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

May 10, 2016

PDUFA target action date of July 24, 2016 for DEXTENZA™ NDA for the treatment of post-surgical ocular pain

Second Phase 3 clinical trial for DEXTENZA for the treatment of allergic conjunctivitis fully enrolled; topline results expected June 2016

First Phase 3 clinical trial for OTX-TP (sustained release travoprost) for the treatment of glaucoma and ocular hypertension with placebo control arm expected to commence in the third quarter of 2016

Conference call today at 8:00 am Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--May 10, 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 first quarter ended March 31, 2016.

“This is an exciting time for Ocular Therapeutix, as we anticipate multiple key milestones throughout the remainder of 2016, including the July 2016 PDUFA date for DEXTENZA for the treatment of post-surgical ocular pain, as well as expected read-outs from our second Phase 3 DEXTENZA clinical trial for the treatment of allergic conjunctivitis and our third Phase 3 clinical trial for the treatment of post-surgical ocular inflammation and pain,” said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. “Following the completion of an End-of-Phase 2 review with the FDA last month, we are also gearing up to initiate the first of two planned Phase 3 clinical trials with OTX-TP for the treatment of glaucoma and ocular hypertension. We believe that successful outcomes for these milestones have the potential to affirm the growing value of our innovative sustained-release platform in addressing diverse applications in ophthalmology.”

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

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

- Based on a New Drug Application (NDA) filed in December with the U.S. Food and Drug Administration (FDA) for DEXTENZA (sustained release dexamethasone), Intracanalicular Depot for the treatment of post-surgical ocular pain, the FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of July 24, 2016 for the NDA.
    - Should the FDA grant marketing approval for DEXTENZA for the treatment of post-surgical ocular pain on the PDUFA action date, the Company expects to apply for a pass through reimbursement code used in the hospital and ambulatory surgery center setting and launch this product in early 2017.

- A third Phase 3 clinical trial for DEXTENZA for post-surgical ocular inflammation and pain is over 90% enrolled, with 395 patients out of a planned total of 436 patients enrolled as of May 3, 2016.
    - The Company expects topline results from the trial 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 aiming to broaden the label to include a post-surgical inflammation indication.

DEXTENZA for the treatment of allergic conjunctivitis

- Ocular Therapeutix has completed enrollment in a second Phase 3 clinical trial to evaluate the safety and efficacy of DEXTENZA for the treatment of allergic conjunctivitis.
    - The Company expects topline results from this trial to be available in June 2016.
    - If the primary efficacy endpoint for ocular itching associated with allergic conjunctivitis is met in the second Phase 3 trial and subject to the approval of the NDA submitted for DEXTENZA for the treatment of post-surgical ocular pain, the Company expects to submit an NDA supplement to the FDA for ocular itching associated with allergic conjunctivitis.

DEXTENZA for the treatment of dry eye disease

- Ocular Therapeutix plans to meet with the FDA in mid-2016 to discuss the results from a recently conducted exploratory Phase 2 clinical trial designed to evaluate a range of objective and subjective measures (signs and symptoms, respectively) and potential Phase 3 clinical trial designs for dry eye-related indications.

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

- Ocular Therapeutix recently completed an End-of-Phase 2 Review with the FDA for OTX-TP (sustained release travoprost) for the treatment of Glaucoma and Ocular Hypertension.

- Based on this review, the Company intends to initiate the first of two planned Phase 3 clinical trials during the third quarter of 2016.
- The primary efficacy endpoint will be superiority in the reduction of intraocular pressure (IOP) from baseline in the OTX-TP treatment arm compared to the placebo arm.
- Importantly, the Phase 3 study design will not include a timolol comparator or validation arm, and will not have active or placebo eye drops administered in either arm.

First Quarter 2016 Financial Results

- As of March 31, 2016, cash, cash equivalents and marketable securities totaled $95.5 million. Cash used in operating activities was $9.3 million in the first quarter of 2016, compared to $6.9 million for the first quarter of 2015. There was $15.6 million in outstanding debt as of March 31, 2016 and no principal payments are due until January 2017. 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 2017.
- Ocular Therapeutix reported a net loss of approximately $10.8 million, or $(0.44) per share, for the quarter ended March 31, 2016, compared to a net loss of $7.6 million, or $(0.35) per share, for the quarter ended March 31, 2015. The first quarter 2016 results include $1.3 million in non-cash charges for stock-based compensation compared to $0.9 million in such non-cash charges in the first quarter of 2015.
- Total operating expenses for the quarter ended March 31, 2016 were $11.0 million, as compared to $7.5 million for the quarter ended March 31, 2015. Research and development (R&D) expenses for the quarter ended March 31, 2016 were $7.1 million, compared to $4.7 million for the quarter ended March 31, 2015. The increases are primarily related to personnel costs and clinical trials of DEXTENZA for the treatment of post-surgical inflammation and pain, DEXTENZA for the treatment of allergic conjunctivitis and OTX-TP for the treatment of glaucoma and ocular hypertension 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 $458,000 in revenue during the three months ended March 31, 2016 from product sales of ReSure® Sealant and from collaborations with corporate partners.
- As of March 31, 2016, there were approximately 24.8 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 8:00 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 3038508. An archive of the webcast will be available until May 24, 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's lead product candidate, DEXTENZA™ (sustained release dexamethasone) Intracanalicular Depot, is in Phase 3 clinical development for post-surgical ocular inflammation and pain and allergic conjunctivitis, and in Phase 2 clinical development for dry eye disease. A New Drug Application (NDA) for the post-operative ocular pain indication has been filed with FDA and has a Prescription Drug User Fee Act (PDUFA) target action date of July 24, 2016. A third Phase 3 clinical trial is being conducted for post-surgical ocular inflammation and pain. For glaucoma and ocular hypertension, the Company has completed its End-of-Phase 2 review with the FDA, and the first of two planned OTX-TP (sustained release travoprost) Phase 3 clinical trials is expected to be initiated in the third quarter of 2016. Ocular Therapeutix 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 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 post-surgical ocular inflammation and pain, including our expectations regarding the pending PDUFA date for the NDA filed with the FDA, DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for 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 and the advancement of the Company's other product candidates, the potential utility of any 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 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 March 31,	
	2016	**2015**
Revenue:		
Product revenue	$ 416	$ 238
Collaboration revenue	42	188
Total revenue:	458	426
Costs and operating expenses:		
Cost of product revenue	99	56
Research and development	7,073	4,719
Selling and marketing	1,389	870
General and administrative	2,406	1,894
Total costs and operating expenses	10,967	7,539
Loss from operations	(10,509)	(7,113)
Other income (expense):		
Interest income	87	40
Interest expense	(418)	(505)
Total other expense, net	(331)	(465)
Net loss	$ (10,840)	$ (7,578)
Net loss per share, basic and diluted	$ (0.44)	$ (0.35)
Weighted average common shares outstanding, basic and diluted	24,751,682	21,362,731
Comprehensive loss:		
Net loss	$ (10,840)	$ (7,578)
Other comprehensive income:		
Unrealized gains on marketable securities	68	—
Total other comprehensive income	68	—
Total comprehensive loss	$ (10,772)	$ (7,578)

OCULAR THERAPEUTIX, INC.

BALANCE SHEETS

(In thousands, except share and per share data)

	March 31, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 46,212	$ 30,784
Marketable securities	49,244	74,280
Accounts receivable	227	193
Inventory	127	134
Prepaid expenses and other current assets	1,287	1,592
Total current assets	97,097	106,983
Property and equipment, net	3,107	3,095
Restricted cash	228	228
Total assets	$ 100,432	$ 110,306
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,063	$ 1,957
Accrued expenses and deferred rent	2,779	3,379
Deferred revenue	—	42
Notes payable, net of discount, current	1,161	—
Total current liabilities	6,003	5,378
Deferred rent, long-term	55	68
Notes payable, net of discount, long-term	14,204	15,272
Total liabilities	20,262	20,718
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at March 31, 2016 and December 31, 2015; no shares issued or outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at March 31, 2016 and December 31, 2015, respectively; 24,758,786 and 24,750,281 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	2	2
Additional paid-in capital	220,184	218,830
Accumulated deficit	(140,016)	(129,176)
Accumulated other comprehensive loss	—	(68)
Total stockholders' equity	80,170	89,588
Total liabilities and stockholders' equity	$ 100,432	$ 110,306

View source version on businesswire.com: http://www.businesswire.com/news/home/20160510005503/en/

Source: Ocular Therapeutix, Inc.

Investors
Ocular Therapeutix, Inc.
Brad Smith
Chief Financial Officer
bsmith@ocutx.com
or

Burns McClellan on behalf of Ocular Therapeutix
Steve Klass, 212-213-0006
sklass@burnsmc.com
or
Media
Ocular Therapeutix, Inc.
Scott Corning
Vice President of Sales and Marketing
scorning@ocutx.com