Ocular Therapeutix™ Reports First Quarter 2024 Results

May 7, 2024

Recent Leadership Appointments Put Ocular on Track to Become a Leader in Retinal Care

Site Activation and Patient Enrollment for AXPAXLI™ SOL-1 Phase 3 wet AMD Trial Progressing with First Subjects Randomized in April 2024

Cash Expected to Support Operations Into 2028, Based on $482.9M March 31, 2024, Cash Balance

June 13, 2024, Investor Day to Outline Updated Corporate Strategy

BEDFORD, Mass., May 07, 2024 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ:OCUL, "Ocular", the "Company"), a biopharmaceutical company committed to enhancing people's vision and quality of life through the development and commercialization of innovative therapies for wet age-related macular degeneration (wet AMD), diabetic retinopathy, and other diseases and conditions of the eye, today reported financial results for the first quarter ended March 31, 2024.

"Ocular's excellent progress in 2024 has put the Company on track to becoming a leading retinal care company. We have substantially enriched the organization with the appointment of recognized leaders in retinal care and clinical development; have completed a successful financing of $325 million in gross proceeds from existing and new top-tier healthcare investors; and have progressed our Phase 3 program for AXPAXLI™ in wet AMD," said Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer of Ocular Therapeutix.

Dr. Dugel added, "The Phase 3 SOL-1 study is making solid progress and our investment in strengthening the clinical team has put Ocular in a strong position to drive enrollment. We look forward to sharing an update on the progress of the study, along with a review of Ocular's corporate strategy, during our Investor Day, planned for Thursday, June 13, 2024."

Recent Achievements and Upcoming Milestones:

- **Appointed Pravin U. Dugel, MD, as Executive Chairman, President and Chief Executive Officer** and added several strategic and clinical retinal experts, advancing Ocular's efforts to become a leading retina care company.
- **Raised gross proceeds of $325 million in a private financing** from existing and new top-tier healthcare investors, extending Ocular's cash runway into 2028.
- **Initiated site activation, screening, and randomization in the Phase 3 AXPAXLI SOL-1 wet AMD study** in accordance with a Special Protocol Assessment agreement with the FDA.
- **Reported positive topline data from two studies**, the Phase 1 HELIOS study of AXPAXLI in patients with non-proliferative diabetic retinopathy (NPDR) and the Phase 2 study of PAXTRAVA™ in patients with glaucoma.
- **Announced an Investor Day on the afternoon of Thursday, June 13, 2024, in New York City**, where senior leadership will review the Company's corporate strategy. Participating key opinion leaders and logistics information for the Investor Day, including details regarding the webcast, will be provided in advance of the event.

First Quarter Ended March 31, 2024, Financial Results

Total cash and cash equivalents were $482.9 million as of March 31, 2024. The Company completed a private placement of common stock and pre-funded warrants in February 2024 that provided gross proceeds of $325.0 million, before deducting placement agent fees and offering expenses. Based on current plans and related estimates of anticipated cash inflows from DEXTENZA®, the Company believes that its current cash balance is sufficient to support its planned expenses, obligations, and capital expenditure requirements into 2028.

Total net revenue was $14.8 million for the first quarter of 2024, a 10.4% increase over total net revenue of $13.4 million in the comparable period in 2023, driven by increased DEXTENZA sales. Total net revenue includes both gross DEXTENZA product revenue, net of discounts, rebates, and returns, which the Company refers to as net product revenue, and collaboration revenue.

Research and development expenses for the first quarter of 2024 were $20.7 million versus $14.7 million for the comparable period in 2023, reflecting an increase in overall clinical expenses associated with product development programs, specifically the SOL-1 Phase 3 clinical trial.

Selling and marketing expenses were $10.2 million in the first quarter of 2024, as compared to $10.8 million for the comparable quarter of 2023, primarily reflecting a decrease in professional fees and a reduction in personnel costs.

General and administrative expenses were $14.1 million for the first quarter of 2024 versus $9.1 million in the comparable quarter of 2023, higher primarily due to an increase in personnel-related costs and other expenses.

Net loss for the first quarter of 2024 was $(64.8) million, or a net loss of $(0.49) per share on both a basic and diluted basis, compared to a net loss of $(30.3) million, or a net loss of $(0.39) per share on both a basic and diluted basis, for the comparable period in 2023. The net loss in the first quarter of 2024 included a $(28.0) million non-cash loss on extinguishment of debt in connection with the conversion of the Company's convertible notes, and a $(5.2) million non-cash loss, net, attributable to the changes in the fair value of the derivative liabilities associated with the Company's convertible notes, through the date of conversion, and the Barings credit facility, as compared to a $(6.6) million non-cash loss attributable solely to the change in the fair value of the derivative liability associated with the Company's convertible notes for the comparable quarter in 2023.

Outstanding shares as of May 3, 2024, were approximately 154.9 million.

About Ocular Therapeutix, Inc.
Ocular Therapeutix, Inc. is a biopharmaceutical company committed to enhancing people's vision and quality of life through the development and commercialization of innovative therapies for wet age-related macular degeneration (wet AMD), diabetic retinopathy (DR), and other diseases and conditions of the eye. AXPAXLI™ (axitinib intravitreal implant, also known as OTX-TKI), Ocular's product candidate for retinal disease, is based on its ELUTYX™ proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently in a Phase 3 clinical trial for wet AMD. The clinical portfolio also includes PAXTRAVA™ (travoprost intracameral implant, also known as OTX-TIC), currently in a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension.

Ocular's expertise in the formulation, development, and commercialization of innovative therapies of the eye and the ELUTYX platform supported the development and launch of its first commercial drug product, DEXTENZA®, an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery and ocular itching associated with allergic conjunctivitis. ELUTYX is also the foundation for two other clinical-stage assets, 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, as well as several preclinical programs.

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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 on the DEXTENZA website.

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, including the timing, design, and enrollment of the Company's SOL-1 Phase 3 clinical trial of AXPAXLI (also called OTX-TKI) for the treatment of wet AMD; the Company's plans to advance the development of AXPAXLI, PAXTRAVA and its other product candidates; the potential utility of any of the Company's product candidates; the Company's objective to become a leader in retinal care; the Company's cash runway and 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 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 initiation, design, timing, conduct and outcomes of ongoing and planned clinical trials; the risk that the FDA will not agree with the Company's interpretation of the written agreement under Special Protocol Assessment for the SOL-1 trial; the risk that even though the FDA has agreed with the overall design of the SOL-1 trial, the FDA may not agree that the data generated by the SOL-1 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 or utilize a different formulation than the earlier trials, or whether preliminary or interim data from a clinical trial will be predictive of final data from such trial; availability of data from clinical trials and expectations for regulatory submissions and approvals; the Company's scientific approach and general development progress; 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; the 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 may 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.

Investors & Media
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Ocular Therapeutix, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2024	December 31, 2023
Assets		

Current assets:		
Cash and cash equivalents	$ 482,888	$ 195,807
Accounts receivable, net	26,546	26,179
Inventory	2,574	2,305
Restricted cash	150	150
Prepaid expenses and other current assets	7,666	7,794
Total current assets	519,824	232,235
Property and equipment, net	11,450	11,739
Restricted cash	1,614	1,614
Operating lease assets	6,059	6,472
Total assets	$ 538,947	$ 252,060
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,453	$ 4,389
Accrued expenses and other current liabilities	16,040	28,666
Deferred revenue	263	255
Operating lease liabilities	1,542	1,586
Total current liabilities	24,298	34,896
Other liabilities:		
Operating lease liabilities, net of current portion	6,407	6,878
Derivative liabilities	19,624	29,987
Deferred revenue, net of current portion	14,068	14,135
Notes payable, net	66,456	65,787
Other non-current liabilities	111	108
Convertible Notes, net	—	9,138
Total liabilities	130,964	160,929
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized and 154,704,086 and 114,963,193 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	15	12
Additional paid-in capital	1,170,394	788,697
Accumulated deficit	(762,426)	(697,578)
Total stockholders' equity	407,983	91,131
Total liabilities and stockholders' equity	$ 538,947	$ 252,060

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

	Three Months Ended March 31,	
	2024	**2023**
Revenue:		
Product revenue, net	$ 14,715	$ 13,214
Collaboration revenue	59	160
Total revenue, net	14,774	13,374
Costs and operating expenses:		
Cost of product revenue	1,326	1,214
Research and development	20,735	14,747
Selling and marketing	10,183	10,835
General and administrative	14,147	9,127
Total costs and operating expenses	46,391	35,923
Loss from operations	(31,617)	(22,549)
Other income (expense):		
Interest income	3,922	563
Interest expense	(4,051)	(1,768)

Change in fair value of derivative liabilities	(5,152)	(6,563)
Loss on extinguishment of debt	(27,950)	—
Other expense	—	(1)
Total other income (expense), net	(33,231)	(7,769)
Net loss	$ (64,848)	$ (30,318)
Net loss per share, basic	$ (0.49)	$ (0.39)
Weighted average common shares outstanding, basic	132,021,945	77,386,287
Net loss per share, diluted	$ (0.49)	$ (0.39)
Weighted average common shares outstanding, diluted	132,021,945	77,386,287