Ocular Therapeutix™ Reports Fourth Quarter and Full Year 2024 Results and Business Highlights

March 3, 2025

Announces several updates to enhance and accelerate AXPAXLI registrational program in wet AMD, potentially supporting label flexibility of 6-12 months to showcase expected best-in-class durability

FDA approves Amendment to SOL-1 Special Protocol Agreement (SPA) to include AXPAXLI re-dosing at Weeks 52 and 76

SOL-1 trial Week 36 primary endpoint data now expected in 1Q 2026 due to requirement for masking until Week 52 to allow for re-dosing

Inclusion of re-dosing in SOL-1, along with exceptional retention seen to date in the study, paves way for reduction of SOL-R trial size to 555 subjects (previously 825), potentially accelerating registration timelines

Additional updates provided on SOL-R non-inferiority margin and rescue criteria

Cash balance of $392.1M as of December 31, 2024, expected to fund operations into 2028 and the Company currently does not intend to raise additional capital this year

FDA feedback on clinical trial design for AXPAXLI in NPDR and DME expected in 1H 2025

Ocular to host a 4Q 2024 conference call and webcast today, March 3rd, at 8:00 AM ET

BEDFORD, Mass., March 03, 2025 (GLOBE NEWSWIRE) -- Ocular Therapeutix, Inc. (NASDAQ: OCUL, "Ocular"), a biopharmaceutical company committed to redefining the retina experience, today reported financial results for the fourth quarter and year ended December 31, 2024 and provided recent business highlights, including updates to the registrational program for AXPAXLI™ (axitinib intravitreal hydrogel) in wet age-related macular degeneration (wet AMD) designed to accelerate a potential path to NDA submission and increased label flexibility.

"2024 was a transformative year for Ocular Therapeutix. We sharpened our focus on a single, bold mission – to redefine the retina experience – starting with wet AMD as our top priority. Despite effective treatments today, the burden of frequent pulsatile dosing leads to high dropout rates and poor long-term visual outcomes. AXPAXLI has the potential to disrupt this paradigm by offering a more sustainable solution and possibly improve long-term outcomes. And we see wet AMD as just the beginning. There is a significant opportunity to expand into non-proliferative diabetic retinopathy (NPDR) and diabetic macular edema (DME), along with several other retinal diseases, where millions remain untreated," said **Pravin U. Dugel, MD, Executive Chairman, President and Chief Executive Officer** of Ocular Therapeutix. "We're executing not only with speed but also with precision. Today we announced key updates designed to accelerate our path to NDA submission while maintaining strong study integrity and alignment with FDA guidance. By incorporating 52-week and 76-week re-dosing in SOL-1, we anticipate a label supporting dosing every 6-12 months, reinforcing AXPAXLI's potential best-in-class durability. Equally important is the exceptional retention we have seen to date in SOL-1. The combination of this outstanding retention and the addition of re-dosing in SOL-1 allows us to reduce the size of SOL-R while ensuring it remains well-powered for success. Trial conduct for both studies remains a top priority, and we are pleased to see the vast majority of SOL-1 rescue treatments continue to track in line with the pre-specified criteria in the protocol. Ultimately, these trials were developed to be complementary and to de-risk the clinical trials' patient populations in a bespoke manner. We expect the complementary nature of the two trials will continue to provide us with a significant advantage in our regulatory and registrational strategy as we prepare for potential commercialization."

Dr. Dugel concluded, "We have started 2025 with confidence and conviction, backed by a world-class team, a groundbreaking asset, strong trial momentum, and a substantial capital position providing runway into 2028 with no plans to raise additional capital this year. With our registrational program for AXPAXLI making significant progress in wet AMD and plans coming into focus this year for NPDR and DME, we believe we are well on our way to becoming a leading retina company."

Recent Achievements and Upcoming Milestones:

- **SOL-1 (Phase 3, wet AMD) Special Protocol Agreement (SPA) further amended to incorporate re-dosing at Weeks 52 and 76.** In this superiority study, all subjects will now be re-dosed at Week 52 and Week 76 with their respective initial treatment of AXPAXLI or aflibercept (2 mg). Patients will be followed for safety until Week 104. While the primary endpoint (proportion of patients who maintain vision) remains at Week 36, results will now be unmasked at Week 52 to enable re-dosing at 12 months, with topline data expected in 1Q 2026. The optimized design enhances the potential for an unprecedented 6-12 month dosing label for AXPAXLI and provides valuable insights into the long-term durability of

AXPAXLI. SOL-1 completed randomization ahead of schedule in December 2024, randomizing 344 subjects across more than 100 clinical trial sites in the U.S. and Argentina. To date, subject retention has been exceptional, and the vast majority of rescue treatments, reviewed on a masked basis, have been in accordance with the pre-specified criteria under the trial protocol.

- **SOL-R (Phase 3, wet AMD) trial protocol modified to randomize approximately 555 subjects (previously 825) as enrollment continues to stay strong.** The Company previously announced that as of January 10, 2025, 311 subjects were enrolled across various stages of loading and randomization in the U.S. and South America. The trial remains robustly powered based on the Company's expectations of how AXPAXLI will perform, as the original randomization target was driven by regulatory re-dosing considerations, now satisfied with the incorporation of re-dosing in SOL-1. Streamlining the execution of SOL-R should accelerate the trial timeline, enhancing both speed and capital efficiency.

  SOL-R is a non-inferiority trial comparing AXPAXLI, administered every 24 weeks, to aflibercept (2 mg), administered every eight weeks. The primary endpoint is the mean change in best corrected visual acuity (BCVA) 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. This is also in line with the FDA draft guidance, which Ocular is adhering to by including an aflibercept (8 mg) masking comparator arm with the exact same dosing frequency as the AXPAXLI arm.

- **FDA feedback on clinical trial design for AXPAXLI in non-proliferative diabetic retinopathy (NPDR) and diabetic macular edema (DME) is anticipated in 1H 2025.** Following positive results from the Phase 1 HELIOS trial of AXPAXLI initially shared in 2024, and subject to receiving FDA feedback, Ocular will continue to evaluate the next steps for AXPAXLI in NPDR and DME. At the Angiogenesis, Exudation, and Degeneration 2025 Virtual Meeting, Ocular presented additional analyses from the HELIOS trial, highlighting the effects of a single AXPAXLI injection on macular volume and its potential to suppress retinal leakage and prevent vision threatening complications for up to 12 months.

"We designed the SOL program to answer the most relevant questions a retina specialist may have about durability, flexibility, and repeatability of AXPAXLI in wet AMD. These complementary studies were built with a strong scientific rationale and close alignment with the FDA," said **Nadia K. Waheed, MD, Chief Medical Officer** of Ocular Therapeutix. "SOL-1 is a superiority study evaluating whether more subjects maintain vision at Week 36 with AXPAXLI versus a single aflibercept (2 mg) injection. Our primary endpoint remains at Week 36, but we will wait until Week 52 to unmask the data so that we can conduct all predefined assessments in a masked manner. The subjects will then be re-treated with AXPAXLI or aflibercept (2 mg) at Week 52 and again at Week 76. SOL-R, on the other hand, is a non-inferiority study assessing AXPAXLI every 24 weeks versus aflibercept (2 mg) every eight weeks. We initially aimed to randomize 825 patients to meet the FDA's re-dosing requirements for AXPAXLI. With re-dosing now included in SOL-1, we can streamline SOL-R to randomize 555 patients while maintaining strong powering assumptions to achieve the non-inferiority margin for the lower bound of -4.5 letters of mean BCVA when compared to aflibercept (2 mg) at Week 56."

Fourth Quarter and Full Year Ended December 31, 2024, Financial Results:

Total cash and cash equivalents were $392.1 million as of December 31, 2024. 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 potential impact of clinical trial activities for AXPAXLI in NPDR and DME, however the Company currently does not intend to raise additional capital this year.

Total net revenue was $17.1 million for the fourth quarter of 2024, a 15.4% increase over total net revenue of $14.8 million in the comparable quarter in 2023. Total net revenue for the full year 2024 was $63.7 million versus $58.4 million in 2023, an increase of 9.0%. This increase was driven by increased gross revenues from DEXTENZA sales, partially offset by higher gross-to-net provisions in the 2024 period compared to the prior year. 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 fourth quarter of 2024 were $41.0 million versus $16.2 million for the comparable quarter in 2023, 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. Overall R&D expenses for the full year 2024 increased to $127.6 million from $61.1 million in 2023, reflecting the timing and conduct of the Company's clinical trials as well as additional personnel and professional services to support these clinical trials.

Selling and marketing expenses were $10.8 million for the fourth quarter of 2024, as compared to $9.2 million for the comparable quarter of 2023, primarily reflecting an increase in professional fees. Overall, selling and marketing expenses for the full year 2024 increased to $41.6 million from $40.5 million for 2023, primarily related to an increase in professional fees.

General and administrative expenses were $14.6 million for the fourth quarter of 2024, as compared to $8.0 million for the comparable quarter of 2023, primarily due to an increase in personnel-related costs, including stock-based compensation. Overall, general and administrative expenses for the full year 2024 increased to $60.7 million from $33.9 million for 2023, primarily due to an increase in personnel-related costs, including stock-based compensation, professional fees including legal costs, and other facilities and IT related costs.

Net loss for the fourth quarter of 2024 was $(48.4) million, or a net loss of $(0.29) per share on both a basic and diluted basis,

compared to a net loss of $(29.2) million, or a net loss of $(0.35) per share on a basic and diluted basis, for the comparable quarter of 2023. The net loss in the fourth quarter of 2024 includes a net gain from the change in fair value of the Company's derivative liability of $0.6 million, which comprises a non-cash gain from fair value measurement of the derivative liability associated with the Barings Credit Facility of $1.2 million, partially offset by expense related to actual royalty fees under the Barings Credit Facility of $0.6 million, compared to a $(6.5) million net loss for the fourth quarter of 2023, which comprises a 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 $6.0 million, and expense related to actual royalty fees under the Barings Credit Facility of $0.5 million.

Overall, the Company reported a net loss of $(193.5) million, or a loss of $(1.22) per share on a basic and diluted basis, for the year ended December 31, 2024 versus a net loss of $(80.7) million, or a loss of $(1.01) per basic share and $(1.02) per diluted share, for the year ended December 31, 2023.

Outstanding shares as of February 27, 2025, were approximately 159.0 million.

Conference Call and Webcast Information:
Ocular Therapeutix will host a conference call and webcast today at 8:00 AM ET to discuss recent business progress and fourth quarter 2024 financial results. To access the call, please dial: *1 (877) 407-9039 (United States)* or *1 (201) 689-8470 (International),* and reference Conference ID *13750940*. The live and archived webcast can also be accessed by visiting the Ocular Therapeutix website on the Events and Presentations section of the Investor Relations page. A replay of the webcast will be archived for at least 30 days.

About AXPAXLI
AXPAXLI™ (axitinib intravitreal hydrogel, also known as OTX-TKI) is an investigational, bioresorbable, 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, a 52-week masked treatment segment and a 52-week safety follow-up, with re-dosing at Weeks 52 and 76. 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 (ETDRS) letters at Day 1 are then randomized to receive a single dose of AXPAXLI or a single dose of aflibercept (2 mg). After all predefined visit assessments at Week 52 and at Week 76, all subjects are re-dosed with their respective initial treatment of AXPAXLI or aflibercept (2 mg). Patients will be followed for safety until Week 104. Throughout the study, subjects are assessed monthly. 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. The study is being conducted under a Special Protocol Agreement (SPA) 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 four months prior to enrollment.

This non-inferiority trial reflects a patient enrichment strategy over the six months prior to randomization that includes five loading doses of anti-VEGF therapy, including aflibercept (2 mg), and monitoring to exclude those subjects with significant retinal fluid fluctuations. Subjects in the first arm receive a single dose of AXPAXLI at Day 1 and are re-dosed at Weeks 24, 48, and every 24 weeks thereafter. 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 every 24 weeks thereafter, aligned with the AXPAXLI treatment arm for adequate masking. Patients will be followed for safety until Week 104. Throughout the study, subjects are assessed monthly. 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 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.

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 biopharmaceutical company committed to redefining the retina experience. AXPAXLI™ (axitinib intravitreal hydrogel, 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 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 and ocular itching associated with allergic conjunctivitis, and in its product candidate PAXTRAVA™ (travoprost intracameral hydrogel or OTX-TIC), which is currently in a Phase 2 clinical trial for the treatment of open-angle glaucoma or ocular hypertension.

Follow the Company on its website, LinkedIn, or X.

Forward-Looking Statements
Any statements in this press release about future expectations, plans, and prospects for the Company, including the commercialization of DEXTENZA or the development and regulatory status of the Company's product candidates; the design of, and the timing of the 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 called OTX-TKI) for the treatment of wet AMD; the Company's plans to advance the development of AXPAXLI and its other product candidates, including in additional indications such as NPDR and DME; 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 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 AXPAXLI for NPDR and DME or any other indication; 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 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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Ocular Therapeutix, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 392,102	$ 195,807
Accounts receivable, net	32,388	26,179
Inventory	3,040	2,305
Restricted cash	—	150
Prepaid expenses and other current assets	13,457	7,794
Total current assets	440,987	232,235
Property and equipment, net	9,389	11,739
Restricted cash	1,614	1,614
Operating lease assets	5,945	6,472
Total assets	$ 457,935	$ 252,060
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,176	$ 4,389
Accrued expenses and other current liabilities	35,117	28,666
Deferred revenue	128	255
Operating lease liabilities	1,933	1,586
Total current liabilities	41,354	34,896
Other liabilities:		
Operating lease liabilities, net of current portion	5,345	6,878
Derivative liabilities	13,246	29,987
Deferred revenue, net of current portion	14,000	14,135
Notes payable, net	68,505	65,787
Other non-current liabilities	141	108
Convertible Notes, net	—	9,138
Total liabilities	142,591	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 December 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.0001 par value; 400,000,000 shares and 200,000,000 shares authorized and 157,749,490 and 114,963,193 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	16	12
Additional paid-in capital	1,206,412	788,697
Accumulated deficit	(891,084)	(697,578)
Total stockholders' equity	315,344	91,131
Total liabilities and stockholders' equity	$ 457,935	$ 252,060

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

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023

Revenue:				
Product revenue, net	$ 17,020	$ 14,677	$ 63,461	$ 57,870
Collaboration revenue	63	125	262	573
Total revenue, net	17,083	14,802	63,723	58,443
Costs and operating expenses:				
Cost of product revenue	1,230	1,386	5,626	5,281
Research and development	40,989	16,195	127,635	61,055
Selling and marketing	10,840	9,246	41,590	40,549
General and administrative	14,600	8,024	60,653	33,940
Total costs and operating expenses	67,659	34,851	235,504	140,825
Loss from operations	(50,576)	(20,049)	(171,781)	(82,382)
Other income (expense):				
Interest income	4,671	1,460	20,282	3,983
Interest expense	(3,106)	(4,153)	(13,577)	(11,338)
Change in fair value of derivative liabilities	623	(6,478)	(480)	(5,188)
Gains and losses on extinguishment of debt, net	—	—	(27,950)	14,190
Other expense	—	—	—	(1)
Total other income (expense), net	2,188	(9,171)	(21,725)	1,646
Net loss	$ (48,388)	$ (29,220)	$ (193,506)	$ (80,736)
Net loss per share, basic	$ (0.29)	$ (0.35)	$ (1.22)	$ (1.01)
Weighted average common shares outstanding, basic	168,019,285	84,429,883	158,265,162	79,827,362
Net loss per share, diluted	$ (0.29)	$ (0.35)	$ (1.22)	$ (1.02)
Weighted average common shares outstanding, diluted	168,019,285	90,199,115	158,265,162	85,596,594