Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Second Quarter Fiscal Year 2026 Financial Results and Provides Corporate Update

May 15, 2026

- *Completed Formal Dispute Resolution Meeting with FDA regarding Complete Response Letter (CRL) for ONS-5010; Decision Expected This Month*
- *Continued expansion of LYTENAVA™ (bevacizumab gamma) in Europe with Commercial Distribution Agreement with Mediconsult AG in Switzerland*
- *Launched Real-World Evidence Study in Germany to Further Strengthen the Overall Value Proposition of LYTENAVA™*

ISELIN, N.J., May 15, 2026 (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 the second quarter of fiscal year 2026 ended March 31, 2026, and provided a corporate update.

"We remain committed to working collaboratively with the FDA to establish a clear path forward toward potential U.S. approval. Our objective is clear: to bring the first FDA-approved ophthalmic formulation of bevacizumab to patients in the United States," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "In addition, we are encouraged by the continued momentum of our European commercial launch of LYTENAVA, highlighted by our expansion into new markets, as well as our recently announced partnership in Switzerland and growing physician adoption in our initial launch countries."

During the second quarter of fiscal year 2026, Outlook Therapeutics continued to advance the commercial rollout of LYTENAVA™ (bevacizumab gamma) in Europe. In anticipation of a potential launch in Switzerland, the Company entered into a Commercial Distribution Agreement with Mediconsult AG for the sale and distribution of LYTENAVA™ (bevacizumab gamma) in Switzerland. As part of the agreement, Mediconsult AG will be responsible for regulatory activities in Switzerland, including seeking and maintaining Marketing Authorization. The Company is targeting a 2027 launch of LYTENAVA™ in Switzerland in 2027, subject to receipt of Marketing Authorization in that country.

Building on the initial launch momentum, Outlook Therapeutics intends to expand into the Netherlands and Ireland later in 2026 and additional European markets and beyond in 2027. As Outlook Therapeutics continues to see increasing physician adoption and demand in the initial launch countries, the Company remains focused on executing its commercialization strategy to pursue additional launches and potential partnerships inside and outside of Europe and further establishing LYTENAVA as a new treatment option for wet AMD.

The Company also launched a real-world evidence study in Germany to further evaluate the performance of LYTENAVA™ in routine clinical practice following its approval in the European Union and the United Kingdom. These data are expected to support reimbursement and market access efforts in key European markets, inform potential regulatory interactions, and further strengthen the overall value proposition of LYTENAVA™ for physicians, patients, and stakeholders.

ONS-5010 U.S. Regulatory Update

Outlook Therapeutics continues to advance its regulatory efforts in the United States for ONS-5010/LYTENAVA™ (bevacizumab-vikg). The Company conducted its formal dispute resolution meeting with the U.S. Food and Drug Administration (FDA) in April 2026 and remains engaged in the process as it awaits the formal decision from the FDA. The Company has provided a comprehensive package of clinical, functional, pharmacodynamic, and safety data, including results from the NORSE TWO and NORSE EIGHT studies, which the Company believes support the efficacy and safety profile of ONS-5010/LYTENAVA™ for the treatment of wet AMD.Outlook Therapeutics remains committed to working collaboratively with the FDA to establish a clear path forward toward potential U.S. approval.

Outlook Therapeutics expects a formal decision from the FDA in May 2026.

Financial Highlights for the Second Fiscal Quarter Ended March 31, 2026

For the second fiscal quarter ended March 31, 2026, Outlook Therapeutics reported net loss attributable to common stockholders of $4.5 million, or $0.05 per basic and diluted share. This compares with net loss attributable to common stockholders of $46.4 million, or $1.50 per basic and diluted share for the same period last year.

For the fiscal quarter ended March 31, 2026, Outlook Therapeutics reported an adjusted net loss attributable to common stockholders of $14.1 million, or $0.16 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $12.4 million, or $0.40 per basic and diluted share for the second fiscal quarter of 2025.

Adjusted net loss attributable to common stockholders for the fiscal quarter ended March 31, 2026, excludes $2.5 million of gain from change in fair value of promissory notes, $0.3 million of gain on extinguishment of debt, and $6.8 million of gain from change in fair value of warrant liability. Adjusted net loss attributable to common stockholders for the fiscal quarter ended March 31, 2025, excludes $33.9 million of warrant inducement expenses, $2.1 million of gain from change in fair value of warrant liability, and $2.1 million of loss from change in fair value of promissory notes.

Net revenue in the fiscal quarter ended March 31, 2026, was offset by recurring fixed distribution costs during the quarter. Overall, unit sales of LYTENAVA in Europe for the second fiscal quarter of 2026 were down approximately 10% compared to the quarter ended December 31, 2025, but have trended upward early in the current quarter. Outlook Therapeutics has taken steps to reduce costs in Europe in an effort to improve margins in future quarters.

In March 2026, Outlook Therapeutics reported that it had restructured its outstanding convertible promissory note to extend the maturity until December 2026, as well as entered into a non-convertible promissory note that was used to reduce the outstanding balance of the convertible note.

Additionally, the Company completed a public offering of common stock and accompanying warrants in March 2026, for approximately $4.0 million of net proceeds, after deducting placement agent fees and other offering expenses. In April 2026, the Company completed a registered direct offering of common stock and, in a concurrent private placement, accompanying warrants, for $4.2 million of net proceeds, after deducting placement agent fees and other offering expenses. As of March 31, 2026, Outlook Therapeutics had cash and cash equivalents of $7.7 million, which does not include the net proceeds of the April 2026 registered direct offering.

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 a 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 retinal 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.

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, gain on extinguishment of debt 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, gain on extinguishment of debt 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 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 "anticipate," "are," "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 Outlook Therapeutics' ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, 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, statements about Outlook Therapeutics' commercialization strategy, including plans for commercial launch of LYTENAVA ™ in additional markets and the timing thereof and potential partnerships in those countries, expectations regarding receipt of Marketing Authorization for LYTENAVA ™ in Switzerland, expectations concerning Outlook Therapeutics' partnership with Mediconsult AG in Switzerland, the potential of ONS-5010/LYTENAVA ™ as a treatment for wet AMD, the market opportunity for LYTENAVA ™ in Europe and the United States, expectations concerning Outlook's financial performance and condition, 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, 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, 2025, filed with the SEC on December 19, 2025, as supplemented by 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 global geopolitical conflict, 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,	
	2026	**2025**	**2026**	**2025**
Revenues, net	$ 128	$ —	$ (1,080)	$ —
Cost of revenues	150	—	179	—
Gross profit	(22)	—	(1,259)	—
Operating expenses:				
Research and development	$ 4,500	$ 4,407	8,135	14,067
Selling, general and administrative	9,505	7,984	18,117	19,931
Loss from operations	(14,027)	(12,391)	(27,511)	(33,998)
Loss on equity method investment	45	36	83	70
Interest expense (income)	—	19	—	(30)
(Gain) loss from change in fair value of promissory notes	(2,495)	2,111	4,249	3,415
Warrant inducement expenses	—	33,857	—	33,857
Gain from change in fair value of warrant liability	(6,838)	(2,060)	(4,046)	(42,333)
Gain on extinguishment of debt	(286)	—	(286)	—
Net loss before income tax	$ (4,453)	$ (46,354)	$ (27,511)	$ (28,977)
Income tax expense	—	3	—	3
Net loss	(4,453)	(46,357)	(27,511)	(28,980)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.05)	$ (1.50)	$ (0.39)	$ (1.05)
Weighted average shares outstanding, basic and diluted	81,836	30,874	70,902	27,518

Condensed Consolidated Balance Sheet Data
(Amounts in thousands)

	March 31, 2026	**September 30, 2025**
Cash and cash equivalents	$ 7,748	$ 8,083
Total assets	$ 21,892	$ 18,584
Current liabilities	$ 38,884	$ 45,815
Total stockholders' deficit	$ (28,995)	$ (32,188)

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 December 31,	
	2026	2025	2026	2025
Net loss attributable to common stockholders, as reported (GAAP)	$ (4,453)	$ (46,357)	$ (27,511)	$ (28,980)
Adjustments for reconciled items:				
(Gain) loss from change in fair value of promissory notes	(2,495)	2,111	4,249	3,415
Warrant inducement expenses	—	33,857	—	33,857
Gain from change in fair value of warrant liability	(6,838)	(2,060)	(4,046)	(42,333)
Gain on extinguishment of debt	(286)	—	(286)	—

Adjusted net loss attributable to common stockholders (non-GAAP)	$ (14,072)	$ (12,449)	$ (27,594)	$ (34,041)
Net loss attributable to common stockholders per share of common stock – basic as reported (GAAP)	$ (0.05)	$ (1.50)	$ (0.39)	$ (1.05)
Adjustments for reconciled items:				
(Gain) loss from change in fair value of promissory notes	(0.03)	0.07	0.06	0.12
Warrant inducement expenses	—	1.10	—	1.23
Gain from change in fair value of warrant liability	(0.08)	(0.07)	(0.06)	(1.54)
Gain on extinguishment of debt	—	—	—	—
Adjusted net loss attributable to common stockholders per share of common stock – basic (non-GAAP)	$ (0.16)	$ (0.40)	$ (0.39)	$ (1.24)
Weighted average shares outstanding, basic	81,835,900	30,874,396	70,901,617	27,517,692
Weighted average shares – diluted	81,835,900	30,874,396	70,901,617	27,517,692

Source: Outlook Therapeutics, Inc.