Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Reports Financial Results for Fiscal Year 2023 and Reiterates ONS-5010 Clinical and Regulatory Path Forward in the U.S. and EU

December 22, 2023

- **Commencement of ONS-5010 NORSE EIGHT clinical trial targeted for first calendar quarter of 2024**
- **Company reaffirms potential for European approval for ONS-5010 with Marketing Authorization Application (MAA) decision date anticipated in the first half of 2024**
- **Resubmission of the ONS-5010 Biologics License Application (BLA) expected by the end of calendar year 2024**

ISELIN, N.J., Dec. 22, 2023 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve U.S. Food and Drug Administration (FDA) approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced recent corporate highlights and financial results for its fiscal year ended September 30, 2023.

"We remain committed to working with the FDA to design and undertake the additional clinical study for ONS-5010 that, if successful, will satisfy the FDA's requirements for approval," commented Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics. "The patient need for an ophthalmic approved bevacizumab remains and we are steadfast in our mission to meet this need."

Upcoming Anticipated Milestones

- FDA response on NORSE EIGHT Special Protocol Assessment (SPA) in early February 2024;
- Commencement of NORSE EIGHT expected in first calendar quarter of 2024;
- MAA decision date in the EU for ONS-5010 expected targeted for first half of 2024;
- Completion of NORSE EIGHT in the U.S. anticipated in 2024; and
- Resubmission of the ONS-5010 BLA expected by the end of calendar year 2024.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Regulatory Update

As previously announced, following a Type A meeting with the FDA held in October 2023, the FDA informed Outlook Therapeutics that it can conduct a non-inferiority study evaluating ONS-5010 versus ranibizumab in a 3-month study of treatment naïve patients with a primary efficacy endpoint at 2 months. Subsequently, as discussed with and recommended by the FDA, Outlook Therapeutics submitted a clinical trial protocol and requested a Type A meeting with the FDA for feedback. The FDA has already provided written feedback on the protocol, which Outlook Therapeutics has incorporated. The revised protocol is the subject of the SPA request, in which Outlook Therapeutics is seeking further confirmation from the FDA that NORSE EIGHT, if successful, addresses the FDA's requirement for a second adequate and well-controlled clinical trial to support the resubmission of the ONS-5010 BLA for wet AMD. The FDA is expected to provide a response to the SPA by early February 2024.

NORSE EIGHT will be a randomized, controlled, parallel-group, masked study of neovascular age-related macular degeneration subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010 or 0.5 mg ranibizumab intravitreal injections. Subjects will receive injections at Day 0 (randomization), Week 4, and Week 8 visits. Approximately 400 patients are expected to be enrolled in the study.

Additionally, the Company previously announced that it submitted an MAA in Europe, which was validated for review in December 2022. The formal review process of the MAA by the European Medicines Agency (EMA) 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 Cencora (formerly AmerisourceBergen) to support the launch of ONS-5010 in international markets.

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

Financial Highlights for the 2023 Fiscal Year Ended September 30, 2023

For the fiscal year ended September 30, 2023, Outlook Therapeutics reported a net loss attributable to common stockholders of $59.0 million, or $0.24 per basic and diluted share, compared to a net loss attributable to common stockholders of $66.1 million, or $0.31 per basic and diluted share, for the prior fiscal year.

As of September 30, 2023, Outlook Therapeutics had cash and cash equivalents of $23.4 million. On December 21, 2023, Outlook Therapeutics reached an agreement with the holder of its outstanding convertible promissory note to extend the maturity until April 1, 2024.

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 FDA-approved ophthalmic formulations of bevacizumab are available currently, 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 would provide an FDA-approved option for physicians that currently prescribe 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 an initial PDUFA goal date of August 29, 2023; the FDA did not approve the BLA during this review cycle and the Company is working with the FDA to address the issues that have been raised so that the BLA may be re-submitted. 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, Outlook Therapeutics and Cencora entered into a strategic commercialization agreement to expand the Company's reach for connecting to retina specialists and their patients. Cencora 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," "estimate," "expect," "intend," "may," "optimistic," "plan," "potential," "target," "will," or "would" 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, expectations concerning our ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, including with respect to an additional clinical trial and CMC issues, expectations concerning the NORSE EIGHT trial design, the timing for initiation and completion of NORSE EIGHT and resubmission of the BLA for ONS-5010, expectations concerning decisions of regulatory bodies, including the FDA and EMA, and the timing thereof, plans for potential commercial launch of ONS-5010, expectations concerning the relationship with Cencora and the benefits and potential expansion thereof, 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, the content and timing of decisions by the FDA, 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, 2023, to be filed with the SEC, and future quarterly reports we file with the SEC, which include uncertainty of future impacts related to macroeconomic factors, including as a result of the ongoing overseas conflict, 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)

	Year ended September 30,	
	2023	**2022**
Operating expenses:		
Research and development	$ 26,453	$ 42,331
General and administrative	26,673	20,740
	53,126	63,071
Loss from operations	(53,126)	(63,071)
Loss on equity method investment	11	49
Interest expense, net	1,560	1,487
Loss on extinguishment of debt	578	1,025
Change in fair value of promissory notes	3,756	883
Change in fair value of warrant liability	(51)	(466)
Loss before income taxes	(58,980)	(66,049)
Income tax expense	3	3
Net loss attributable to common stockholders	$ (58,983)	$ (66,052)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.24)	$ (0.31)
Weighted average shares outstanding, basic and diluted	250,177	212,079

Consolidated Balance Sheet Data
(Amounts in thousands)

	September 30,	
	2023	**2022**
Cash and cash equivalents	$ 23,392	$ 17,397
Total assets	$ 32,301	$ 28,528
Current liabilities	$ 46,732	$ 19,730
Total stockholders' (deficit) equity	$ (14,438)	$ 8,737

Source: Outlook Therapeutics, Inc.