Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Reports Financial Results for First Quarter Fiscal Year 2024 and Provides Corporate Update

February 14, 2024

- **NORSE EIGHT underway with first subject dosed and additional clinical sites beginning enrollment**
- **Continue to expect planned resubmission of the ONS-5010 Biologics License Application (BLA) by the end of CY2024**
- **Anticipate review decision from European regulators in the first half of CY2024**

ISELIN, N.J., Feb. 14, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve regulatory approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced financial results for first quarter fiscal year 2024 and provided a corporate update.

"We are proud of the recent progress our team has made. In January 2024, we received confirmation that the FDA has reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA they approved. We also reached agreement that if the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the CRL. Importantly, the first subject was enrolled in NORSE EIGHT in January 2024," commented Russell Trenary, President and Chief Executive Officer. "In addition, through a Type A meeting and additional interactions, we have identified the approaches needed to resolve the CMC comments in the CRL. We are working to address the open items and expect to resolve these comments prior to the expected completion of NORSE EIGHT. Finally, we have entered into purchase agreements for a financing of up to $172 million, subject to shareholder approval, to support our regulatory efforts and launch preparations."

Upcoming Anticipated Milestones

- Closing of private placement financing in March 2024, subject to receipt of stockholder approval and other closing conditions;
- MAA decision date in the EU for ONS-5010 targeted for first half of 2024;
- Completion of NORSE EIGHT in the United States 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 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 (NORSE EIGHT). In January 2024, Outlook Therapeutics announced that it received written agreement on the NORSE EIGHT trial protocol from the FDA under a SPA for NORSE EIGHT. The SPA confirms that if the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to fully address the clinical deficiency identified in the Complete Response Letter (CRL). In addition, through a Type A meeting and additional interactions, Outlook Therapeutics has identified the approaches needed to resolve the Chemistry, Manufacturing and Controls (CMC) comments in the CRL. Outlook Therapeutics is working to address the open CMC items in the CRL and expects to resolve these comments prior to the expected completion of NORSE EIGHT.

NORSE EIGHT is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD 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. The primary endpoint will be mean change in BCVA from baseline to week 8. Outlook Therapeutics expects NORSE EIGHT topline results and resubmission of the ONS-5010 BLA by the end of calendar year 2024.

Additionally, the formal review process of the ONS-5010 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, 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) would be the first approved ophthalmic formulation of bevacizumab in the U.S. or EU.

Financial Highlights for the Fiscal First Quarter Ended December 31, 2023

For the fiscal first quarter ended December 31, 2023, Outlook Therapeutics reported a net loss attributable to common stockholders of $11.2 million, or $0.04 per basic and diluted share, compared to a net loss attributable to common stockholders of $18.7 million, or $0.08 per basic and diluted share, for the same period last year.

In January 2024, the Company announced that it has entered into definitive securities purchase agreements with certain institutional and accredited investors to purchase shares of common stock and accompanying warrants in private placements, the closing of which is conditioned upon stockholder approval of the transactions and certain other corporate actions, expected in the first quarter of 2024. The private placements are expected to provide up to $65 million in gross proceeds at closing, before deducting placement agent fees and offering expenses. In addition, Outlook Therapeutics will have the potential to receive additional gross proceeds of up to $107 million upon the full cash exercise of the warrants being issued in the private placements, before deducting placement agent fees and offering expenses. The warrants include a feature that allows Outlook Therapeutics to require cash exercise if certain stock price and milestone conditions are met.

At December 31, 2023, Outlook Therapeutics had cash and cash equivalents of $10.4 million. Assuming closing of the private placements as planned

(subject to closing conditions) and full cash exercise of the related warrants, the proceeds from the private placements are expected to support business operations, complete the execution of NORSE EIGHT, resubmit the ONS-5010 BLA and, if approved, support the commercial launch of ONS-5010.

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 and EMA 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. If ONS-5010 ophthalmic bevacizumab is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA and/or EMA 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 Outlook Therapeutics' multi-year commercial planning process, Outlook Therapeutics and Cencora entered into a strategic commercialization agreement to expand the Outlook Therapeutics' 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," "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 Outlook Therapeutics' 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 completion of NORSE EIGHT and resubmission of the BLA for ONS-5010, the private placement, including expected proceeds from the issuance of the shares of common stock and exercise of the warrants, satisfaction of closing conditions, including receipt of necessary stockholder approvals, and uses of proceeds, the sufficiency of Outlook Therapeutics' resources, including funds from the financing, to fund its operations through various milestones, 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, receipt of necessary stockholder approvals for the private placements, 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, filed with the SEC on December 22, 2023, and future quarterly reports Outlook Therapeutics files with the SEC, which include uncertainty of market conditions and 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)

	Three months ended December 31,	
	2023	**2022**

Operating expenses:		
Research and development	$ 4,529	$ 9,862
General and administrative	5,794	5,826
	10,323	15,688
Loss from operations	(10,323)	(15,688)
Income on equity method investment	(3)	(22)
Interest (income) expense, net	(188)	2,449
Loss on extinguishment of debt	-	578
Change in fair value of promissory notes	993	-
Change in fair value of warrant liability	53	(30)
Net loss attributable to common stockholders	$ (11,178)	$ (18,663)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.04)	$ (0.08)
Weighted average shares outstanding, basic and diluted	260,258	227,411

Consolidated Balance Sheet Data

(Amounts in thousands)

	December 31, 2023	September 30, 2023
Cash and cash equivalents	$ 10,357	$ 23,392
Total assets	$ 21,685	$ 32,301
Current liabilities	$ 45,969	$ 46,732
Total stockholders' deficit	$ (24,343)	$ (14,438)

Source: Outlook Therapeutics, Inc.