



Ocular Therapeutix™ Reports First Quarter 2018 Financial Results and Business Update

May 8, 2018

Targeting DEXTENZA™ NDA Resubmission in the Second Quarter of 2018

BEDFORD, Mass.--(BUSINESS WIRE)--May 8, 2018-- Ocular Therapeutix™, Inc.(NASDAQ: OCUL), a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye, today announced financial results for the first quarter ended March 31, 2018 and provided a business update.

"We entered 2018 with an exciting set of opportunities that include a number of regulatory and clinical milestones," said Antony Mattessich, President and Chief Executive Officer. "With the right strategy, objectives and leadership in place, we are able to turn our full attention to execution and, most importantly, to the demonstration of our ability to deliver on the immense promise of our platform technology. Top among our objectives is the continued advancement of our product pipeline and the re-submission of DEXTENZA which we continue to target for the second quarter of 2018."

Key Highlights and Upcoming Events

- **DEXTENZA™ New Drug Application (NDA) resubmission to the U.S. Food and Drug Administration (FDA) remains on track for the second quarter of 2018.** DEXTENZA is a long-acting, preservative-free formulation of dexamethasone that uses Ocular Therapeutix's proprietary hydrogel technology and offers a full course of steroid treatment to treat post-surgical ocular pain in a single administration. The Company has made significant progress addressing not only the specific issues raised by the FDA in its most recent Complete Response Letter, but also the implementation of upgrades to the overall quality systems and key operating procedures necessary to reach GMP compliance. Based on the progress, Ocular Therapeutix is reiterating prior guidance that it is targeting resubmission of the NDA in the second quarter of 2018.
- **OTX-TP (travoprost insert) Phase 3 topline efficacy data for the treatment of glaucoma now expected in the first half of 2019.** OTX-TP is a long-acting, preservative-free formulation of travoprost for patients with primary open-angle glaucoma and ocular hypertension. While enrollment in this large trial has continued steadily, it has proceeded more slowly than projected. Therefore, the Company is adjusting guidance that topline data will now be available in the first half of 2019 rather than the second half of 2018. To address this enrollment issue, the Company is intensifying efforts with current sites to identify eligible patients and continues to add new sites to help complete enrollment.
- **Plans to initiate an open label one-year safety extension study for OTX-TP (travoprost insert) for glaucoma in the second quarter 2018.** The Company will initiate an open-label, one-year safety extension study with its first Phase 3 study. This study will contribute to the safety data to support OTX-TP's eventual product registration.
- **First patient dosed in OTX-TIC (travoprost implant) U.S. Phase 1 clinical trial with plans to report clinical data in the first half of 2019.** OTX-TIC is Ocular Therapeutix's second glaucoma program targeting patients needing a higher level of intraocular pressure reduction. The product is a bioresorbable, travoprost-containing hydrogel implant delivered via intracameral injection. The U.S. Phase 1 trial is a multi-center, open-label, proof-of-concept clinical trial to evaluate the safety, efficacy, durability, and tolerability of OTX-TIC in patients with primary open-angle glaucoma and ocular hypertension.
- **Plans to initiate ex-U.S. Phase 1 clinical trial for OTX-TKI (tyrosine kinase inhibitor implant) in the second quarter of 2018.** OTX-TKI is a bioresorbable, hydrogel fiber implant with anti-angiogenic properties, delivered by intravitreal injection. Preclinical data have demonstrated the ability to deliver an efficacious dose of OTX-TKI to the posterior segment of the eye for the treatment of VEGF-induced retinal leakage for an extended duration of up to twelve months. The study will be a multi-center, open-label, dose escalation study to test the safety, durability, and tolerability of OTX-TKI. The Company also plans to evaluate biological activity by following visual acuity over time and measuring retinal thickness using standard optical coherence tomography (OCT).
- **Regeneron collaboration continues for the development of OTX-IVT (aflibercept implant).** The Company, along with Regeneron, continues to progress on the development of an extended-delivery formulation of the VEGF trap aflibercept (EYLEA®), delivered by intravitreal injection, for the treatment of retinal diseases such as wet Age-Related Macular Degeneration (AMD). The Company remains encouraged by the engagement of both teams and the multiple possibilities to which this partnership could lead.

First Quarter 2018 Financial Results

- As of March 31, 2018, cash and cash equivalents totaled \$62.9 million. Cash used in operating activities was \$12.5 million in the first quarter of 2018, compared to \$14.6 million for the first quarter of 2017. The decrease of \$2.1 million was due to a savings in operating expenses as a result of the restructuring in the third quarter of 2017.
- Ocular Therapeutix reported a net loss of approximately \$(13.8) million, or \$(0.40) per share, for the quarter ended March

31, 2018, compared to a net loss of \$(16.0) million, or \$(0.58) per share, for the comparable quarter in 2017. The net loss for the first quarter of 2018 included \$2.4 million in non-cash charges for stock-based compensation and depreciation compared to \$2.0 million in similar non-cash charges for the first quarter of 2017.

- Total costs and operating expenses for the three-month period ended March 31, 2018 were \$13.8 million, as compared to \$16.1 million for the comparable period in 2017. Increases in (i) Research and Development expenses to advance the clinical and preclinical development of the Company's hydrogel platform technology and its portfolio of drug product candidates and (ii) General and Administrative expenses driven by increased professional fees primarily from higher litigation expenses were more than offset by significant savings in Selling and Marketing expenses due to the restructuring in the third quarter of 2017.
- Ocular Therapeutix generated \$340 thousand in revenue during the three-month period ended March 31, 2018 from product sales of ReSure® Sealant, as compared to \$475 thousand during the three-month period ended March 31, 2017.
- As of May 1, 2018, there were approximately 37.3 million shares issued and outstanding.
- Based on the Company's current plans and forecasted expenses, Ocular Therapeutix believes that existing cash and cash equivalents, will fund operating expenses, debt service obligations, and capital expenditure requirements through the first quarter of 2019, exclusive of any potential payment under the Regeneron partnership. This is of course subject to a number of assumptions about the Company's clinical development programs and other aspects of our business.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 4:30 pm 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 3148379. An archive of the webcast will be available until August 8, 2018 on the Company's website.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a biopharmaceutical company focused on the formulation, development, and commercialization of innovative therapies for diseases and conditions of the eye using its proprietary bioresorbable hydrogel-based formulation technology. Ocular Therapeutix's lead product candidate, DEXTENZA™ (dexamethasone insert), 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 primary open-angle glaucoma and ocular hypertension. The Company's earlier stage assets include OTX-TIC, an extended-delivery travoprost intracameral implant for the reduction of intraocular pressure in patients with glaucoma and ocular hypertension, as well as sustained release intravitreal implants for the treatment of retinal diseases. These intravitreal implants include the development of OTX-TKI, a tyrosine kinase inhibitor (TKI), and, in collaboration with Regeneron, OTX-IVT, an extended-delivery 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 regulatory submissions for and the timing and conduct of, or implications of results from, clinical trials of DEXTENZA™ for the treatment of post-surgical ocular pain and inflammation, including with respect to manufacturing deficiencies identified by the FDA, the Company's expectations regarding resubmitting its NDA to the FDA and the prospects for approvability of DEXTENZA for these indications, OTX-TP for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TIC for the treatment of primary open-angle glaucoma and ocular hypertension, OTX-TKI for the treatment of retinal diseases including wet AMD, and OTX-IVT as an extended-delivery formulation of the VEGF trap aflibercept for the treatment of retinal diseases including wet AMD; the ongoing development of the Company's extended-delivery hydrogel depot technology; the potential utility of any of the Company's product candidates; potential commercialization of the Company's product candidates; the potential benefits and future operation of the collaboration with Regeneron Pharmaceuticals, including any potential future payments thereunder; 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, timing 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, the outcome of the Company's ongoing legal proceedings 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	
	March 31,	
	2018	2017
Revenue:		
Product revenue	\$ 340	\$ 475
Total revenue	340	475
Costs and operating expenses:		
Cost of product revenue	80	115
Research and development	8,227	6,729
Selling and marketing	717	6,027
General and administrative	4,771	3,276
Total costs and operating expenses	13,795	16,147
Loss from operations	(13,455)	(15,672)
Other income (expense):		
Interest income	176	92
Interest expense	(486)	(443)
Total other expense, net	(310)	(351)
Net loss	\$ (13,765)	\$ (16,023)
Net loss per share, basic and diluted	\$ (0.40)	\$ (0.58)
Weighted average common shares outstanding, basic and diluted	34,792,848	27,643,746
Comprehensive loss:		
Net loss	\$ (13,765)	\$ (16,023)
Other comprehensive loss:		
Unrealized loss on marketable securities	—	(4)
Total other comprehensive loss	—	(4)
Total comprehensive loss	\$ (13,765)	\$ (16,027)

Ocular Therapeutix, Inc.**Balance Sheets****(In thousands, except share and per share data)****(Unaudited)**

	March 31,	December
	2018	31,
		2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 62,911	\$ 41,538
Accounts receivable	170	226
Inventory	139	122
Prepaid expenses and other current assets	1,256	1,453
Total current assets	64,476	43,339
Property and equipment, net	10,595	10,478
Restricted cash	1,614	1,614
Total assets	\$ 76,685	\$ 55,431
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,477	\$ 3,571
Accrued expenses and deferred rent	3,603	4,310
Notes payable, net of discount, current	6,071	5,545
Total current liabilities	13,151	13,426
Deferred rent, long-term	3,336	3,387
Notes payable, net of discount, long-term	11,014	12,471
Total liabilities	27,501	29,284
Commitments and contingencies (Note 10)		
Stockholders' equity:		

Preferred stock, \$0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2018 and December 31, 2017, respectively	—	—
Common stock, \$0.0001 par value; 100,000,000 shares authorized and 37,280,054 and 29,658,202 shares issued and outstanding at March 31, 2018 and December 31, 2017	4	3
Additional paid-in capital	300,210	263,409
Accumulated deficit	(251,030)	(237,265)
Total stockholders' equity	49,184	26,147
Total liabilities and stockholders' equity	\$ 76,685	\$ 55,431

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