Ocular Therapeutix™ Reports Fourth Quarter and Year End 2017 Financial Results and Business Update

March 8, 2018

Anticipating DEXTENZA™ NDA Resubmission in the First Half of 2018

BEDFORD, Mass.--(BUSINESS WIRE)--Mar. 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 fourth quarter and the twelve months ended December 31, 2017 and provided a business update.

"It gives me great pleasure to turn the page on 2017 and look forward to 2018 with a rebuilt team in place and an exciting set of near-term opportunities before us," said Antony Mattessich, President and Chief Executive Officer. "We have gained significant momentum in making the changes we believe are necessary to resubmit our New Drug Application for DEXTENZA and advance our pipeline. Based on this momentum, we can reaffirm our guidance that we are on track for a resubmission of our DEXTENZA NDA in the first half 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 first half of 2018.*** DEXTENZA is a long-acting form of dexamethasone that uses Ocular Therapeutix's proprietary hydrogel technology to treat post-surgical ocular pain and inflammation. In November, the Company completed its formal response to the May 2017 FDA Form 483 in which the Company addressed the FDA's observations concerning the manufacturing processes of and analytical testing related to DEXTENZA. In December the Company requested a meeting with the FDA to describe its remediation efforts and resubmission plans and seek feedback. A meeting was granted in January and preliminary written responses from the FDA to the Company's questions fully addressed its meeting objectives. The Company determined that the meeting would no longer be necessary because of the completeness of the FDA's response and that the FDA's comments have not required any substantial change in its manufacturing or regulatory plans. Subject to satisfactorily addressing the FDA inspectional observations and demonstrating consistency in its commercial stage manufacturing process, the Company plans to resubmit its NDA for DEXTENZA for the treatment of post-surgical pain in the first half of 2018 and would then expect a decision from the FDA by the end of 2018.
- ***Topline efficacy data from the Phase 3 Trial of OTX-TP (travoprost insert) for mild to moderate glaucoma expected in second half 2018.*** In 2016, the Company began enrollment of its first Phase 3 clinical trial, a 550-patient prospective, multi-center, randomized, parallel-arm, double masked, vehicle-controlled trial to evaluate the safety and efficacy of OTX-TP in the treatment of subjects with open-angle glaucoma or ocular hypertension. The primary efficacy endpoint is the statistically superior reduction of intraocular pressure (IOP) from baseline with OTX-TP compared to placebo inserts at 2, 6 and 12 weeks following insertion. These include statistically superior IOP reduction at three diurnal time points of 8:00 AM, 10:00 AM, and 4:00 PM, at each of these weeks. In addition, while not a primary endpoint, the IOP reduction will also need to be clinically meaningful for regulatory approval. The Company expects to have topline efficacy results in the fourth quarter of 2018.

- ***Submitted U.S. Investigational New Drug (IND) Application for OTX-TIC (travoprost implant) and plans to initiate the U.S. Phase 1 clinical trial in the first half 2018.*** OTX-TIC is Ocular Therapeutix's second glaucoma program and it targets a more severe patient population. The Company is developing OTX-TIC as its bioresorbable travoprost-containing hydrogel implant delivered via an intracameral injection. OTX-TIC targets patients with moderate to severe glaucoma who need a higher level of intraocular pressure reduction. The Company has initiated a Phase 1 clinical trial with OTX-TIC outside the United States. This trial is a prospective, single-center study designed to evaluate the safety, efficacy and tolerability of OTX-TIC compared to travoprost eye drops in patients with primary open-angle glaucoma or ocular hypertension. The Company also submitted a U.S. IND in the first quarter of 2018 enabling it to conduct a multi-center, open label, clinical trial evaluating the safety, efficacy, durability, and tolerability of OTX-TIC in patients in the same indication. Based on the results from these trials, the Company plans to advance OTX-TIC into a full development program.
- ***Expect to initiate ex-U.S. Phase 1 clinical trial for OTX-TKI (Tyrosine Kinase Inhibitor Implant) in the first half 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 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 Company is currently planning for a Phase 1 clinical trial to begin outside the U.S. in the first half of 2018. The trial 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).

- ***Continuing progress with Regeneron for the development of a sustained release formulation of VEGF trap aflibercept.*** Regeneron initiated a non-human primate trial of an extended release hydrogel-based formulation of its protein-based anti-vascular endothelial growth factor (VEGF) trap, aflibercept, for the treatment of wet age-related macular degeneration (wet AMD) in early 2018. The Company remains encouraged about the engagement of both teams and the multiple possibilities this partnership could lead to.
- ***Completed the transition of the management team.*** Ocular Therapeutix expanded its leadership team with the additions of Naymisha Patel, Vice President of Quality and Kevin Hanley, Senior Vice President, Technical Operations. Naymisha brings over 20 years of experience working with blue-chip biotechnology companies and she has a proven record in quality management, process improvement, regulatory submissions and regulatory compliance. Kevin joins the Company from Pfizer and brings to the Company over 30 years of experience managing biopharmaceutical technical operations, with demonstrated success in technology transfer and process scale-up for the manufacturing of proteins from development through manufacturing approval. These appointments to the management team represent critical additions to ensure the Company's core DEXTENZA manufacturing capabilities meet cGMP standards and that the Company can supply the anticipated commercial needs of DEXTENZA ahead of a potential FDA approval. Since July 2017 Ocular Therapeutix has appointed new team members to six of the top nine management positions in the Company, bringing in over 100 years of biopharmaceutical experience.

Fourth Quarter and Year End 2017 Financial Results

- In January 2018, Ocular Therapeutix completed a follow-on public offering raising net proceeds of $35.1 million that consisted of 7,475,000 shares of common stock, including those shares exercised by the underwriter of its option to purchase additional shares, pursuant to a shelf registration statement that was previously filed with and declared effective by the Securities and Exchange Commission.
- As of December 31, 2017, cash, cash equivalents and marketable securities totaled $41.5 million. Cash used in operating activities was $10.4 million in the fourth quarter of 2017 and $50.5 million for the year ended December 31, 2017.
- There was $18.0 million in outstanding debt as of December 31, 2017 with an interest-only payment period through February 1, 2018.
- Ocular Therapeutix reported a net loss of approximately $(13.1) million, or $(0.44) per share, for the quarter ended December 31, 2017, compared to a net loss of $(12.8) million, or $(0.52) per share, for the quarter ended December 31, 2016. The fourth quarter 2017 results include $2.6 million in non-cash charges for stock-based compensation and depreciation compared to $2.0 million in such non-cash charges in the fourth quarter of 2016. The Company reported a net loss of approximately $(63.4) million, or $(2.20) per share, for the year ended December 31, 2017, compared to a net loss of $(44.7) million, or $(1.80) per share, for the year ended December 31, 2016. The 2017 results include $8.9 million in non-cash charges for stock-based compensation and depreciation compared to $6.8 million in such non-cash charges in 2016.
- Total costs and operating expenses for the three and twelve month periods ended December 31, 2017 were $13.2 million and $63.8 million, respectively, as compared to $12.9 million and $45.2 million for the comparable periods in 2016. Research and development (R&D) expenses for the three and twelve month periods ended December 31, 2017 were $7.9 million and $30.9 million, respectively, compared to $7.3 million and $27.1 million for the comparable periods in 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 $0.5 million and $1.9 million in revenue during the three month and twelve month periods ended December 31, 2017 from product sales of ReSure® Sealant and from collaborations with corporate partners.
- As of December 31, 2017, there were approximately 29.7 million shares issued and outstanding.
- Based on the proceeds from the January offering plus existing cash on-hand, the Company believes that it has adequate cash to fund its operating expenses, debt service obligations and capital expenditures requirements through the first quarter of 2019. This forecast does not include a potential $10 million option payment under the Regeneron collaboration that would be due if Regeneron determines to advance the program into human clinical trials.

Conference Call & Webcast Information

Members of the Ocular Therapeutix management team will host a live conference call and webcast today at 8:30 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 9371369. An archive of the webcast will be available until March 15, 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 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 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 implants 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 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 Food and Drug Administration (FDA), the Company's expectations regarding resubmitting its NDA to the FDA and the prospects for approvability of DEXTENZA for these indications, the Company's clinical development of DEXTENZA for the treatment of allergic conjunctivitis, DEXTENZA for the treatment of dry eye disease, OTX-TP for the treatment of mild to moderate glaucoma and ocular hypertension, OTX-TIC for the treatment of moderate to severe glaucoma and ocular hypertension, and OTX-TKI for the treatment of wet age-related macular degeneration, the ongoing development of the Company's sustained release 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 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)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	**2016**	**2017**	**2016**
Revenue:				
Product revenue	$ 487	$ 511	$ 1,923	$ 1,845
Collaboration revenue	—	—	—	42
Total revenue	487	511	1,923	1,887
Costs and operating expenses:				
Cost of product revenue	113	127	457	443
Research and development	7,908	7,328	30,880	27,065
Selling and marketing	903	2,526	17,000	6,701
General and administrative	4,279	3,002	15,509	11,004
Total costs and operating expenses	13,203	12,983	63,846	45,213
Loss from operations	(12,716)	(12,472)	(61,923)	(43,326)
Other income (expense):				
Interest income	104	68	424	304
Interest expense	(490)	(418)	(1,892)	(1,680)
Other income (expense), net	–	–	5	(1)
Total other expense, net	(386)	(350)	(1,463)	(1,377)
Net loss	(13,102)	(12,822)	$ (63,386)	$ (44,703)
Net loss per share, basic and diluted	$ (0.44)	$ (0.52)	$ (2.20)	$ (1.80)
Weighted average common shares outstanding, basic and diluted	29,658,202	24,888,602	28,818,196	24,816,348
Comprehensive loss:				
Net loss	$ (13,102)	$ (12,822)	$ (63,386)	$ (44,703)
Other comprehensive income (loss):				
Unrealized gain on marketable securities	—	(10)	5	63
Total other comprehensive income	—	(10)	5	63

Total comprehensive loss	$ (13,102)	$ (12,832)	$ (63,381)	$ (44,640)

Balance Sheets

(In thousands, except share and per share data)

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 41,538	$ 32,936
Marketable securities	—	35,209
Accounts receivable	226	250
Inventory	122	113
Prepaid expenses and other current assets	1,453	1,390
Total current assets	43,339	69,898
Property and equipment, net	10,478	3,313
Restricted cash	1,614	1,728
Total assets	$ 55,431	$ 74,939
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,571	$ 2,116
Accrued expenses and deferred rent	4,310	4,635
Notes payable, net of discount, current	5,545	1,549
Total current liabilities	13,426	8,300
Deferred rent, long-term	3,387	537
Notes payable, net of discount, long-term	12,471	14,094
Total liabilities	29,284	22,931
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized at December 31, 2017 and December 31, 2016; no shares issued or outstanding at December 31, 2017 and December 31, 2016	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized at December 31, 2017 and December 31, 2016; 29,658,202 and 25,024,100 shares issued and outstanding at December 31 2017 and December 31, 2016, respectively	3	3
Additional paid-in capital	263,409	225,889
Accumulated deficit	(237,265)	(173,879)
Accumulated other comprehensive loss	—	(5)
Total stockholders' equity	26,147	52,008
Total liabilities and stockholders' equity	$ 55,431	$ 74,939

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