



Ocular Therapeutix™ Reports First Quarter 2025 Results and Business Highlights

May 5, 2025

AXPAXLI™ SOL trials for wet AMD progressing rapidly following recent updates to accelerate and enhance the registrational program

Following positive FDA feedback for potential AXPAXLI NPDR registrational trial, Ocular is actively planning next steps in NPDR and DME

SOL-1 retention remains exceptional as trial is on track for 1Q 2026 topline data readout

SOL-R continues to have strong enrollment through streamlined, accelerated execution

Cash balance of \$349.7M as of March 31, 2025, with expected runway through topline data for SOL-1 and SOL-R and into 2028

BEDFORD, Mass., May 05, 2025 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), a fully-integrated biopharmaceutical company committed to redefining the retina experience, today reported financial results for the first quarter ended March 31, 2025, and provided recent business highlights.

"We continue to advance the SOL registrational program for our product candidate AXPAXLI in wet AMD with urgency and precision. Our unwavering focus is on redefining the retina experience. Delivering a more sustainable therapy designed to drive better long-term outcomes is central to this effort. Earlier this year, we implemented strategic regulatory updates designed to accelerate the SOL program, enhancing capital and operational efficiencies. We believe these refinements could position AXPAXLI for an unprecedented 6 to 12-month dosing regimen on the label for the treatment of wet AMD and potentially enable an earlier NDA submission. These enhancements were made in alignment with FDA feedback and preserve the scientific integrity and robust powering of our two complementary registrational studies, SOL-1 and SOL-R," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer** of Ocular Therapeutix. "In addition to our momentum in wet AMD, we are thrilled with the positive written feedback received from the FDA on the design of a potential registrational trial for AXPAXLI in NPDR. These encouraging interactions represent a meaningful step forward as we plan our next steps in both NPDR and DME."

"Backed by a world-class team, strong capital position, and disciplined execution, we believe we are in an outstanding position as we pursue our goal of becoming a leading retina company," concluded **Dr. Dugel**.

Recent Achievements and Upcoming Milestones:

- **SOL-1 (Phase 3, wet AMD) retention remains exceptional and the vast majority of rescues, evaluated on a masked basis, continue to be per protocol. Topline data are on track for 1Q 2026.** In March, the Company announced that the FDA accepted an amendment to the SOL-1 Special Protocol Assessment (SPA) agreement that includes re-dosing of all subjects at Weeks 52 and 76 with their respective initial treatment of AXPAXLI or aflibercept (2 mg). Subjects will remain masked and are then followed for safety until the end of year two. This optimized design enhances the potential to achieve label flexibility for dosing AXPAXLI every 6 to 12 months and should provide valuable insights into AXPAXLI's long-term durability.
- **SOL-R (Phase 3, wet AMD) enrollment continues to be strong following the recent reduction in target randomization to approximately 555 subjects (previously 825).** The strong SOL-1 subject retention observed to date and re-dosing amendment have enabled Ocular to reduce the size of the SOL-R non-inferiority study while continuing to meet the FDA requirements for long-term safety data. Streamlining the execution of SOL-R is expected to accelerate the trial readout and, if successful, the AXPAXLI wet AMD NDA submission timeline. SOL-R remains robustly powered at 90% with the non-inferiority margin of -4.5 ETDRS letter per FDA guidance.
- **Written feedback received from FDA on AXPAXLI registrational trial in non-proliferative diabetic retinopathy (NPDR).** The FDA provided positive feedback to Ocular on a potential registrational trial design for AXPAXLI in NPDR. Following recent changes more broadly within the FDA, Ocular has not noticed any disruption in the cadence and nature of its dialogue with the Agency to date and continues to maintain productive interactions. The Company is actively planning next steps in the development of AXPAXLI for NPDR and diabetic macular edema (DME) and expects to provide further details at a later date.

First Quarter Ended March 31, 2025, Financial Results:

Total cash and cash equivalents were \$349.7 million as of March 31, 2025. 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, debt service obligations, and capital expenditure requirements into 2028. This cash projection does not factor in the impact of potential clinical trial activities for AXPAXLI in NPDR

and DME.

Total net revenue was \$10.7 million for the first quarter of 2025, a 27.6% decrease as compared to total net revenue of \$14.8 million in the comparable quarter in 2024. This decrease was driven by decreased gross revenues from 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.

The Company's net product revenue was \$10.6 million for the three months ended March 31, 2025, reflecting a decrease of \$4.1 million or 27.7% over the comparable quarter in 2024. The Company believes the decline in first quarter 2025 DEXTENZA net sales is primarily attributable to the impact of its pricing strategy on distributor stocking patterns and buying patterns by ambulatory surgical centers (ASCs), hospital outpatient departments (HOPDs), and physicians' offices, as well as the recent inclusion of DEXTENZA into the cost performance category of the Centers for Medicare & Medicaid Services' Merit-based Incentive Payment System (MIPS) for 2025.

The Company anticipates that net product revenue on a quarterly basis should increase for the remainder of 2025, driven primarily by expected increases in the number of units sold, as clinicians adjust to the impact of MIPS, and as the Company increases sales efforts directed towards HOPDs, which are receiving separate payment for DEXTENZA in 2025 after being ineligible for separate payments in 2024.

Research and development expenses for the first quarter of 2025 were \$42.9 million versus \$20.7 million for the comparable quarter in 2024, reflecting an increase in overall clinical expenses associated with the SOL-1 and SOL-R Phase 3 clinical trials, as well as additional personnel and professional services to support these clinical trials.

Selling and marketing expenses were \$14.1 million for the first quarter of 2025, as compared to \$10.2 million for the comparable quarter of 2024, primarily reflecting an increase in personnel-related costs, including stock-based compensation expense, and professional fees associated with pre-commercialization activities for AXPAXLI.

General and administrative expenses were \$16.3 million for the first quarter of 2025, as compared to \$14.1 million for the comparable quarter of 2024, primarily due to an increase in personnel-related costs, including stock-based compensation expense.

Net loss for the first quarter of 2025 was \$(64.1) million, or a net loss of \$(0.38) per share on both a basic and diluted basis, compared to a net loss of \$(64.8) million, or a net loss of \$(0.49) per share on a basic and diluted basis, for the comparable quarter of 2024. The net loss in the first quarter of 2025 includes a net loss from the change in fair value of our derivative liability of \$(1.0) million, which is comprised of a non-cash loss from fair value measurement of the derivative liability associated with the Barings Credit Facility of \$(0.6) million, and expense related to actual royalty fees under the Barings Credit Facility of \$(0.4) million, compared to a \$(5.2) million net loss for the first quarter of 2024, which is comprised of a net non-cash loss attributable to fair value measurements of the derivative liabilities associated with the Barings Credit Facility and the Company's convertible notes of \$(4.6) million, and expense related to actual royalty fees under the Barings Credit Facility of \$(0.5) million.

Outstanding shares as of May 1, 2025, were approximately 159.3 million.

About AXPAXLI

AXPAXLI™ (also known as OTX-TK1) is an investigational, bioresorbable, intravitreal hydrogel incorporating axitinib, a small molecule, multi-target, tyrosine kinase inhibitor with anti-angiogenic properties, being evaluated for the treatment of wet AMD, diabetic retinopathy, diabetic macular edema, and other retinal diseases.

About the SOL-1 Study

The registrational Phase 3 SOL-1 trial (NCT06223958) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (1:1), parallel group study that involves more than 100 clinical trial sites located in the U.S. and Argentina. In December 2024, the trial completed randomization of 344 evaluable treatment-naïve subjects with a diagnosis of wet AMD in the study eye.

The superiority study has an eight-week loading segment prior to randomization. During the loading segment, subjects who have 20/80 vision or better and who satisfy other enrollment criteria receive two doses of aflibercept (2 mg) at Week -8 and Week -4. Eligible subjects who achieve best corrected visual acuity (BCVA) of 20/20 at Day 1 or gain at least 10 early treatment diabetic retinopathy study (ETDRS) letters at Day 1 are then randomized to receive a single dose of AXPAXLI or a single dose of aflibercept (2 mg). At Week 52 and at Week 76, all subjects are re-dosed with their respective initial treatment of AXPAXLI or aflibercept (2 mg). Subjects will be followed for safety until the end of Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2. The clinical trial protocol requires that, during the study, subjects in either arm meeting pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg).

The primary endpoint of SOL-1 is the proportion of subjects who maintain visual acuity, defined as a loss of <15 ETDRS letters of BCVA, at Week 36. Subjects will continue to be evaluated for durability up to Week 52. The study is being conducted under a Special Protocol Assessment (SPA) agreement with the FDA.

About the SOL-R Study

The registrational Phase 3 SOL-R trial (NCT06495918) is designed to evaluate the safety and efficacy of AXPAXLI in a multi-center, double-masked, randomized (2:2:1), three-arm study that will involve sites located in the U.S. and the rest of the world. The trial is intended to randomize approximately 555 subjects who are treatment-naïve or were diagnosed with wet AMD in the study eye within about four months prior to enrollment.

This non-inferiority trial reflects a patient enrichment strategy over the six months prior to randomization that includes three screening doses of any anti-VEGF therapy, excluding brolocizumab-dbl, and monitoring to exclude those subjects with significant retinal fluid fluctuations. Subjects that continue to meet eligibility will enter a run-in period and receive two loading doses of aflibercept (2 mg) prior to Day 1. Subjects in the first arm receive a single dose of AXPAXLI at Day 1 and are re-dosed at Weeks 24, 48, and 72. Subjects in the second arm receive aflibercept (2 mg) on-label every eight weeks. Subjects in the third arm receive a single dose of aflibercept (8 mg) at Day 1 and are re-dosed at Weeks 24, 48, and 72, aligned with the AXPAXLI treatment arm for adequate masking. Subjects will be followed for safety until the end of Year 2. Throughout the study, subjects are assessed monthly. Trial subjects and designated study personnel will remain masked through the end of Year 2. Subjects in any arm that meet pre-specified rescue criteria will receive a supplemental dose of aflibercept (2 mg). The pre-specified rescue criteria include loss of ≥ 10 letters of BCVA from baseline or a combination of worsening anatomical measures and BCVA loss.

The primary endpoint of SOL-R is to demonstrate non-inferiority in mean BCVA change from baseline between the AXPAXLI and on-label aflibercept

(2 mg) arms at Week 56. As per the protocol agreed to by the FDA, the non-inferiority margin for the lower bound is -4.5 letters of mean BCVA when compared to aflibercept (2 mg) dosed every eight weeks. In a written Type C response received in August 2024, and a subsequent written response received in December 2024, the FDA agreed that the SOL-R repeat dosing wet AMD study, with a primary endpoint at Week 56, should be appropriate as an adequate and well-controlled study in support of a potential New Drug Application and product label for wet AMD.

About Wet AMD

Wet age-related macular degeneration (wet AMD) is a leading cause of severe, irreversible vision loss affecting approximately 14.5 million individuals globally and 1.7 million in the United States alone (2024 Market Scope[®] Retinal Pharmaceuticals Market Report). Wet AMD causes vision loss due to abnormal new blood vessel growth and hyperpermeability and associated retinal vascularity in the macula, which is primarily stimulated by local upregulation of vascular endothelial growth factor (VEGF). Without prompt and continuous treatment to control this exudative activity, patients develop irreversible vision loss. With proper treatment, patients may maintain visual function for a period of time and may temporarily regain lost vision. Challenges with current therapies include pulsatile, repeated intraocular injections, treatment-related adverse events and up to 40% patient discontinuation within one year of initiating treatment with continued disease progression. Taken together, these factors lead to undertreatment and a lack of long-term vision improvement for patients.

About Ocular Therapeutix, Inc.

Ocular Therapeutix, Inc. is a fully-integrated biopharmaceutical company committed to redefining the retina experience. AXPAXLI[™] (also known as OTX-TKI), Ocular's investigational product candidate for retinal disease, is an axitinib intravitreal hydrogel based on its ELUTYX[™] proprietary bioresorbable hydrogel-based formulation technology. AXPAXLI is currently in Phase 3 clinical trials for wet age-related macular degeneration (wet AMD).

Ocular's pipeline also leverages the ELUTYX technology in its commercial product DEXTENZA[®], an FDA-approved corticosteroid for the treatment of ocular inflammation and pain following ophthalmic surgery in adults and pediatric patients and ocular itching associated with allergic conjunctivitis in adults and pediatric patients aged two years or older, and in its investigational product candidate PAXTRAVA[™] (also known as OTX-TIC), which is a travoprost intracameral hydrogel that is currently in a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension.

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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 of and regulatory submissions regarding the Company's product candidates; the design of, and the timing of the screening, enrollment and randomization of patients in and the availability of data from the Company's SOL-1 and SOL-R Phase 3 clinical trials of AXPAXLI (also known as OTX-TKI) for the treatment of wet AMD; the Company's plans to advance the development of AXPAXLI, including in additional indications such as NPDR and DME, and its other product candidates; the potential utility or adoption, if approved, of any of the Company's product candidates; 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", "designed", "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 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 any product or product candidate that receives regulatory approval; the ability to retain regulatory approval of 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 ongoing and planned clinical trials; the risk that the FDA will not agree with the Company's interpretation of the written agreement under the Special Protocol Assessment for the SOL-1 trial; the risk that the FDA may not agree that the protocol and statistical analysis plan of SOL-R or that the data generated by the SOL-1 and SOL-R trials support marketing approval, even if the trials are successful; the risk that the Company and the FDA may not agree on the registrational pathway for any of its product candidates; 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, whether preliminary or interim data from a clinical trial (including masked safety or masked rescue data from the Company's SOL-1 trial) will be predictive of final data from such trial, or whether data from a clinical trial assessing a product candidate for one indication will be predictive of results in other indications; 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; 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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(in thousands, except share and per share data)

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 349,681	\$ 392,102
Accounts receivable, net	25,221	32,388
Inventory	3,269	3,040
Prepaid expenses and other current assets	9,523	13,457
Total current assets	387,694	440,987
Property and equipment, net	10,784	9,389
Restricted cash	1,614	1,614
Operating lease assets	5,828	5,945
Total assets	<u>\$ 405,920</u>	<u>\$ 457,935</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,626	\$ 4,176
Accrued expenses and other current liabilities	31,080	35,117
Deferred revenue	64	128
Operating lease liabilities	2,156	1,933
Total current liabilities	37,926	41,354
Other liabilities:		
Operating lease liabilities, net of current portion	4,866	5,345
Derivative liability	13,852	13,246
Deferred revenue, net of current portion	14,000	14,000
Notes payable, net	69,202	68,505
Other non-current liabilities	144	141
Total liabilities	139,990	142,591
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, 2025 and December 31, 2024, respectively	—	—
Common stock, \$0.0001 par value; 400,000,000 shares and 400,000,000 shares authorized and 159,262,024 and 157,749,490 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	16	16
Additional paid-in capital	1,221,051	1,206,412
Accumulated deficit	(955,137)	(891,084)
Total stockholders' equity	265,930	315,344
Total liabilities and stockholders' equity	<u>\$ 405,920</u>	<u>\$ 457,935</u>

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

	Three Months Ended March 31,	
	2025	2024
Revenue:		
Product revenue, net	\$ 10,634	\$ 14,715
Collaboration revenue	64	59
Total revenue, net	10,698	14,774
Costs and operating expenses:		
Cost of product revenue	1,262	1,326
Research and development	42,857	20,735
Selling and marketing	14,148	10,183
General and administrative	16,348	14,147
Total costs and operating expenses	74,615	46,391

Loss from operations	<u>(63,917)</u>	<u>(31,617)</u>
Other income (expense):		
Interest income	3,826	3,922
Interest expense	(2,984)	(4,051)
Change in fair value of derivative liabilities	(978)	(5,152)
Loss on extinguishment of debt	—	(27,950)
Total other expense, net	<u>(136)</u>	<u>(33,231)</u>
Net loss	<u>\$ (64,053)</u>	<u>\$ (64,848)</u>
Net loss per share, basic	<u>\$ (0.38)</u>	<u>\$ (0.49)</u>
Weighted average common shares outstanding, basic	<u>169,396,989</u>	<u>132,021,945</u>
Net loss per share, diluted	<u>\$ (0.38)</u>	<u>\$ (0.49)</u>
Weighted average common shares outstanding, diluted	<u>169,396,989</u>	<u>132,021,945</u>