Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Reports Financial Results for First Quarter Fiscal Year 2025 and Provides Corporate Update

February 14, 2025

- **ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Biologics License Application (BLA) resubmission on track to meet target of Q1 CY2025**
- **LYTENAVA™ (bevacizumab gamma) on track for first commercial launches in Germany and the United Kingdom (UK) planned for Q2 CY2025**

ISELIN, N.J., Feb. 14, 2025 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company that achieved regulatory approval in the European Union (EU) and the United Kingdom (UK) for the first authorized use of an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD), today announced financial results for the first quarter of fiscal year 2025 and provided a corporate update.

"With all of the recent progress made at Outlook Therapeutics and the upcoming milestones over the next few months, we expect to be a very different company by the end of 2025," commented Lawrence Kenyon, Chief Financial Officer and Interim Chief Executive Officer of Outlook Therapeutics. "In 2025, we plan to start realizing our goal of providing patients, physicians and payers with an approved ophthalmic formulation of bevacizumab. This year, we anticipate beginning to generate the first revenue for Outlook Therapeutics with the launch of LYTENAVA™ in Germany and the UK and our BLA is on track for resubmission this quarter."

Upcoming Anticipated Milestones

- Resubmission of the ONS-5010 BLA targeted for Q1 CY2025;
- Initial commercial launches in Germany and the UK planned to commence in Q2 CY2025; and
- Potential for US FDA approval of ONS-5010 in Q3 CY2025.

LYTENAVA™ (bevacizumab gamma) European Commercial Update

In May 2024, the European Commission granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD in the EU. Additionally, in July 2024, the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the same indication in the UK. In December 2024, the National Institute for Health and Care Excellence (NICE) recommended LYTENAVA™ (bevacizumab gamma) as an option for the treatment of wet AMD. Plans for a potential 2025 launch in Germany and the UK are ongoing. Outlook Therapeutics remains confident that ONS-5010 / LYTENAVA™ is an important therapy for the treatment of wet AMD in place of off-label repackaged bevacizumab that has not received regulatory approval for use in retina diseases such as wet AMD. Outlook Therapeutics intends to launch LYTENAVA™ (bevacizumab gamma) in Germany and the UK in the second quarter of calendar year 2025.

LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in adults in the EU and UK. Currently, over 2.5 million injections of off-label, repackaged bevacizumab are administered to patients across Europe each year, with about one third of these injections in Germany alone. In Germany, there are an estimated 1.6 million anti-VEGF retina injections each year, with over half of those injections representing use of off-label, repackaged bevacizumab. For Germany, LYTENAVA™ (bevacizumab gamma) represents an opportunity for patients there to receive an approved, cGMP produced bevacizumab for the first time. The UK market represents approximately 1.3 million anti-VEGF retina injections each year, but use of repackaged bevacizumab is not authorized. In the UK, LYTENAVA™ (bevacizumab gamma) represents the first time that most patients will have access to the therapy.

Authorization may also be sought in other European countries, Japan, and elsewhere. Outlook Therapeutics has entered into a strategic collaboration with Cencora (formerly AmerisourceBergen) to support the commercial launch of LYTENAVA™ globally following regulatory approvals. The collaborative and integrated approach is designed to support market access and efficient distribution of LYTENAVA™ to benefit all stakeholders, including retina specialists, providers and patients.

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

Outlook Therapeutics believes that the complete data set for NORSE EIGHT, combined with the data from the other NORSE clinical trials, provides the required clinical evidence to support approval of the ONS-5010 BLA in the US. Outlook Therapeutics plans to resubmit the BLA for ONS-5010 in the first quarter of calendar 2025. If approved by the U.S. Food and Drug Administration (FDA), Outlook Therapeutics plans to commercialize ONS-5010 / LYTENAVA™ (bevacizumab-vikg) directly in the US.

In November 2024, Outlook Therapeutics reported that in the NORSE EIGHT clinical trial, the second of two adequate and well controlled clinical trials evaluating ONS-5010 in wet AMD patients, ONS-5010 did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the FDA. 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 / LYTENAVA™ or 0.5 mg ranibizumab intravitreal injections. Subjects received injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint is the mean change in best corrected visual acuity (BCVA) from baseline to week 8.

In January 2025, Outlook Therapeutics announced results from the completed analysis of the 12-week safety and efficacy results for NORSE EIGHT, which indicated that ONS-5010 demonstrated clinically meaningful anatomic and functional improvements at each study timepoint. Results from the 12-week analysis demonstrated the difference in the mean between ONS-5010 and ranibizumab was -1.009 best corrected visual acuity (BCVA) letters with a 95% confidence interval of (-2.865, 0.848) in the NORSE EIGHT trial. Applying the statistical parameters from the week 8 primary endpoint with the lower bound of the non-inferiority margin at -3.5 with a 95% confidence interval, the noninferiority margin was met at week 12, indicating that the two study arms are not different at this timepoint. In the intent-to-treat (ITT) population, NORSE EIGHT demonstrated a mean 5.5

letter improvement in BCVA in the ONS-5010 arm and 6.5 letter improvement in BCVA in the ranibizumab arm. BCVA data across all study timepoints demonstrated an improvement in vision, increasing over time, and the presence of biologic activity. Overall, in NORSE EIGHT, ONS-5010 demonstrated mean visual acuity improvements of +3.3 letters at week 4, +4.2 letters at week 8, and +5.5 letters at week 12. Additionally, the complete NORSE EIGHT data set showed that anatomical response was similar between treatments, with a reduction in central retinal thickness of -123.9 microns for ONS-5010 treated eyes and -127.3 microns for the ranibizumab group, virtually no difference between the arms. Central retinal thickness is a key indicator of effectiveness used by retina specialists in the treatment of wet AMD.

Financial Highlights for the Fiscal First Quarter Ended December 31, 2024

For the fiscal first quarter ended December 31, 2024, Outlook Therapeutics reported net income attributable to common stockholders of $17.4 million, or $0.72 per basic and diluted share, compared to a net loss attributable to common stockholders of $11.2 million, or $0.86 per basic and diluted share, for the same period last year. For the fiscal first quarter ended December 31, 2024, Outlook Therapeutics also reported an adjusted net loss attributable to common stockholders[1] of $21.6 million, or $0.89 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $10.1 million, or $0.78 per basic and diluted share, for fiscal first quarter of 2024.

Adjusted net loss attributable to common stockholders for the fiscal first quarter ended December 31, 2024 includes $1.3 million of loss from change in fair value of warrant liability and $40.3 million of gain from change in fair value of convertible promissory notes. Adjusted net loss attributable to common stockholders includes $1.0 million of loss from change in fair value of warrant liability and $0.1 million of loss from change in fair value of convertible promissory notes for the fiscal first quarter ended December 31, 2023.

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[1] Adjusted net loss attributable to common stockholders and adjusted net loss attributable to common stockholders per share of common stock – basic and diluted are non-U.S. GAAP financial measures. See “Non-GAAP Financial Measures” below.

In January 2025, Outlook Therapeutics received $17.8 million in gross proceeds from its previously announced warrant exercise inducement with certain holders of existing warrants to purchase the Company’s common stock. As of December 31, 2024, Outlook Therapeutics had cash and cash equivalents of $5.7 million, excluding the proceeds received from the warrant exercise inducement in January 2025.

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

ONS-5010 / LYTENAVA™ is an ophthalmic formulation of bevacizumab for the treatment of wet AMD. LYTENAVA™ (bevacizumab gamma) is the subject of a centralized Marketing Authorization granted by the European Commission in the European Union (EU) and Marketing Authorization granted by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) for the treatment of wet AMD.

In the United States, ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is investigational.

Bevacizumab-vikg (bevacizumab gamma in the EU and UK) 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 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 focused on the development and commercialization of ONS-5010 / LYTENAVA ™ (bevacizumab-vikg; bevacizumab gamma), for the treatment of retina diseases, including wet AMD. LYTENAVA™ (bevacizumab gamma) is the first ophthalmic formulation of bevacizumab to receive European Commission and MHRA Marketing Authorization for the treatment of wet AMD. Outlook Therapeutics is working to initiate its commercial launch of LYTENAVA™ (bevacizumab gamma) in the EU and the UK as a treatment for wet AMD, expected in the second quarter of calendar 2025. In the United States, ONS-5010 / LYTENAVA™ is investigational, is being evaluated in an ongoing non-inferiority study for the treatment of wet AMD, and if successful, the data may be sufficient for Outlook to resubmit a BLA to the FDA in the United States. If approved in the United States, ONS-5010/LYTENAVA™, would be the first approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD.

Non-GAAP Financial Measures

Outlook Therapeutics prepares its consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) and pursuant to accounting requirements of the Securities and Exchange Commission (SEC). In an effort to provide investors with additional information regarding the results and to provide a meaningful period-over-period comparison of Outlook Therapeutics’ financial performance, Outlook Therapeutics sometimes uses non-U.S. GAAP financial measures (NGFM) as defined by the SEC. In this press release, Outlook Therapeutics uses “adjusted net loss attributable to common stockholders,” which is defined as net loss attributable to common stockholders excluding warrant related expenses (i.e., the excess of the fair value of the warrants upon issuance over the proceeds of the private placements that closed on March 18, 2024 and April 15, 2024) and changes in fair value of warrants and convertible promissory notes, as well as “adjusted net loss attributable to common stockholders per share of common stock – basic and diluted,” which is defined as net loss attributable to common stockholders per share of common stock – basic and diluted excluding warrant related expenses and changes in fair value of warrants and convertible promissory notes. Management uses these NGFMs because they adjust for certain non-cash items that impact financial results but not cash flows and that management believes are not related to its core business. Management uses these NGFMs to evaluate Outlook Therapeutics’ financial performance against internal budgets and targets. Management believes that these NGFMs are useful for evaluating Outlook Therapeutics’ core operating results and facilitating comparison across reporting periods. Outlook Therapeutics believes these NGFMs should be considered in addition to, and not in lieu of, GAAP financial measures. Outlook Therapeutics’ NGFMs may be different from the same NGFMs used by other companies. Reconciliations to the closest U.S. GAAP financial measures are provided in the tables below.

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,” “expect,” “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, the potential to resubmit the BLA for ONS-5010 and the timing thereof, 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 decisions of regulatory bodies and the timing thereof, plans for commercial launch of LYTENAVA™ inGermany and the UK and the timing thereof, including the potential to launch with a partner, expected timing of revenue generation in Germany and the UK, the potential of ONS-5010 / LYTENAVA™ as a treatment for wet AMD, the market opportunity for LYTENAVA™ ir Germany and the UK, plans for commercial launch of ONS-5010 / LYTENAVA™ in additional countries, 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 and commercializing pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, including the risk that the data from the NORSE EIGHT trial does not support the resubmission or subsequent filing by the FDA of the ONS-5010 BLA, the content and timing of decisions by regulatory bodies, the sufficiency of Outlook Therapeutics’ resources, 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, 2024, filed with the SEC on December 27, 2024, 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 conflicts, fluctuations in interest rates and 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,	
	2024	**2023**
Operating expenses:		
Research and development	$ 9,660	$ 4,529
General and administrative	11,947	5,794
Loss from operations	(21,607)	(10,323)
Loss (income) on equity method investment	33	(3)
Interest income	(49)	(188)
Loss from change in fair value of promissory notes	1,304	993
(Gain) loss from change in fair value of warrant liability	(40,273)	53
Net income (loss)	$ 17,378	$ (11,178)
Per share information:		
Net income (loss) per share of common stock, basic	$ 0.72	$ (0.86)
Net income (loss) per share of common stock, diluted	$ 0.72	$ (0.86)
Weighted average shares outstanding, basic	24,234	13,013
Weighted average shares outstanding, diluted	24,234	13,013

Consolidated Balance Sheet Data
(Amounts in thousands)

	December 31, 2024	September 30, 2024
Cash and cash equivalents	$ 5,703	$ 14,928

Total assets	$	17,006	$	28,823
Current liabilities	$	48,237	$	42,554
Total stockholders' deficit	$	(50,290)	$	(73,077)

Reconciliation Between Reported Net Income (Loss) (GAAP) and Adjusted Net (Loss) (Non-GAAP), in each case Attributable to Common Stockholders

(Amounts in thousands, except per share data)

	Three months ended December 31,	
	2024	2023
Net income (loss) attributable to common stockholders, as reported (GAAP)	$ 17,378	$ (11,178)
Adjustments for reconciled items:		
Loss from change in fair value of promissory notes	1,304	993
(Gain) loss from change in fair value of warrant liability	(40,273)	53
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (21,591)	$ (10,132)
Net income (loss) attributable to common stockholders per share of common stock - basic and diluted as reported (GAAP)	$ 0.72	$ (0.86)
Adjustments for reconciled items:		
Loss from change in fair value of promissory notes	0.05	0.08
(Gain) loss from change in fair value of warrant liability	(1.66)	-
Adjusted net loss attributable to common stockholders per share of common stock - basic and diluted (non-GAAP)	$ (0.89)	$ (0.78)

Weighted average shares - basic	24,233,957.00	13,012,833.00
Weighted average shares - diluted	24,233,957.00	13,012,833.00
Weighted average shares - basic	24,233,957	13,012,833
Add in the incremental shares for warrants	-	-
Weighted average shares - diluted for warrants	24,233,957	13,012,833
Weighted average shares - basic	24,233,957	13,012,833
Add in the incremental shares for convertible debt	-	-
Weighted average shares - diluted for convertible debt	24,233,957	13,012,833

OUTLOOK THERAPEUTICS

Source: Outlook Therapeutics, Inc.