



Ocular Therapeutix™ Announces Plans to Proceed with an NDA Submission for OTX-DP for Treatment of Post-Surgical Ocular Pain Indication; Reports First Quarter 2015 Financial Results

May 15, 2015

Company Provides Updates on Anticipated Clinical Milestones and Development Plans

Conference Call Today at 8:00 am Eastern Time

BEDFORD, Mass.--(BUSINESS WIRE)--May 15, 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 first quarter ended March 31, 2015 and provided an update on its clinical and preclinical programs for its proprietary hydrogel platform technology. Following a meeting with the Food and Drug Administration (FDA) in April 2015, the Company now plans to submit a New Drug Application (NDA) for OTX-DP for the treatment of post-surgical ocular pain. The Company also received conditional acceptance of the name DEXTENZA™ from the FDA for its OTX-DP product candidate. A request for a proprietary name review is planned as part of the NDA submission.

"We are pleased with the overall progress of our pipeline of sustained release drug delivery products in clinical and preclinical development. We continue to advance our clinical programs for the treatment of post-surgical ocular inflammation and pain, allergic conjunctivitis, inflammatory dry eye disease and glaucoma, with several anticipated milestones in the near-term. Furthermore, last week we presented preclinical data on our sustained release hydrogel depot for the delivery of anti-vascular endothelial growth factors (anti-VEGF) for the treatment of wet age-related macular degeneration at the recent annual ARVO meeting in Denver. This is a promising platform for a condition that is one of the leading causes of blindness," said Amar Sawhney, Ph.D., President and Chief Executive Officer.

Dr. Sawhney further commented, "We remain confident about our program for post-surgical ocular inflammation and pain, and our plans for the regulatory and clinical pathway for this product candidate. We intend to submit an NDA for a post-surgical ocular pain indication and conduct an additional Phase 3 clinical trial. Our goal is to subsequently submit an NDA supplement to expand the labeling for the inflammation indication, subject to favorable results from the additional trial and the initial approval of the NDA for the pain indication."

Clinical Update for DEXTENZA for the Treatment of Post-Surgical Ocular Inflammation and Pain

Following a Pre-NDA Clinical meeting held with FDA in April 2015, Ocular Therapeutix is charting a path forward for DEXTENZA for the treatment of post-surgical ocular inflammation and pain. The Company's plan now includes:

- Submission of an NDA for DEXTENZA for a post-surgical ocular pain indication in the second half of 2015.
- Initiation of an additional Phase 3 clinical trial for DEXTENZA for post-operative ocular inflammation and pain with modifications to the trial design based on learnings from the previously completed second Phase 3 trial, including the exclusion of patients on high-dose nonsteroidal anti-inflammatory drugs (NSAIDs), randomizing patients in a 1:1 ratio into treatment and placebo groups and providing more protocol specificity regarding the administration of rescue medications.
- Submission of an NDA supplement for DEXTENZA to broaden the indication to include treatment of post-operative ocular inflammation, subject to favorable results from the additional Phase 3 clinical trial and the approval of the NDA for DEXTENZA for the pain indication.

Recent Highlights for Other Key Development Programs

Sustained release depots for treatment of retinal diseases

At the recent Association for Research in Vision and Ophthalmology (ARVO) annual meeting in Denver, Ocular Therapeutix presented a total of eight posters, three of which highlighted the company's sustained release hydrogel depot platform technology.

The data presented on back-of-the-eye depots focused on demonstrating the viability of the platform for treating retinal diseases using bevacizumab and other anti-VEGF agents as model proteins. In preclinical studies, data showed *in-situ* formed bioresorbable anti-VEGF hydrogel depots maintain their structure and bioactivity within the company's hydrogel. Data further showed tolerability and drug release of clinically meaningful concentration and duration.

Decreasing the frequency of intravitreal injections with a sustained release modality remains a major clinical challenge in treating chronic diseases such as age-related macular degeneration (AMD) and diabetic macular edema (DME).

A multi-pronged strategy is being pursued to seek to maximize the potential of this technology for back-of-the-eye diseases. The Company is pursuing ongoing collaborations with several different pharmaceutical companies using protein based anti-VEGF agents and internal development efforts using bevacizumab. Additionally, the delivery of small molecule drugs, such as tyrosine-kinase inhibitors, or TKIs, in the Company's hydrogel depot are being evaluated. The Company believes this class of drugs is well suited to the Company's hydrogel depot platform given its high potency, multiple targeting capability, and low water solubility. The Company plans to continue evaluating these multiple pathways as additional preclinical milestones are achieved.

OTX-TP product candidate for the treatment of glaucoma

- The Company's OTX-TP product candidate for the treatment of glaucoma and ocular hypertension is now in a Phase 2b clinical trial at multiple sites in the United States, which is more than 80% enrolled and remains on track to report topline efficacy data in the fourth quarter of 2015.

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

- The DEXTENZA product candidate is being investigated for the treatment of allergic conjunctivitis, for which two Phase 3 trials are to be conducted beginning in the middle of 2015.
- DEXTENZA is also being investigated for the treatment of inflammatory dry eye disease and is currently nearing enrollment completion in an exploratory Phase 2 clinical trial, with topline efficacy data to be released in the fourth quarter of 2015.

First Quarter 2015 Financial Results

- Ocular Therapeutix reported a net loss of approximately \$7.6 million, or \$(0.35) per share, for the quarter ended March 31, 2015, compared to a net loss of \$7.0 million, or \$(2.45) per share, for the quarter ended March 31, 2014. The first quarter 2015 results include \$0.9 million in non-cash charges for stock-based compensation compared to \$2.9 million in non-cash charges for stock-based compensation and licensing and consultant fees paid in common stock in the first quarter of 2014.
- Total operating expenses for the quarter ended March 31, 2015 were \$7.5 million as compared to \$6.9 million for the quarter ended March 31, 2014. Research and development (R&D) expenses for the quarter ended March 31, 2015 were \$4.7 million, compared to \$4.9 million for the quarter ended March 31, 2014. In the quarter ended March 31, 2014, there was \$1.7 million in non-cash licensing fees paid in common stock relating to the Company's intellectual property rights. This was partially offset by increases in personnel costs and clinical trials of DEXTENZA and OTX-TP product candidates.
- Ocular Therapeutix generated \$0.4 million in revenue during the three months ended March 31, 2015 from product sales of ReSure[®] Sealant and from collaborations with corporate partners.
- As of March 31, 2015, cash and cash equivalents and marketable securities totaled \$67.4 million. Cash used in operating activities was \$6.9 million for the three months ended March 31, 2015.
- There was \$15.0 million in outstanding debt as of March 31, 2015, with an interest only period through September 30, 2015.
- As of May 3, 2015, there were approximately 21.4 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 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 34331440. An archive of the webcast will be available until May 29, 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 Phase 2 clinical development for glaucoma, allergic conjunctivitis 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, initiation and conduct of a third clinical trial of OTX-DP for post-surgical inflammation and pain, the ongoing development of the Company's sustained release hydrogel depot technology, the timing and conduct of the Company's Phase 2b clinical trial of OTX-TP for the treatment of glaucoma and ocular hypertension, the Company's Phase 3 clinical trials of OTX-DP for allergic conjunctivitis and the Company's Phase 2 clinical trial of OTX-DP for the treatment of inflammatory dry eye disease, the advancement of the Company's other 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 Annual Report on Form 10-K for the year ended December 31, 2014 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

(In thousands, except share and per share data)

(Unaudited)

	Three Months ended March 31,	
	2015	2014
Product revenue	\$ 238	\$ 27
Collaboration revenue	188	-
Total revenue	426	27
Operating Expenses:		
Cost of product revenue	56	9
Research and development	4,719	4,958
Selling and marketing	870	310
General and administrative	1,894	1,575
Total operating expenses	7,539	6,852
Loss from operations	(7,113)	(6,825)
Other income (expense):		
Interest income	40	1
Interest expense	(505)	(43)
Other (expense) income, net	-	(141)
Total other expense, net	(465)	(183)
Net loss and comprehensive loss	(7,578)	(7,008)
Accretion of redeemable convertible preferred stock to redemption value	-	(6)
Net loss attributable to common stockholders	\$ (7,578)	\$ (7,014)
Net loss per share attributable to common stockholders per share, basic and diluted	\$ (0.35)	\$ (2.45)
Weighted average shares outstanding, basic and diluted	21,362,731	2,859,752

OCULAR THERAPEUTIX, INC.

BALANCE SHEETS

(In thousands, except share and per share data)

(Unaudited)

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 12,523	\$ 37,393
Marketable securities	54,900	37,435
Accounts receivable	352	329
Inventory	158	133
Prepaid expenses and other current assets	1,537	893
Total current assets	69,470	76,183
Property and equipment, net	1,799	1,782
Restricted cash	228	228
Total assets	\$ 71,497	\$ 78,193
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,195	\$ 1,316
Accrued expenses	1,922	3,016
Deferred revenue	250	188
Notes payable, net of discount, current	2,860	1,354
Total current liabilities	7,227	5,874
Deferred rent, long-term	103	112
Notes payable, net of discount, long-term	12,094	13,511
Total liabilities	19,424	19,497
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 authorized at March 31, 2015 and December 31, 2014; no shares issued or outstanding at March 31, 2015 and December 31, 2014	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized at March 31, 2015 and December 31, 2014; 21,428,571 and 21,333,507 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	2	2
Additional paid-in capital	149,077	148,122
Accumulated deficit	(97,006)	(89,428)
Total stockholders' equity	52,073	58,696
Total liabilities and stockholders' equity	\$ 71,497	\$ 78,193

Source: Ocular Therapeutix, Inc.

Investors:

Ocular Therapeutix, Inc.

Brad Smith

Chief Financial Officer

bsmith@ocutx.com

or

Burns McClellan on behalf of Ocular Therapeutix

Kimberly Minarovich, 212-213-0006

kminarovich@burnsmc.com

or

Media:

Ocular Therapeutix, Inc.

Scott Corning

Vice President of Sales and Marketing

scorning@ocutx.com