Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Reports Financial Results for Third Quarter Fiscal Year 2023 and Reiterates Key Anticipated Near-Term Milestones

August 14, 2023

- **Prescription Drug User Fee Act (PDUFA) goal date of August 29, 2023 for ONS-5010, an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD)**

ISELIN, N.J., Aug. 14, 2023 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve FDA approval for the first ophthalmic formulation of bevacizumab for the treatment of wet AMD, today announced recent corporate highlights and financial results for its fiscal third quarter ended June 30, 2023.

Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics, commented, “We continue to be focused on our pre-launch activities and positioning for Outlook Therapeutics as an innovative leader in the anti-VEGF space. By meeting strict FDA requirements for an ophthalmic approved formulation of bevacizumab, we believe we can enhance the standard of care. If we achieve FDA approval, it will be the catalyst to transform Outlook Therapeutics into a commercial-stage company.”

Upcoming Anticipated Milestones

- PDUFA goal date of August 29, 2023;
- Evaluation of ONS-5010 in a pre-filled syringe in the NORSE SEVEN clinical trial expected to be complete in 2024; and
- MAA decision date from the EMA’s CHMP in the EU for ONS-5010 expected in first half of 2024.

Commercial Planning Underway to Support Potential Approval of the First Ophthalmic Formulation of Bevacizumab for Use in Retinal Indications

According to GlobalData, the use of unapproved repackaged IV bevacizumab from compounding pharmacies is estimated to account for approximately 50% of all wet AMD injections in the United States each year. This represents approximately 3.5 million injections of off-label, repackaged bevacizumab each year in the United States alone. Globally, the nine major markets account for an estimated $13.1 billion market for anti-VEGF drugs to treat retina diseases.

Because patients, physicians and payors rely heavily on bevacizumab as an important option for treating wet AMD, ONS-5010 has been developed to address the concerns for not meeting standards required for ophthalmic approval, including potential potency and safety issues that have been reported to be associated with using off-label, repackaged bevacizumab from compounding pharmacies, such as:

- Study reports published in *JAMA* indicating 81% of all tested syringes of repackaged bevacizumab received from 11 different compounding pharmacies contained less drug protein concentration than the control arm, which could result in lower clinical efficacy.
- Non-standard materials used to transfer and hold repackaged bevacizumab which can potentially add particulates to non-ophthalmic approved bevacizumab, which in turn may fail to meet the standards FDA requires for ophthalmic approval.

In August 2022, Outlook Therapeutics submitted a PHSA 351(a) BLA for ONS-5010 as an original biologic application. ONS-5010, if approved, is not a biosimilar because the PHSA requires a biosimilar to have the same “conditions of use” (e.g., indications) as a reference product. AVASTIN, the currently marketed non-ophthalmic formulation of bevacizumab, is not approved by FDA for the treatment of wet AMD or other retinal diseases.

In the NORSE TWO Phase 3 clinical trial, which compared ONS-5010 (dosed monthly) with LUCENTIS (using the PIER dosing regimen of 3 consecutive months of loading doses followed by 2 more doses separated by 3 months each), ONS-5010 consistently improved BCVA by ≥ 15 letters from baseline to 11 months (41.7% compared to 23.1% in LUCENTIS group, p = 0.0052). Patients receiving ONS-5010 also demonstrated statistically significant mean change in BCVA of 11.2 letters compared to 5.8 letters in the control arm (p = 0.0043). Additionally, the majority of ONS-5010 subjects maintained or gained BCVA during the study (defined as change from baseline in BCVA ≥ 0), with at least 80% of ONS-5010 subjects gaining or maintaining BCVA each month. Safety evaluations revealed similar safety profiles of ONS-5010 and the comparator LUCENTIS. In fact, only one serious ocular adverse event occurred in the ONS-5010 arm (increase in intraocular pressure that was treated and resolved) in 1100 injections.

If approved, ONS-5010 / LYTENAVA™ (bevacizumab-vikg) will be the first ophthalmic formulation of bevacizumab.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Pre-Launch Preparations Proceeding as Planned

In anticipation of potential FDA marketing approval in 2023, Outlook Therapeutics has begun commercial inventory production, with best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance, and with drug product manufacturer Aji Bio-pharma Services for the finished drug product.

Outlook Therapeutics is actively building out its own sales and commercial team, and additionally entered into a strategic distribution partnership with AmerisourceBergen in September 2022, in preparation for the anticipated commercial launch in the United States of ONS-5010. As Outlook Therapeutics moves toward a potential launch in the United States, AmerisourceBergen’s commercialization support has expanded to include additional services. Through the agreement with AmerisourceBergen, Outlook Therapeutics expects to significantly increase market access and efficient distribution of ONS-5010, if approved by the FDA. Moreover, working with AmerisourceBergen will help to provide Outlook Therapeutics with an accelerated pathway to deliver a high-quality customer experience to retina specialists. Outlook Therapeutics has also been in collaborative discussions with payors and the retina community to bring ONS-5010 to market benefiting all stakeholders – patients, clinicians, and payors.

Outlook Therapeutics also submitted a Marketing Authorization Application (MAA) in Europe, which was validated for review in December 2022. The formal review process of the MAA by the EMA's Committee for Medicinal Products for Human Use (CHMP) is underway with an estimated decision date expected in the first half of 2024. In addition to pursuing potential strategic partnering opportunities in the EU and other regions, such as the current partnership with Syntone Biopharma JV in China, Outlook Therapeutics is also exploring potential expanded relationships with AmerisourceBergen to support the launch of ONS-5010 in international markets. AmerisourceBergen increased its global capabilities in 2021 with the acquisition of PharmaLex and Alliance Healthcare, leading wholesalers and specialized service providers of healthcare products in Europe.

In addition to the clinical development program evaluating ONS-5010 for wet AMD, Outlook Therapeutics has received agreements from the FDA on three Special Protocol Assessments (SPAs) for three additional registration clinical trials. These SPAs cover the protocols for a planned registration clinical trial evaluating ONS-5010 to treat branch retinal vein occlusion (BRVO), NORSE FOUR, and two planned registration clinical trials evaluating the drug candidate for the treatment of diabetic macular edema (DME), NORSE FIVE and NORSE SIX.

Financial Highlights for the Fiscal Third Quarter Ended June 30, 2023

For the fiscal third quarter ended June 30, 2023, Outlook Therapeutics reported a net loss attributable to common stockholders of $20.7 million, or $0.08 per basic and diluted share, compared to a net loss attributable to common stockholders of $17.5 million, or $0.08 per basic and diluted share, for the same period last year.

As of June 30, 2023, Outlook Therapeutics had cash and cash equivalents of $33.7 million, which is expected to be sufficient to fund its operations through the anticipated approval of the BLA for ONS-5010 in the third calendar quarter of 2023, and potentially through the fourth calendar quarter of 2023.

About ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Because no currently approved ophthalmic formulations of bevacizumab are available, clinicians wishing to treat retinal patients with bevacizumab have had to use unapproved repackaged IV bevacizumab provided by compounding pharmacies, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 can replace the need to use unapproved repackaged oncologic IV bevacizumab from compounding pharmacies for the treatment of wet AMD.

Bevacizumab-vikg is a recombinant humanized monoclonal antibody (mAb) that selectively binds with high affinity to all isoforms of human vascular endothelial growth factor (VEGF) and neutralizes VEGF's biologic activity through a steric blocking of the binding of VEGF to its receptors Flt-1 (VEGFR-1) and KDR (VEGFR-2) on the surface of endothelial cells. Following intravitreal injection, the binding of bevacizumab-vikg to VEGF prevents the interaction of VEGF with its receptors on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation in the retina.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company working to achieve FDA approval for the launch of ONS-5010/ LYTENAVA ™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. The FDA accepted Outlook Therapeutics' BLA submission for ONS-5010 to treat wet AMD with a PDUFA goal date of August 29, 2023. The submission is supported by Outlook Therapeutics' wet AMD clinical program, which consists of three clinical trials: NORSE ONE, NORSE TWO, and NORSE THREE. If ONS-5010 ophthalmic bevacizumab is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, United Kingdom, Europe, Japan, and other markets. As part of the Company's multi-year commercial planning process, and in anticipation of potential FDA approval in August 2023, Outlook Therapeutics and AmerisourceBergen have entered into a strategic commercialization agreement to expand the Company's reach for connecting to retina specialists and their patients. AmerisourceBergen will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance services and other services in the United States. For more information, please visit www.outlooktherapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are "forward-looking statements," including those relating to future events. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "may," "might," "intend," "potential," "predict," "should," or "will," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include, among others, statements about ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, including benefits therefrom to patients, payors and physicians, including potential approval and commercial launch of ONS-5010 and the timing thereof, expectations about the sufficiency of our capital, upcoming anticipated milestones, expectations concerning decisions of regulatory bodies, including the FDA and the EMA, and the timing thereof, our estimated market, expectations concerning our relationship with AmerisourceBergen and the benefits and potential expansion thereof, plans for and the timing of potential future clinical trials, including the expected completion of NORSE SEVEN and the expected commencement of NORSE FOUR, NORSE FIVE and NORSE SIX, potential strategic partners, plans for regulatory submissions, approvals and commercialization of ONS-5010 in other markets and other statements that are not historical fact. Although Outlook Therapeutics believes that it has a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting Outlook Therapeutics and are subject to risks, uncertainties and factors relating to its operations and business environment, all of which are difficult to predict and many of which are beyond its control. These risk factors include those risks associated with developing pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, as well as those risks detailed in Outlook Therapeutics' filings with the Securities and Exchange Commission (the "SEC"), including the Annual Report on Form 10-K for the fiscal year ended September 30, 2022 as supplemented by the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, in each case as filed with the SEC and future quarterly reports we file with the SEC, which include the uncertainty of future impacts related to macroeconomic factors, including as a result of the ongoing conflict between Russia and Ukraine, high interest rates, inflation and potential future bank failures on the global business environment. These risks may cause actual results to differ materially from those expressed or implied by forward-looking statements in this press release. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Outlook Therapeutics does not undertake any obligation to update, amend or clarify these forward-looking statements whether as a result of new information, future events or otherwise, except as may be required under

applicable securities law.

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Outlook Therapeutics, Inc.
Consolidated Statements of Operations
(Amounts in thousands, except per share data)

	Three months ended June 30,		Nine months ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 11,101	$ 11,249	$ 21,509	$ 33,341
General and administrative	7,040	5,775	19,158	15,742
Loss from operations	(18,141)	(17,024)	(40,667)	(49,083)
Loss (income) on equity method investment	7	12	2	42
Interest (income) expense, net	(395)	357	1,866	1,127
Loss on extinguishment of debt	-	-	578	1,025
Change in fair value of promissory notes	2,910	377	2,913	883
Change in fair value of warrant liability	12	(230)	(37)	(455)
Loss before income taxes	(20,675)	(17,540)	(45,989)	(51,705)
Income tax expense	-	-	3	2
Net loss attributable to common stockholders	$ (20,675)	$ (17,540)	$ (45,992)	$ (51,707)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.08)	$ (0.19)	$ (0.25)
Weighted average shares outstanding, basic and diluted	256,882	220,498	246,879	209,108

Consolidated Balance Sheet Data
(Amounts in thousands)

	June 30, 2023	September 30, 2022
Cash and cash equivalents	$ 33,709	$ 17,397
Total assets	$ 44,447	$ 28,528
Current liabilities	$ 49,930	$ 19,730
Total stockholders' (deficit) equity	$ (5,503)	$ 8,737

Source: Outlook Therapeutics, Inc.