Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Financial Results for Third Quarter Fiscal Year 2022 and Reiterates Key Anticipated Near-Term Milestones

August 10, 2022

- **Planned re-submission of ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Biologics License Application (BLA) to U.S. Food and Drug Administration (FDA) on track**

ISELIN, N.J., Aug. 10, 2022 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a pre-commercial biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced its financial results for its fiscal third quarter ended June 30, 2022, provided recent corporate highlights, and reiterated its anticipated near-term milestones.

Recent Corporate Highlights

- Announced the full cash pre-payment of its $12.3 million unsecured convertible promissory note dated November 4, 2020, as amended November 16, 2021; and
- Confirmed plans to re-submit ONS-5010 BLA by September 2022.

“We have received invaluable line-of-sight related to the additional requirements for a successful ONS-5010 BLA re-submission. Following productive feedback from the FDA, we established a clear path forward and are highly focused on executing the necessary items to meet our planned re-submission by September of this year. Additionally, we continue to position ourselves operationally and financially for the potential FDA approval and subsequent launch of ONS-5010. Our confidence in its potential remains unwavering. If approved, ONS-5010 would be the first FDA-approved ophthalmic formulation of bevacizumab, avoiding the public health risk to patients of off-label treatment of bevacizumab. We believe there is value in achieving the strict safety and efficacy requirements associated with an FDA approval, and we expect to meet these standards,” commented Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics.

Upcoming Anticipated Milestones

- Complete re-submission of BLA for ONS-5010 for the treatment of wet age-related macular degeneration (wet AMD);
- Receive Prescription Drug User Fee Act (PDUFA) target action date from FDA;
- Continue progress with ongoing pre-launch commercial preparations in anticipation of potential approval for ONS-5010 in 2023; and
- Submission of Marketing Authorisation Application (MAA) in EU for ONS-5010.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Development Updates

Outlook Therapeutics’ wet AMD clinical program for ONS-5010 consists of three completed clinical trials, NORSE ONE, NORSE TWO, and NORSE THREE. Based on a compilation of the data from these trials, Outlook Therapeutics submitted the BLA to the FDA in March 2022. NORSE ONE, a proof-of-concept and clinical experience trial, helped validate the protocols and approach for NORSE TWO, the pivotal safety and efficacy trial. The NORSE TWO data were highly statistically significant and clinically relevant for the primary and all secondary endpoints. NORSE THREE was an open-label supplementary safety trial conducted to ensure that a sufficient number of patients had been dosed with ONS-5010 ophthalmic bevacizumab to support the regulatory submission.

Following conversations with the FDA about the submission, the Company voluntarily withdrew the BLA in May 2022 and is actively working to provide supplemental information that the FDA has requested. Outlook Therapeutics has confirmed the FDA requirements and expects to resubmit the BLA by September 2022.

As previously announced, if ONS-5010 receives FDA approval, Outlook Therapeutics plans to submit a supplementary application (sBLA) for approval to provide the product in a pre-filled, silicone oil liquid-free syringe that meets the FDA’s strict specifications for ophthalmic use. To support the anticipated submission of this sBLA, Outlook Therapeutics is conducting its NORSE SEVEN clinical trial to compare the safety of ONS-5010 in vials versus pre-filled syringes. NORSE SEVEN is expected to enroll approximately 120 subjects with visual impairment due to retinal disorders. Patients will be treated for three months; the enrollment of patients in the arm of the study receiving ONS-5010 in vials has already been completed.

Pre-Launch Commercial Planning Underway

According to GlobalData, 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. Globally, the nine major markets account for an estimated $13.1 billion market for anti-VEGF drugs to treat retina diseases.

In anticipation of potential FDA marketing approval in 2023, Outlook Therapeutics has begun commercial launch planning, including best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance, and with drug product manufacturer Aji Bio-pharma Services for finished drug product. The Company also is actively building out its distribution and commercial team structures.

To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians, and payors – Outlook Therapeutics has been in collaborative discussions with payors and the retina community. Outlook Therapeutics is also developing registration documents on a parallel path for approvals in Europe and expects to submit them in the fourth quarter of calendar 2022. Outlook Therapeutics continues to explore potential strategic commercialization partners, such as the current partnership with Syntone Biopharma JV in China. Outlook Therapeutics expects ONS-5010, if approved, to be a safe and cost-effective choice for patients, clinicians, and payors worldwide for retinal indications.

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, 2022

For the fiscal third quarter ended June 30, 2022, Outlook Therapeutics reported a net loss attributable to common stockholders of $17.5 million, or $0.08 per basic and diluted share, compared to a net loss attributable to common stockholders of $12.2 million, or $0.07 per basic and diluted share, for the same period last year.

At June 30, 2022, Outlook Therapeutics had cash and cash equivalents of $26.0 million. Outlook Therapeutics' cash and cash equivalents on hand are expected to provide funding into the first calendar quarter of 2023.

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

ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development to be administered 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 must 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 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. VEGF is a protein that promotes the growth of abnormal new blood vessels and promotes leakage from these vessels, leading to retinal edema and hemorrhage. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Since the advent of anti-VEGF therapy, it has become the standard-of-care treatment option within the retina community globally.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a pre-commercial biopharmaceutical company working to develop and launch 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. 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. 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 expectations of market exclusivity, potential approval and commercial launch of ONS-5010 and the timing thereof, including the expectation of timing of the resubmission of the BLA for ONS-5010, and the success thereof, and subsequent receipt of a PDUFA date, expectations about the sufficiency of our capital, 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, 2021 filed with the SEC, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and future quarterly reports we file with the SEC, which include the uncertainty of future impacts related to the ongoing COVID-19 pandemic and the impacts of the pandemic and other macroeconomic factors, including as a result of the ongoing conflict between Russia and Ukraine, 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,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 11,249	$ 8,546	$ 33,341	$ 29,023
General and administrative	5,775	2,930	15,742	9,268
	17,024	11,476	49,083	38,291
Loss from operations	(17,024)	(11,476)	(49,083)	(38,291)
Loss on equity method investment	12	435	42	435
Interest expense, net	357	257	1,127	667
Loss on extinguishment of debt	-	-	1,025	-
Change in fair value of convertible promissory note	377	-	883	-
Change in fair value of warrant liability	(230)	29	(455)	364
Loss before income taxes	(17,540)	(12,197)	(51,705)	(39,757)
Income tax expense (benefit)	-	-	2	2
Net loss attributable to common stockholders	$ (17,540)	$ (12,197)	$ (51,707)	$ (39,759)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.07)	$ (0.25)	$ (0.27)
Weighted average shares outstanding, basic and diluted	220,498	168,421	209,108	146,861

Consolidated Balance Sheet Data
(Amounts in thousands)

	June 30, 2022	September 30, 2021
Cash and cash equivalents	$ 26,021	$ 14,477
Total assets	$ 38,588	$ 22,811
Current liabilities	$ 18,430	$ 6,752
Total stockholders' equity	$ 20,082	$ 4,607

Source: Outlook Therapeutics, Inc.