Application (NDA) resubmission to the U.S. Food and Drug Administration (FDA), and a re-inspection of manufacturing operations by the FDA which was completed in May of 2017, the Company received an FDA Form-483 containing inspectional observations concerning manufacturing processes and analytical testing related to the manufacturing of DEXTENZA drug product that led to a Complete Response Letter (CRL) from the FDA in July 2017.
    - Following the Company's initial response to the Form FDA-483 submitted to the FDA in May 2017, Ocular Therapeutix submitted its responses to the FDA's remaining inspectional observations in November 2017.
    - The Company intends to meet with the FDA in early 2018 to review plans to resubmit its NDA for DEXTENZA for the treatment of post-surgical ocular pain.
    - Subject to addressing the FDA inspectional observations and demonstrating consistency in future manufacturing runs, the Company plans to resubmit its NDA for DEXTENZA in the first half of 2018.

OTX-TP (travoprost insert) and OTX-TIC (travoprost intracameral injection) for the reduction of intraocular pressure (IOP) in patients with glaucoma and ocular hypertension

- Ocular Therapeutix continues to enroll patients in its first Phase 3 clinical trial for OTX-TP (travoprost insert) for the reduction of IOP in patients with glaucoma and ocular hypertension.
    - The Company expects topline efficacy data from the completed trial in the second half of 2018.
    - Subject to allocation of available funding, the Company plans to initiate its second Phase 3 trial in 2018.
- Ocular Therapeutix is also developing an intracameral product candidate, OTX-TIC, which is a bioresorbable extended release travoprost implant delivered via a fine-gauge needle injection. The Company is developing OTX-TIC to potentially address the need for a higher level of IOP reduction for patients who have moderate to severe glaucoma.
    - In the third quarter of 2017, the Company initiated a pilot human clinical trial outside the United States to assess safety and obtain initial efficacy data.
    - The Company also expects to file an Investigational New Drug (IND) application in the first quarter of 2018 and initiate a second Phase 1 trial in the United States in the first half of 2018.

Sustained release intravitreal depots for the treatment of serious retinal diseases

- Ocular Therapeutix is engaged in the preclinical development of its extended release intravitreal tyrosine kinase inhibitor injection (OTX-TKI) using the Company's proprietary bioresorbable hydrogel fiber technology.
    - The Company expects to initiate a Phase 1 clinical trial outside the United States for OTX-TKI in the first half of 2018.
- In partnership with Regeneron Pharmaceuticals, Ocular Therapeutix also 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.

Corporate

- The Company strengthened its management team with the appointments of Michael Goldstein, M.D., MBA, as Chief

Medical Officer, and Donald Notman, MBA, as Chief Financial Officer.

- Dr. Goldstein is a highly-accomplished ophthalmologist who also serves as Co-Director, Cornea and External Disease Service and Assistant Professor of Ophthalmology at the New England Eye Center and Tufts University School of Medicine. He has held several senior medical leadership positions with ophthalmology-focused pharmaceutical companies and published extensively in multiple ophthalmology scientific journals.
- Mr. Notman brings a notable track record of success to Ocular Therapeutix with over 20 years of financial operations and senior-level investment banking experience.

Third Quarter 2017 Financial Results

- As of September 30, 2017, cash and cash equivalents totaled $51.2 million. Cash used in operating activities was $14.4 million in the third quarter of 2017, compared to $7.3 million for the third quarter of 2016. The Company expects that cash and cash equivalents will be sufficient to fund operating expenses, debt service obligations and capital expenditures into the fourth quarter of 2018.
- Ocular Therapeutix reported a net loss of approximately $(15.6) million, or $(0.54) per share, for the quarter ended September 30, 2017, compared to a net loss of $(9.6) million, or $(0.39) per share, for the quarter ended September 30, 2016. The third quarter 2017 results include $2.2 million in non-cash charges for stock-based compensation and depreciation compared to $1.6 million in such non-cash charges in the third quarter of 2016.
- The Company continues to advance the clinical and preclinical development of its hydrogel-based formulation technology and its portfolio of drug product candidates. Total costs and operating expenses for the quarter ended September 30, 2017 were $15.7 million, as compared to $9.7 million for the quarter ended September 30, 2016. The increase was primarily due to an increase in costs associated with the Company’s recent initiative to enhance operations and reduce expenses surrounding the delayed DEXTENZA launch as announced in August 2017, personnel expenses supporting the Company’s ongoing development programs, and facilities costs associated with the relocation of the Company’s corporate headquarters. Research and development expenses for the quarter ended September 30, 2017 were $8.1 million, compared to $5.7 million for the quarter ended September 30, 2016. The increase was primarily due to an increase in personnel costs and facilities expenses associated with increased lab space at our corporate headquarters.
- Ocular Therapeutix generated $0.5 million in revenue during the three-month period ended September 30, 2017 from product sales of ReSure® Sealant.
- As of September 30, 2017, there were approximately 29.4 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 p.m. 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 7468418. An archive of the webcast will be available until November 21, 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-based formulation 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. OTX-TP (travoprost insert) is in Phase 3 clinical development for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension. The Company’s earlier stage assets include OTX-TIC, a sustained release travoprost intracameral injection for the reduction in intraocular pressure in patients with glaucoma and ocular hypertension, as well as sustained release intravitreal injections for the treatment of retinal diseases. These injections include the development of OTX-TKI, a tyrosine kinase inhibitor (TKI), and, in collaboration with Regeneron, an extended release protein-based anti-vascular endothelial growth factor (VEGF) trap. 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 product development efforts and regulatory submissions for and the timing and conduct of clinical trials of DEXTENZA for the treatment of post-surgical ocular inflammation and pain, including the Company’s expectations regarding refiling its NDA with the FDA and the prospects for approvability of DEXTENZA for these indications, 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 intravitreal depot, the potential utility of any of the Company’s product candidates, potential commercialization 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 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 manufacturing operations, the Company's scientific approach and general development progress, the availability or commercial potential of the Company's product candidates, the availability 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,	
	2017	**2016**	**2017**	**2016**
Revenue:				
Product revenue	$ 523	$ 477	$ 1,436	$ 1,334
Collaboration revenue	—	—	—	42
Total revenue	523	477	1,436	1,376
Costs and operating expenses:				
Cost of product revenue	125	112	344	316
Research and development	8,126	5,686	22,972	19,737
Selling and marketing	3,238	1,294	16,097	4,175
General and administrative	4,230	2,623	11,230	8,002
Total costs and operating expenses	15,719	9,715	50,643	32,230
Loss from operations	(15,196)	(9,238)	(49,207)	(30,854)
Other income (expense):				
Interest income	115	69	320	236
Interest expense	(491)	(426)	(1,402)	(1,262)
Other income (expense), net	5	(1)	5	(1)
Total other expense, net	(371)	(358)	(1,077)	(1,027)
Net loss	(15,567)	(9,596)	$ (50,284)	$ (31,881)
Net loss per share, basic and diluted	$ (0.54)	$ (0.39)	$ (1.76)	$ (1.29)
Weighted average common shares outstanding, basic and diluted	29,087,654	24,853,880	28,601,179	24,792,087
Comprehensive loss:				
Net loss	$ (15,567)	$ (9,596)	$ (50,284)	$ (31,881)
Other comprehensive income (loss):				
Unrealized gain on marketable securities	—	(5)	5	73
Total other comprehensive income	—	(5)	5	73
Total comprehensive loss	$ (15,567)	$ (9,601)	$ (50,279)	$ (31,808)

Balance Sheets
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2017	**December 31, 2016**
Assets		
Current assets:		
Cash and cash equivalents	$ 51,165	$ 32,936
Marketable securities	—	35,209
Accounts receivable	278	250
Inventory	127	113
Prepaid expenses and other current assets	883	1,390
Total current assets	52,453	69,898
Property and equipment, net	10,218	3,313
Restricted cash	1,728	1,728
Total assets	$ 64,399	$ 74,939
Liabilities and Stockholders' Equity		

Current liabilities:		
Accounts payable	$ 2,599	$ 2,116
Accrued expenses and deferred rent	4,353	4,635
Notes payable, net of discount, current	3,993	1,549
Total current liabilities	10,945	8,300
Deferred rent, long-term	3,608	537
Notes payable, net of discount, long-term	13,924	14,094
Total liabilities	28,477	22,931
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at September 30, 2017 and December 31, 2016; no shares issued or outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at September 30, 2017 and December 31, 2016; 29,388,131 and 25,024,100 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	3	3
Additional paid-in capital	260,082	225,889
Accumulated deficit	(224,163)	(173,879)
Accumulated other comprehensive loss	—	(5)
Total stockholders' equity	35,922	52,008
Total liabilities and stockholders' equity	$ 64,399	$ 74,939

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Source: Ocular Therapeutix™, Inc.

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