Ocular Therapeutix™ Provides Third Quarter 2023 Financial Results and Corporate Update

November 7, 2023

FDA Agrees to Overall Design of the First Pivotal Trial for AXPAXLI in Wet AMD under a Special Protocol Assessment; Expect First Subject Dosed by Year-End

Top-line Data from U.S.-based HELIOS Trial Evaluating AXPAXLI for Treatment of Non-Proliferative Diabetic Retinopathy Anticipated to be Presented in in Q2 2024

Top-line Data from U.S.-based Phase 2 Clinical Trial of OTX-TIC for Treatment of Primary Open-Angle Glaucoma or Ocular Hypertension Anticipated to be Presented at ASCRS Meeting in Early April 2024

DEXTENZA® Net Product Revenue in Q3 2023 was $15.0 million, Representing Growth of Approximately 26% Over Q3 2022

BEDFORD, Mass., Nov. 07, 2023 (GLOBE NEWSWIRE) -- 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 reported financial results for the third quarter ended September 30, 2023, and provided updates on its ophthalmology pipeline.

"We made significant progress at Ocular Therapeutix in the third quarter," said Antony Mattessich, President and CEO. "In a critical step forward for our clinical program, we initiated the first pivotal trial evaluating AXPAXLI for the treatment of wet AMD and subsequently have received FDA agreement with our overall clinical plan under a Special Protocol Assessment. We are thrilled to have agreement with the FDA regarding our trial design and are very excited to continue moving forward toward our goal of bringing a potentially transformative new treatment to wet AMD patients coping with vision loss."

Business Updates

AXPAXLI *(axitinib intravitreal implant) for the potential treatment of wet age-related macular degeneration (wet AMD) and other retinal vascular diseases.*

- The Company initiated the first pivotal clinical trial, or the SOL trial, evaluating AXPAXLI for the treatment of wet AMD. The trial is designed as a superiority trial and will enroll approximately 300 evaluable wet AMD subjects who are treatment naïve in the study eye. The trial is designed to be a multi-center, parallel-group Phase 3 trial that will be run primarily at U.S. sites with subjects randomized to one injection of aflibercept or one implant of AXPAXLI followed by as needed supplemental anti-VEGF treatment based on pre-specified criteria. The Company plans to use a single implant of AXPAXLI with an optimized drug load of 450 µg of axitinib per implant. This optimized configuration is expected to provide for a slightly increased daily release of the drug and is designed to improve synchronization of axitinib drug depletion with hydrogel bioresorption. The Company currently plans to assess the safety and efficacy of AXPAXLI by measuring best corrected visual acuity (BCVA) and central subfield thickness (CSFT) at 36 weeks. AXPAXLI is also referred to by its laboratory code, OTX-TKI.
- In October 2023, the Company received written agreement under a Special Protocol Assessment (SPA) from the U.S. Food and Drug Administration (FDA) for the SOL trial, securing alignment with the FDA on both the protocol design and the statistical analysis plan. The Company gained agreement on several crucial aspects including: the study population to be enrolled in our clinical trial, the identification of a suitable control arm for AXPAXLI, the determination of its dosing regimen, the definition of baseline, the selection of a primary endpoint and its corresponding timing, as well as the establishment of an appropriate sample size to ensure the statistical robustness of our pivotal trial.
- With the agreement under the SPA, the Company will begin enrolling patients in the SOL trial and expects to dose the first subject by year-end.

AXPAXLI *(axitinib intravitreal implant) for the treatment of non-proliferative diabetic retinopathy (NPDR).*

- The Company completed enrollment of the HELIOS trial, a U.S.-based, double-masked Phase 1 clinical trial in 22 subjects randomized 2:1 to either a single implant of AXPAXLI containing 600 µg of axitinib or a sham control.
- The Company plans to present nine-month, top-line clinical data from the trial in Q2 2024.

OTX-TIC (travoprost intracameral implant) for the treatment of primary open-angle glaucoma (OAG) or ocular hypertension (OHT).

- The Company plans to report top-line data from the single-dose portion of its U.S.-based Phase 2 prospective, multi-center, randomized, controlled clinical trial evaluating the safety, tolerability, and efficacy of OTX-TIC for the treatment of subjects with OAG or OHT compared to DURYSTA® at the ASCRS meeting in early April 2024.
- The Company has designed the Phase 2 clinical trial to evaluate whether OTX-TIC can demonstrate a clinically meaningful

decrease in intraocular pressure while preserving endothelial cell health.

- A repeat-dose sub-study in the Phase 2 clinical trial continues to enroll a small sub-set of subjects with OAG or OHT to evaluate the safety of a repeat, sustained release dose of OTX-TIC 26 µg. These subjects will be followed for at least 6 months after their enrollment in the sub-study in order to evaluate their endothelial cell health.

OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease and OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease.

- The Company is conducting a small study to evaluate the performance of OTX-DED versus fast-dissolving collagen plugs and no inserts at all with the intention of identifying a potential placebo control for future trials of these product candidates.
- The Company plans to use the results of this study to inform the next steps for both the OTX-DED and OTX-CSI programs.

DEXTENZA (dexamethasone ophthalmic insert) 0.4mg approved for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis.

- Net product revenue of DEXTENZA for Q3 2023 was $15.0 million, approximately 26% ahead of Q3 2022 net product revenue of $11.9 million and in line with Q2 2023 net product revenue of $15.0 million.
- In November 2023, the Centers for Medicare and Medicaid Services (CMS) released the final rulemaking for CY 2024 under the Outpatient Prospective Payment System (OPPS). The final rule confirms:
    - DEXTENZA will continue to be separately reimbursed by Medicare in the ambulatory surgical center (ASC) setting under the non-opioid pain provision; and
    - CPT 68841, the code that describes the insertion of DEXTENZA, maintains a Q1 status indicator. The Company intends to request that CMS reconsider its decision and provide for a separate facility payment in the 2024 (CY 2025) rule-making cycle.
- The Company believes that DEXTENZA is currently used in less than 5% of cataract procedures and that growth may be driven by a continued focus on sales to ASCs, specifically strategic accounts that own and control multiple ASCs.

Third Quarter Ended September 30, 2023 Financial Results

Total net revenue, which includes both gross DEXTENZA product revenue net of discounts, rebates, and returns, which the Company refers to as net product revenue, and collaboration revenue was $15.1 million for the third quarter of 2023, an increase of approximately 26% over third quarter 2022 net revenues of $12.0 million and in line with second quarter net revenue of $15.2 million. For the third quarter of 2023, DEXTENZA net product revenue grew to $15.0 million from $11.9 million over the comparable period in 2022 while collaboration revenue was approximately $0.1 million for each period.

Research and development expenses for the third quarter of 2023 were $15.0 million versus $13.7 million for the comparable period in 2022, driven primarily by an increase in expenses associated with clinical trial programs and personnel-related costs, including stock-based compensation to support those programs.

Selling and marketing expenses in the third quarter of 2023 were $9.3 million as compared to $10.2 million for the comparable quarter of 2022, reflecting primarily a decrease in professional fees and services.

General and administrative expenses were $8.6 million for the third quarter of 2023 versus $8.5 million in the comparable quarter of 2022, primarily due to an increase in personnel-related costs, including stock-based compensation offset by lower professional related fees and services.

The Company reported a net loss for the third quarter of 2023 of $(0.5) million, or a net loss of $(0.01) per share on a basic basis and ($0.25) per share on a diluted basis, compared to a net loss of $(24.2) million, or a net loss of $(0.31) per share on both a basic and diluted basis per share for the comparable period in 2022. Net loss in the third quarter of 2023 included a $ 6.7 million non-cash gain attributable to a change in the fair value of the derivative liabilities associated with the Company's convertible notes and the Barings credit facility. The Company also recorded gains and losses from debt extinguishment, net, of $14.2 million in the third quarter of 2023. Non-cash charges for stock-based compensation and depreciation and amortization were $5.4 million in the third quarter of 2023 versus $4.7 million for the comparable quarter in 2022. As of November 3, 2023, the Company had approximately 79.4 million shares outstanding.

2023 Financial Guidance

- The Company anticipates DEXTENZA net product revenue guidance for the full year 2023 to come in at the upper end of the current $55 and $60 million range provided by the Company. The current range represents anticipated growth of approximately 10% to 20% over 2022. The growth is anticipated to be driven by sales of DEXTENZA for the treatment of post-surgical inflammation and pain in the ASC setting.
- As of September 30, 2023, the Company had $110.6 million in cash and cash equivalents versus $102.3 million as of December 31, 2022. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA and anticipated cash outflows from operating expenses, the Company believes that its existing cash and cash equivalents are sufficient to enable the Company to fund planned operating expenses, debt service obligations and capital expenditure requirements into 2025 and comply with the Company's $20.0 million minimum cash covenant in connection with the

Barings Credit Agreement. This cash guidance is subject to a number of assumptions including the revenues, expenses and reimbursement associated with DEXTENZA, and the pace of research and clinical development programs, among other aspects of the 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. A live audio webcast will be available at www.ocutx.com. Interested parties may also register for the webcast via this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

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 ELUTYX™. Ocular Therapeutix's first commercial drug product, DEXTENZA®, is an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. Ocular Therapeutix's earlier stage development assets include: AXPAXLI (axitinib intravitreal implant), currently in a pivotal Phase 3 trial for wet AMD and a Phase 1 clinical trial for the treatment of diabetic retinopathy; OTX-TIC (travoprost intracameral implant), currently in a Phase 2 clinical trial for the treatment of primary open-angle glaucoma or ocular hypertension; and OTX-CSI (cyclosporine intracanalicular insert) for the chronic treatment of dry eye disease and OTX-DED (dexamethasone intracanalicular insert) for the short-term treatment of the signs and symptoms of dry eye disease, both of which have completed Phase 2 clinical trials.

About DEXTENZA

DEXTENZA is FDA-approved for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. DEXTENZA is a corticosteroid intracanalicular insert placed in the punctum, a natural opening in the inner portion of the lower eyelid, and into the canaliculus and is designed to deliver dexamethasone to the ocular surface for up to 30 days without preservatives. DEXTENZA resorbs and exits the nasolacrimal system without the need for removal.

Please see full Prescribing and Safety Information at www.DEXTENZA.com.

About AXPAXLI
AXPAXLI is an investigational bioresorbable, hydrogel implant incorporating axitinib, a small molecule, multi-target, tyrosine kinase inhibitor with anti-angiogenic properties, being evaluated for the treatment of wet AMD and other retinal diseases. AXPAXLI is also referred to by its laboratory code, OTX-TKI.

Forward Looking Statements
Any statements in this press release about future expectations, plans, and prospects for the Company, including the commercialization of DEXTENZA; the development, regulatory status and prospects of the Company's product candidates, including the timing and design of the Company's pivotal trials of AXPAXLI (also called OTX-TKI) for the treatment of wet AMD including the SOL trial, of the Company's ongoing HELIOS trial evaluating AXPAXLI for the treatment of non-proliferative diabetic retinopathy, and of the Company's ongoing Phase 2 clinical trial evaluating OTX-TIC for the treatment of primary open-angle glaucoma or ocular hypertension; the Company's plans to advance the development of its product candidates or preclinical programs; the potential utility of any of the Company's product candidates; projected net product revenue, in-market sales and other financial and operational metrics of DEXTENZA; the Company's cash runway and 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 preclinical and 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, the timing and costs involved in commercializing DEXTENZA or any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of DEXTENZA or any product or product candidate that receives regulatory approval; the ability to maintain and the sufficiency of product, procedure and any other reimbursement codes for DEXTENZA; the initiation, design, timing, conduct and outcomes of clinical trials; the risk that the FDA will not agree with the Company's interpretation of the written agreement under the SPA; the risk that even though the FDA has agreed with the overall design of the SOL trial, the FDA may not agree that the data generated by the SOL trial supports potential marketing approval; uncertainty as to whether the data from earlier clinical trials will be predictive of the data of later clinical trials, particularly later clinical trials that have a different design than the earlier 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 current and future products and product candidates; the Company's ability to meet supply demands for its current and future products; uncertainties inherent in estimating the Company's cash runway, future expenses and other financial results, including its ability to fund future operations, including clinical trials; Company's existing indebtedness and the ability of the Company's creditors to accelerate the maturity of such indebtedness upon the occurrence of certain events of default; the Company's ability to enter into strategic alliances or generate additional funding on a timely basis, on favorable terms, or at all; 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 press 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, whether as a result of new information, future events or otherwise, except as required by law. 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 press release.

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Ocular Therapeutix, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Product revenue, net	$ 14,950	$ 11,913	$ 43,193	$ 36,555
Collaboration revenue	131	52	449	864
Total revenue, net	15,081	11,965	43,642	37,419
Costs and operating expenses:				
Cost of product revenue	1,377	1,073	3,895	3,528
Research and development	15,019	13,719	44,860	39,919
Selling and marketing	9,315	10,186	31,304	29,390
General and administrative	8,584	8,531	25,915	23,875
Total costs and operating expenses	34,295	33,509	105,974	96,712
Loss from operations	(19,214)	(21,544)	(62,332)	(59,293)
Other income (expense):				
Interest income	1,212	285	2,524	375
Interest expense	(3,426)	(1,797)	(7,187)	(5,175)
Change in fair value of derivative liabilities	6,722	(1,133)	1,290	8,598
Gains and losses on extinguishment of debt, net	14,190	—	14,190	—
Other income (expense), net	—	1	(1)	(1)
Total other income (expense), net	18,698	(2,644)	10,816	3,797
Net loss	$ (516)	$ (24,188)	$ (51,516)	$ (55,496)
Net loss per share, basic	$ (0.01)	$ (0.31)	$ (0.66)	$ (0.72)
Weighted average common shares outstanding, basic	79,373,272	76,975,839	78,276,341	76,829,434
Net loss per share, diluted	$ (0.25)	$ (0.31)	$ (0.77)	$ (0.73)
Weighted average common shares outstanding, diluted	85,142,504	76,975,839	84,045,573	82,598,666

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

	September 30, 2023	**December 31, 2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 110,550	$ 102,300
Accounts receivable, net	23,589	21,325
Inventory	2,257	1,974
Prepaid expenses and other current assets	4,862	4,028
Total current assets	141,258	129,627
Property and equipment, net	12,494	9,856

Restricted cash	1,764	1,764
Operating lease assets	6,868	8,042
Total assets	$ 162,384	$ 149,289
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,984	$ 5,123
Accrued expenses and other current liabilities	28,887	24,097
Deferred revenue	317	576
Operating lease liabilities	1,878	1,599
Total current liabilities	35,066	31,395
Other liabilities:		
Operating lease liabilities, net of current portion	7,251	8,678
Derivative liabilities	24,022	6,351
Deferred revenue, net of current portion	14,197	13,387
Notes payable, net	65,124	25,257
Other non-current liabilities	106	93
Convertible Notes, net	8,765	28,749
Total liabilities	154,531	113,910
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 79,412,114 and 77,201,819 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	8	8
Additional paid-in capital	676,203	652,213
Accumulated deficit	(668,358)	(616,842)
Total stockholders' equity	7,853	35,379
Total liabilities and stockholders' equity	$ 162,384	$ 149,289

Source: Ocular Therapeutix, Inc.