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

August 8, 2017

Conference Call Today at 5:00pm Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--Aug. 8, 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 second quarter ended June 30, 2017, and provided a corporate update.

"This is an important time for Ocular Therapeutix as we focus our efforts on the resubmission of our NDA for DEXTENZA™ for the treatment of post-surgical ocular pain while continuing to advance our pipeline programs," said Antony Mattessich, Chief Executive Officer. "My goal as CEO is to fully realize the opportunities for Ocular Therapeutix by deepening the Company's expertise in biopharmaceuticals. I believe our hydrogel technology represents an important innovation in the field of ophthalmology and has great potential to improve outcomes across a wide range of diseases of the eye by improving the performance of both small and large molecules. We are focused on execution and working as diligently as possible to achieve our vision."

Recent Updates and Anticipated Near-Term Milestones Across Key Development Programs

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

- In July 2017, Ocular Therapeutix received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA), regarding resubmission of a New Drug Application (NDA) for DEXTENZA™ (dexamethasone insert) 0.4mg for the treatment of ocular pain following ophthalmic surgery. The CRL did not identify any efficacy or safety concerns with respect to the clinical data for DEXTENZA provided in the NDA, nor any need for additional clinical trials for the NDA approval.

- The CRL from the FDA referred to deficiencies in manufacturing processes and analytical testing related to manufacture of drug product for commercial production identified in an outstanding Form FDA-483. The Form FDA-483 was received following an FDA pre-NDA approval re-inspection of the Ocular Therapeutix manufacturing facility that was completed in May 2017. Ocular Therapeutix plans to produce additional commercial batches of DEXTENZA and submit data from these batches to the FDA with the resubmission of its NDA.

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

- Ocular Therapeutix continues to enroll patients in its first Phase 3 clinical trial for OTX-TP (travoprost insert) for the treatment of glaucoma and ocular hypertension. Topline efficacy data from the trial is expected in the second half of 2018.
    - 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 of 8am, 10am, and 4pm, at intervals of 2, 6 and 12 weeks following insertion.
    - 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 Company plans to initiate its second Phase 3 clinical trial with OTX-TP for the treatment of glaucoma and ocular hypertension in 2017.

OTX-TIC (travoprost intracameral injection) for the treatment of moderate to severe glaucoma and ocular hypertension

- Ocular Therapeutix is developing an intracameral product candidate, OTX-TIC, which is a bioresorbable travoprost-containing hydrogel depot 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.
    - The Company plans to initiate a pilot human clinical trial in 2017 to assess safety and obtain initial efficacy data.

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 (TKI) depot (OTX-TKI) using the Company's proprietary bioresorbable hydrogel fiber technology.
    - At the ARVO Annual Meeting in May 2017, Ocular Therapeutix presented preclinical data, demonstrating for the first time the ability to deliver an efficacious dose of TKI to the posterior segment of the eye for the treatment of VEGF-induced retinal leakage for an extended duration of up to six months.
    - The Company expects to enter Phase 1 clinical testing with OTX-TKI by the end of 2017.

- 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.

Second Quarter 2017 Financial Results

- As of June 30, 2017, cash, cash equivalents and marketable securities totaled $66.0 million. Cash used in operating activities was $11.3 million in the second quarter of 2017, compared to $9.8 million for the second quarter of 2016. 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 2018.
- Ocular Therapeutix reported a net loss of approximately $(18.7) million, or $(0.64) per share, for the quarter ended June 30, 2017, compared to a net loss of $(11.4) million, or $(0.46) per share, for the quarter ended June 30, 2016. The second quarter 2017 results include $2.1 million in non-cash charges for stock-based compensation and depreciation compared to $1.7 million in such non-cash charges in the second quarter of 2016.
- Total costs and operating expenses for the quarter ended June 30, 2017 were $18.8 million, as compared to $11.5 million for the quarter ended June 30, 2016. Research and development expenses for the quarter ended June 30, 2017 were $8.1 million, compared to $7.0 million for the quarter ended June 30, 2016. 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 $0.4 million in revenue during the three-month period ended June 30, 2017 from product sales of ReSure® Sealant.
- As of June 30, 2017, there were approximately 29.1 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 5:00pm 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 59980638. An archive of the webcast will be available until August 22, 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) 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 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 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 with respect to the manufacturing deficiencies identified by 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 June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenue:				
Product revenue	$ 438	$ 441	$ 913	$ 857
Collaboration revenue	—	—	—	42
Total revenue	438	441	913	899
Costs and operating expenses:				
Cost of product revenue	104	105	219	204
Research and development	8,117	6,978	14,846	14,051
Selling and marketing	6,832	1,492	12,859	2,881
General and administrative	3,724	2,973	7,000	5,379
Total costs and operating expenses	18,777	11,548	34,924	22,515
Loss from operations	(18,339)	(11,107)	(34,011)	(21,616)
Other income (expense):				
Interest income	113	80	205	167
Interest expense	(468)	(418)	(911)	(836)
Total other expense, net	(355)	(338)	(706)	(669)
Net loss	(18,694)	(11,445)	$ (34,717)	$ (22,285)
Net loss per share, basic and diluted	$ (0.64)	$ (0.46)	$ (1.22)	$ (0.90)
Weighted average common shares outstanding, basic and diluted	29,026,259	24,770,059	28,352,348	24,761,498
Comprehensive loss:				
Net loss	$ (18,694)	$ (11,445)	$ (34,717)	$ (22,285)
Other comprehensive income (loss):				
Unrealized gain on marketable securities	9	10	5	78
Total other comprehensive income	9	10	5	78
Total comprehensive loss	$ (18,685)	$ (11,435)	$ (34,712)	$ (22,207)

Balance Sheets

(In thousands, except share and per share data)

(Unaudited)

	June 30, 2017	**December 31, 2016**
Assets		
Current assets:		
Cash and cash equivalents	$ 63,049	$ 32,936
Marketable securities	3,000	35,209
Accounts receivable	211	250
Inventory	90	113
Prepaid expenses and other current assets	1,978	1,390
Total current assets	68,328	69,898
Property and equipment, net	9,619	3,313
Restricted cash	1,728	1,728
Total assets	$ 79,675	$ 74,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,307	$ 2,116
Accrued expenses and deferred rent	4,379	4,635
Notes payable, net of discount, current	2,444	1,549
Total current liabilities	13,130	8,300

Deferred rent, long-term	3,146	537
Notes payable, net of discount, long-term	15,374	14,094
Total liabilities	31,650	22,931
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at June 30, 2017 and December 31, 2016; no shares issued or outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at June 30, 2017 and December 31, 2016; 29,055,460 and 25,024,100 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	3	3
Additional paid-in capital	256,618	225,889
Accumulated deficit	(208,596)	(173,879)
Accumulated other comprehensive loss	—	(5)
Total stockholders' equity	48,025	52,008
Total liabilities and stockholders' equity	$ 79,675	$ 74,939

View source version on businesswire.com: http://www.businesswire.com/news/home/20170808006386/en/

Source: Ocular Therapeutix, Inc.

Investors
Burns McClellan
Steve Klass, 212-213-0006
sklass@burnsmc.com
or
Ocular Therapeutix
George Migausky
Interim Chief Financial Officer
gmigausky@ocutx.com
or
Media
Ocular Therapeutix
Scott Corning
Vice President of Marketing & Commercial Operations
scorning@ocutx.com