Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Financial Results for Fiscal Year 2025

December 19, 2025

ISELIN, N.J., Dec. 19, 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 announced financial results for fiscal year 2025.

Financial Highlights for the Fiscal Year Ended September 30, 2025

For the fiscal year ended September 30, 2025, Outlook Therapeutics reported net loss attributable to common stockholders of $62.4 million, or $1.79 per basic and diluted share, and $1.4 million of revenue. This compares with net loss attributable to common stockholders of $75.4 million, or $4.06 per basic and diluted share, and no revenue for the prior year.

Revenue in fiscal 2025 consisted of the initial sales in June 2025 into the sales channels in Germany and the UK for LYTENAVA ™ (bevacizumab gamma) where title to the product has transferred to the distributor. Overall, there has been a sustained increase in both the number of accounts ordering LYTENAVA™ and the breadth of prescribing clinicians across both markets during the early stages of fiscal year 2026. In addition to optimal market access and pricing at the national and sub-national level in both the UK and Germany, recent developments that should contribute to continued improvements in unit sales include LYTENAVA™ acceptance into the tender framework in the UK in December 2025 and the initiation of a multi-center non-interventional study in Germany to gather real-world data. Gross profit for fiscal 2025 was impacted negatively due to increased reserves for short-dated inventory included in the original shipments to the UK in June 2025.

Overall expenses in fiscal 2025 were $4.6 million lower than fiscal 2024 primarily due to a significant reduction in R&D expenses associated with the completion of the NORSE Eight clinical trial in fiscal 2024. The reduction in R&D expenses was partially offset by increased SG&A expenses primarily related to launching LYTENAVA™ in Europe in June 2025.

As of September 30, 2025, Outlook Therapeutics had cash and cash equivalents of $8.1 million, which does not include $14.9 million of net proceeds from sales under its at-the-market offering program after September 30, 2025.

"Over the course of fiscal year 2025, our team has worked diligently to position Outlook Therapeutics for success. We are preparing now for potential approval and progressing commercial launch activities in the U.S., as we await a decision from the FDA in just a few short weeks," commented Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "In Europe, our initial shipments of inventory are being used to prime and prepare to grow the market. Commercial activities remain ongoing as we push ahead with our efforts to expand into the next wave of country launches, including Austria and the Netherlands. Outside the U.S., we continue to identify potential partners for additional expansion. As we close out the remainder of 2025, our commitment remains focused on providing patients and physicians with access to an approved ophthalmic formulation of bevacizumab."

Upcoming Near Term Milestone

- U.S. Food and Drug Administration (FDA) PDUFA goal date for ONS-5010 is December 31, 2025.

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

ONS-5010/LYTENAVA ™ is an ophthalmic formulation of bevacizumab produced in the United States 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 Medicines and Healthcare products Regulatory Agency (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 commenced commercial launch of LYTENAVA™ (bevacizumab gamma) in Germany and the UK as a treatment for wet AMD.

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

Forward-Looking Statements

This press release contains statements that are, or may be deemed to be "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 "aim," "anticipate," "believe," "can," "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, expectations

concerning future levels of sales for LYTENAVA™, plans for commercial launch of LYTENAVA™ in additional markets and the timing thereof 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, the market opportunity for LYTENAVA™ in Europe and the United States, 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 acceptance of Outlook Therapeutics' products by healthcare professionals and patients as safe, effective, and cost-effective, the impact of governmental and semi-governmental laws, regulations and guidelines, reliance on third-party service providers, suppliers, and manufacturers, 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 June 30, 2025 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)

	Year ended September 30,	
	2025	**2024**
Revenues, net	$ 1,413	$ –
Cost of revenues	1,356	–
Gross profit	57	–
Operating expenses:		
Research and development	27,181	41,763
Selling, general and administrative	39,938	29,940
Loss from operations	(67,062)	(71,703)
Loss on equity method investment	141	101
Interest income	(90)	(906)
Interest expense	283	3,157
Loss from change in fair value of promissory notes	6,075	2,457
Warrant related expenses	–	37,490
Warrant inducement expenses	33,522	–
Gain from change in fair value of warrant liability	(43,016)	(38,638)
Loss before income taxes	(63,977)	(75,364)
Income tax (benefit) expense	(1,552)	3
Net loss	$ (62,425)	$ (75,367)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (1.79)	$ (4.06)
Weighted average shares outstanding, basic and diluted	34,796	18,549

Condensed Consolidated Balance Sheet Data
(Amounts in thousands)

	September 30,	
	2025	2024
Cash and cash equivalents	$ 8,083	$ 14,928
Total assets	$ 18,584	$ 28,823
Current liabilities	$ 45,815	$ 42,554
Total stockholders' deficit	$ (32,188)	$ (73,077)

Source: Outlook Therapeutics, Inc.