Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Reports Financial Results for Fiscal Year 2022 and Provides Corporate Update

December 29, 2022

- **Attained U.S. Food and Drug Administration (FDA) Prescription Drug User Fee Act (PDUFA) goal date of August 29, 2023 for ONS-5010 / LYTENAVA™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD)**

- **Secured approximately $55 million gross proceeds from recent financings, expected to provide funding through the anticipated FDA approval of ONS-5010 in the third calendar quarter of 2023**

ISELIN, N.J., Dec. 29, 2022 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a 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 year ended September 30, 2022, and provided recent corporate highlights.

Recent Corporate Highlights

- Closed on approximately $50 million net proceeds from two new financings to support pre-launch activities through anticipated approval of ONS-5010 in third calendar quarter 2023.
  - Approximately $25 million registered direct equity offering priced at-the-market under Nasdaq rules.
  - Approximately $30 million net proceeds from issuance of an unsecured convertible promissory note with an initial conversion price of $2.00.
- Received validation of Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) for ONS-5010/ LYTENAVA™ (bevacizumab-vikg).
- Announced that the FDA accepted its Biologics License Application (BLA) for ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the treatment of wet AMD and set a PDUFA goal date of August 29, 2023.
- Entered into a strategic commercialization agreement with AmerisourceBergen, a global healthcare company and leader in specialty pharmaceutical distribution and services who will provide third-party logistics (3PL) services and distribution, as well as medical information and pharmacovigilance services in the United States.
- Strengthened Board of Directors with appointment of Julia Haller, MD, one of the country's most accomplished professionals in ophthalmic education, research and clinical ophthalmic practice.

"Our fiscal year 2022 laid a solid foundation for what we believe will be a transformational 2023. We are driving our commercialization planning towards expected launch with the accepted FDA filing of our BLA for ONS-5010 and PDUFA date set for August 29, 2023, and review of our MAA in the EU underway with a decision date expected in early 2024. We believe that ONS-5010 has the potential to be a game-changer for patients and physicians in the retina community, and we now have the necessary capital to support these efforts. We remain steadfast in our mission to enhance the standard of care in the retinal anti-VEGF space," commented C. Russell Trenary III, President and Chief Executive Officer of Outlook Therapeutics. "On behalf of the entire team, I would like to thank all stakeholders for their continued support and look forward to what we believe will be an exciting future for Outlook Therapeutics."

Upcoming Anticipated Milestones

- Continued progress with ongoing pre-launch commercial preparations in anticipation of potential approval for ONS-5010 in 2023;
- PDUFA goal date of August 29, 2023; and
- Estimated decision date from the EMA's Committee for Medicinal Products for Human Use (CHMP) on the Company's submitted MAA in EU for ONS-5010 expected in early 2024.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Pre-Launch Commercial Planning Underway

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. 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 the finished drug product.

Outlook Therapeutics is actively building out its sales and commercial team, and in September 2022, Outlook Therapeutics entered into a strategic commercialization agreement with AmerisourceBergen 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 will expand 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. To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians, and payors – Outlook Therapeutics has also 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 submitted them in December 2022. The formal review process of the MAA by the EMA's CHMP is now set to begin with an estimated decision date expected in early 2024 and is also exploring a relationship with AmerisourceBergen to support the launch of ONS-5010 in international markets. AmerisourceBergen expanded its global distribution capabilities in 2021 with the acquisition of Alliance Healthcare, a leading wholesaler of healthcare products in Europe. Additionally, Outlook Therapeutics continues to explore potential strategic commercialization partners, such as the current partnership with Syntone Biopharma JV in China.

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.

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

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.

Financial Highlights for the 2022 Fiscal Year Ended September 30, 2022

For the fiscal year ended September 30, 2022, Outlook Therapeutics reported a net loss attributable to common stockholders of $66.1 million, or $0.31 per basic and diluted share, compared to a net loss attributable to common stockholders of $53.2 million, or $0.35 per basic and diluted share, for fiscal 2021.

At September 30, 2022, Outlook Therapeutics had cash and cash equivalents of $17.4 million.

Subsequent to September 30, 2022, the Company closed a registered direct equity offering priced at-the-market under Nasdaq rules, resulting in aggregate gross proceeds of approximately $25.0 million. Additionally, the Company closed on an unsecured convertible promissory note (the "Note") with a face amount of $31.8 million and net proceeds of approximately $30.0 million after original issue discount and after deducting the Lender's transaction costs covered by the Company in connection with the issuance. The combined proceeds from the Note and the registered direct offering are expected to provide funding through the anticipated FDA approval of ONS-5010 in the third 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 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. 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 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 expectations of market exclusivity, 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 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 to be filed with the SEC 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)

	Year ended September 30,	
	2022	**2021**
Operating expenses:		
Research and development	$ 42,331	$ 38,958
General and administrative	20,740	12,769
	63,071	51,727
Loss from operations	(63,071)	(51,727)
Loss on equity method investment	49	46
Interest expense, net	1,487	936
Loss on extinguishment of debt	1,025	-
Change in fair value of unsecured convertible promissory note	883	-
Change in fair value of warrant liability	(466)	452
Loss before income taxes	(66,049)	(53,161)
Income tax expense	3	2
Net loss attributable to common stockholders	$ (66,052)	$ (53,163)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.31)	$ (0.35)
Weighted average shares outstanding, basic and diluted	212,079	152,676

Consolidated Balance Sheet Data
(Amounts in thousands)

	September 30,	
	2022	**2021**

Cash and cash equivalents	$	17,397	$	14,477
Total assets	$	28,528	$	22,811
Current liabilities	$	19,730	$	6,752
Total stockholders' equity	$	8,737	$	4,607

Source: Outlook Therapeutics, Inc.