Outlook Therapeutics, Inc. Logo

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

May 15, 2025

- **LYTENAVA ™ (bevacizumab gamma) on track for planned first commercial launches in Germany and the United Kingdom (UK) in Q2 CY2025**
- **Prescription Drug User Fee Act (PDUFA) goal date of August 27, 2025 in the United States**

ISELIN, N.J., May 15, 2025 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company focused on enhancing the standard of care for bevacizumab for the treatment of retina diseases, today reported financial results for the second quarter of fiscal year 2025 and provided a corporate update.

"Outlook Therapeutics remains on track in 2025 to transform into a commercial-stage company with the planned upcoming commercial launch of LYTENAVA™ (bevacizumab gamma) in Germany and the United Kingdom for the treatment of wet AMD. In addition to the commercial progress we are making in Europe, in the U.S. we are positioned to potentially receive FDA approval later this year for ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) for the treatment of wet AMD, with a PDUFA decision date scheduled for August 27th. We continue to build momentum and remain laser focused on our goal of providing patients, physicians and payers with a much needed, approved ophthalmic formulation of bevacizumab," commented Lawrence Kenyon, Chief Financial Officer and Interim Chief Executive Officer of Outlook Therapeutics.

Upcoming Anticipated Milestones

- Initial commercial launches in Germany and the UK planned to commence in Q2 CY2025; and
- Potential for approval from the U.S. Food and Drug Administration (FDA) of ONS-5010 in Q3 CY2025.

LYTENAVA™ (bevacizumab gamma) European Commercial Update

Outlook Therapeutics continues to advance its plans to launch LYTENAVA™ (bevacizumab gamma) in Germany and the UK, expected to take place in the second quarter of calendar year 2025. In May 2024, the European Commission granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD in the European Union (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.

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, off-label repackaged bevacizumab is one of the most frequently used first-line anti-VEGF treatments in Europe (approximately 2.8 million injections annually) and the United States (approximately 2.7 million injections annually) for the treatment of retinal diseases[1]. ONS-5010/LYTENAVA™ has the potential to mitigate certain risks associated with the current off-label use of repackaged bevacizumab.

Outlook Therapeutics may also seek authorization in other European countries, Japan, and elsewhere. As previously announced, Outlook Therapeutics has entered into a strategic collaboration with Cencora (formerly AmerisourceBergen) to support the commercial launch of LYTENAVA ™ globally following regulatory approvals. The collaboration and integrated approach are designed to support market access and efficient distribution of LYTENAVA ™ to benefit all stakeholders, including retina specialists, providers and patients in certain European markets and, if approved, in the United States.

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

In April 2025, Outlook Therapeutics announced that the FDA acknowledged receipt of the resubmission of the Biologics License Application (BLA) for ONS-5010 (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab for the treatment of wet AMD. The FDA has determined that the BLA is a Class 2 review, which results in a six-month review period from the date of resubmission. The FDA set a PDUFA goal date of August 27, 2025. ONS-5010, if approved, will be branded as LYTENAVA™ (bevacizumab-vikg) in the United States for the treatment of wet AMD and is expected to receive 12 years of regulatory exclusivity.

The ONS-5010 BLA resubmission was based on the efficacy and safety demonstrated in NORSE EIGHT, as well as additional chemistry, manufacturing and controls (CMC) information requested by the FDA. As previously announced, following Type A meetings with the FDA in Q4 CY2023 to address the ONS-5010 Complete Response Letter (CRL), the FDA informed Outlook Therapeutics that, in order to meet the FDA's requirement for a second adequate and well-controlled clinical trial of ONS-5010, it could conduct a non-inferiority study evaluating ONS-5010 versus ranibizumab in a 12 week study of treatment naïve patients with a primary efficacy endpoint at 8 weeks (NORSE EIGHT). Outlook Therapeutics believes that the complete data set for NORSE EIGHT and the additional CMC information in the BLA resubmission, combined with the data from the other NORSE clinical trials, provides the required evidence to support approval of the ONS-5010 BLA in the United States.

Financial Highlights for the Fiscal Second Quarter Ended March 31, 2025

For the fiscal second quarter ended March 31, 2025, Outlook Therapeutics reported a net loss attributable to common stockholders of $46.4 million, or $1.50 per basic and diluted share, compared to a net loss attributable to common stockholders of $114.3 million, or $8.01 per basic and diluted share, for the same period last year. For the fiscal second quarter ended March 31, 2025, Outlook Therapeutics also reported an adjusted net loss attributable to common stockholders of $12.5 million, or $0.40 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $22.1 million, or $1.55 per basic and diluted share, for fiscal second quarter 2024.

Adjusted net loss attributable to common stockholders for the fiscal second quarter ended March 31, 2025 includes $33.9 million of warrant

inducement expenses, $2.1 million of loss from change in fair value of convertible promissory notes and $2.1 million of gain from change in fair value of warrant liability. Adjusted net loss attributable to common stockholders for the fiscal second quarter ended March 31, 2024 includes $34.1 million of warrant related expenses, $49.6 million of loss from change in fair value of warrant liability and $8.5 million of loss from change in fair value of convertible promissory notes.

As of March 31, 2025, Outlook Therapeutics had cash and cash equivalents of $7.6 million.

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 EU and Marketing Authorization granted by the MHRA in the UK for the treatment of wet AMD.

In the United States, ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is investigational. In certain European Union Member States ONS-5010/LYTENAVA™ must receive pricing and reimbursement approval before it can be sold.

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) to enhance the standard of care for bevacizumab for the treatment of retina diseases. 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, and a BLA has been resubmitted to the FDA. 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 inducement expenses 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 inducement 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," "on track," "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, plans for commercial launch of LYTENAVA™ in Germany and the UK 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, including market exclusivity, the potential to receive approval from the FDA and the timing thereof, the potential of ONS-5010/LYTENAVA™ as a treatment for wet AMD and to mitigate certain risks associated with the current off-label use of repackaged bevacizumab, the market opportunity for LYTENAVA™ in Europe and the United States, 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 approval 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, as supplemented by the Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2024 and future 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, tariffs and trade tensions, 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 March 31,		Six months ended March 31,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 4,407	$ 13,509	$ 14,067	$ 18,038
General and administrative	7,984	5,431	19,931	11,225
Loss from operations	(12,391)	(18,940)	(33,998)	(29,263)
Loss on equity method investment	36	30	70	28
Interest expense (income), net	19	3,084	(30)	2,895
Loss from change in fair value of promissory notes	2,111	8,519	3,415	9,512
Warrant related expenses	—	34,098	—	34,098
Warrant inducement expenses	33,857	—	33,857	—
(Gain) loss from change in fair value of warrant liability	(2,060)	49,615	(42,333)	49,668
Loss before income taxes	(46,354)	(114,286)	(28,977)	(125,464)
Income tax expense	3	3	3	3
Net loss	$ (46,357)	$ (114,289)	$ (28,980)	$ (125,467)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.50)	$ (8.01)	$ (1.05)	$ (9.20)
Weighted average shares outstanding, basic and diluted	30,874	14,270	27,518	13,638

Consolidated Balance Sheet Data
(Amounts in thousands)

	March 31, 2025	**September 30, 2024**
Cash and cash equivalents	$ 7,556	$ 14,928
Total assets	$ 19,075	$ 28,823
Current liabilities	$ 24,822	$ 42,554
Total stockholders' deficit	$ (32,463)	$ (73,077)

Reconciliation Between Reported Net 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 March 31,		Six months ended March 31,	
	2025	2024	2025	2024
Net loss attributable to common stockholders, as reported (GAAP)	$ (46,358)	$ (114,289)	$ (28,980)	$ (125,467)
Adjustments for reconciled items:				
Loss from change in fair value of promissory notes	2,111	8,519	3,415	9,512
Warrant related expenses	—	34,098	—	34,098

Warrant inducement expenses	33,857	—	33,857	—
(Gain) loss from change in fair value of warrant liability	(2,060)	49,615	(42,333)	49,668
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (12,450)	$ (22,057)	$ (34,041)	$ (32,189)
Net loss attributable to common stockholders per share of common stock - basic and diluted as reported (GAAP)	$ (1.50)	$ (8.01)	$ (1.05)	$ (9.20)
Adjustments for reconciled items:				
Loss from change in fair value of promissory notes	0.07	0.59	0.12	0.70
Warrant related expenses	—	2.39	—	2.50
Warrant inducement expenses	1.10	—	1.23	—
(Gain) loss from change in fair value of warrant liability	(0.07)	3.48	(1.54)	3.64
Adjusted net loss attributable to common stockholders per share of common stock - basic and diluted (non-GAAP)	$ (0.40)	$ (1.55)	$ (1.24)	$ (2.36)
Weighted average shares outstanding, basic and diluted	30,874,396	14,270,289	27,517,692	13,638,126

[1] (Citeline (2023), Global Data (2023) and Market Scope (2022); ASRS 2024 Membership Survey Presented at ASRS NY 2022; Market Scope 2024 US Retina Quarterly Updates; GlobalData: Age-Related Macular Degeneration: Global Drug Forecast and Market Analysis to 2028 (April 2020)

Source: Outlook Therapeutics, Inc.