Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Third Quarter Fiscal Year 2026 Financial Results and Provides Business Update Highlighting FDA Approval of LYTENAVA ™

August 14, 2026

The only FDA-approved ophthalmic bevacizumab, LYTENAVA™, addresses a significant need in the U.S. wet AMD market where bevacizumab is already widely used

Advancing the U.S. launch strategy for LYTENAVA, including broad market access, reimbursement, pricing, medical affairs, and supply capabilities

Potential to exceed $500 million in annual U.S. LYTENAVA sales by 2030

Company to host corporate update conference call today, August 14th, at 8:30 AM ET —registration details below

ISELIN, N.J., Aug. 14, 2026 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company focused on the development and commercialization of LYTENAVA™ (bevacizumab-vikg, bevacizumab gamma) for the treatment of retinal diseases, today reported financial results for the third quarter of fiscal year 2026, ended June 30, 2026, and provided a business update. The Company continues to advance preparations for the U.S. commercial launch of LYTENAVA, the only FDA-approved ophthalmic bevacizumab for the treatment of wet age-related macular degeneration (wet AMD).

"FDA approval of LYTENAVA marks a defining moment for Outlook Therapeutics and creates a significant opportunity for the Company in the United States," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "Our priorities are clear: build an exceptional commercial team with deep retina and launch experience, prepare for our planned U.S. launch by the end of calendar 2026, and execute a strategy that reflects today's competitive and evolving wet AMD treatment landscape. We believe LYTENAVA is well positioned to become an important treatment option for retina physicians and their patients."

Outlook Therapeutics is advancing preparations for the U.S. commercial launch of LYTENAVA, planned before the end of calendar 2026. The Company is expanding payer engagement, scaling commercial supply, and building a focused commercial organization informed by feedback from retina physicians, practices, and other key stakeholders. Based on current estimates, management believes LYTENAVA has the potential to exceed $500 million in annual U.S. sales by 2030.

The Company has established its customer segmentation and targeting strategy to prioritize retina practices with the greatest potential for early adoption and is building its commercial team with experienced leaders with deep expertise in retina, product launches, and the increasingly competitive and complex wet AMD and anti-VEGF market. The Company's launch and go-to-market strategy is designed to reflect the evolving biosimilar landscape, affordability considerations, and the potential for additional market entrants, while supporting broad patient access and reimbursement. As part of these efforts, the Company plans to submit an application for a permanent Healthcare Common Procedure Coding System or HCPCS code by October 1, 2026, to support reimbursement following launch.

"Our launch strategy reflects a deep understanding of the retina market and the needs of patients, physicians, practices, and payers," continued Mr. Jahr. "We are taking a targeted approach to customer engagement, pricing, and reimbursement, while building the commercial and supply capabilities needed to support the introduction of LYTENAVA in the United States. We believe this foundation will position us to drive broad access and successful adoption following launch."

In Europe, Outlook Therapeutics continues to expand the commercialization of LYTENAVA in Germany, Austria and the United Kingdom. The Company is also preparing for a planned launch in the Netherlands later in 2026 following its Netherlands submission. In Switzerland, the Company's partner, Mediconsult, is leading regulatory and commercial activities in support of an anticipated launch in 2027.

Wet AMD remains a leading cause of vision loss among older adults, and anti-VEGF therapies represent the current standard of care for millions of patients worldwide. At the center of the Company's strategy is a commitment to ensuring broad patient access and reimbursement while removing barriers to adoption for both patients and practices.

"For retina practices, the approval of LYTENAVA represents more than a new treatment option. It addresses a longstanding need for an FDA-approved bevacizumab specifically for ophthalmic use. The patient services and support resources available alongside LYTENAVA can also help practices navigate access and support eligible patients with wet AMD throughout their treatment journey," said Albert Shirakian, CEO, Retina Vitreous Associates Medical Group.

"We have been working closely with the Outlook Therapeutics team since LYTENAVA received FDA approval and appreciate their commitment to meeting a longstanding need in retina care. Having an FDA-approved bevacizumab specifically for ophthalmic use gives physicians an important new option, supported by the clinical data and quality standards of the FDA approval process. We are encouraged by this new treatment option for physicians and patients in the treatment of wet AMD," stated Miguel A. Busquets, MD, FACS, FASRS, Vice Chairman, EyeCare Partners.

Financial Results for the Third Quarter Fiscal Year 2026 ended June 30, 2026

For the third fiscal quarter ended June 30, 2026, Outlook Therapeutics reported net loss attributable to common stockholders of $20.3 million, or $0.15 per basic and diluted share. This compares with net loss attributable to common stockholders of $20.2 million, or $0.55 per basic and diluted share for the same period last year.

For the fiscal quarter ended June 30, 2026, Outlook Therapeutics reported an adjusted net loss attributable to common stockholders of $10.9 million, or $0.09 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $15.8 million, or $0.44 per basic and diluted share for the third fiscal quarter of 2025.

Adjusted net loss attributable to common stockholders for the fiscal quarter ended June 30, 2026, excludes $1.1 million of loss from change in fair value of promissory notes, $1.3 million of loss on extinguishment of debt, and $7.0 million of loss from change in fair value of warrant liability. Adjusted net loss attributable to common stockholders for the fiscal quarter ended June 30, 2025, excludes $2.0 million of loss from change in fair value of warrant liability, and $2.3 million of loss from change in fair value of promissory notes.

Subsequent to the quarter end, in August 2026, the Company announced a public offering of 55,555,556 shares of common stock and accompanying warrants to purchase 55,555,556 shares of common stock, at a combined public offering price of $0.99 per share and accompanying warrant, for approximately $51.1 million of net proceeds, after deducting underwriting discounts and commissions and other estimated offering expenses. As of June 30, 2026, Outlook Therapeutics had cash and cash equivalents of $11.2 million, which does not include the proceeds from the public offering.

Conference Call and Webcast

As previously announced, Outlook Therapeutics will host a conference call and webcast to discuss the Company's third quarter fiscal year 2026 operational and financial results today, August 14, 2026, at 8:30 AM ET.

The call will be hosted by members of Outlook Therapeutics' leadership team, Bob Jahr, Chief Executive Officer and Lawrence A. Kenyon, Executive Vice President and Chief Financial Officer. Interested participants and investors may access the conference call by dialing 877-407-8291 (domestic) or +1 201-689-8345 (international) and referencing the Outlook Therapeutics conference call. The webcast will be accessible here and will be archived following the live event.

About LYTENAVA™ (bevacizumab-vikg, bevacizumab gamma)

LYTENAVA ™ is an ophthalmic formulation of bevacizumab produced in the United States for the treatment of wet AMD. In theUnited States, ONS-5010/LYTENAVA (bevacizumab-vikg) is the only ophthalmic formulation approved by the FDA. LYTENAVA™ (bevacizumab gamma) is also 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 certain European Union Member States, 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 IgG1 monoclonal antibody specific tofor human vascular endothelial growth factor (VEGF). Bevacizumab binds VEGF and prevents the interaction of VEGF to its receptors (Flt-1 and KDR) on the surface of endothelial cells. LYTENAVA binds to all isoforms of VEGF-A, thereby preventing interaction with receptors VEGFR-1 and VEGFR-2. By inhibiting VEGF-A, LYTENAVA suppresses endothelial cell proliferation, neovascularization, and vascular permeability. Inhibition of such activity targets a pathophysiologic process that contributes to vision loss.

Important Safety Information and Indication

LYTENAVA (bevacizumab-vikg) is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD).

Contraindications

LYTENAVA is contraindicated in patients with ocular or periocular infections, in patients with active intraocular inflammation, and in patients with a known hypersensitivity to bevacizumab products or any of the ingredients in LYTENAVA. Hypersensitivity reactions may manifest as severe intraocular inflammation.

Warnings and Precautions

Intravitreal injections have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering LYTENAVA. In addition, patients should be monitored following the injection to permit early treatment should an infection occur.

Increases in intraocular pressure have been noted post-injection (up to 60 minutes) while being treated with LYTENAVA. Monitor intraocular pressure prior to and following intravitreal injection with LYTENAVA and manage appropriately.

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LYTENAVA clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

Adverse Reactions

The most common adverse reaction (≥1%) reported in patients receiving LYTENAVA was conjunctival hemorrhage (4%), eye pain (2%), and vitreous floaters (2%). These are not all the possible side effects of LYTENAVA.

You are encouraged to report side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Outlook Therapeutics at 1-833-999-OTLK (6855).

Please see the full U.S. Prescribing Information for LYTENAVA here.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company focused on the development and commercialization of LYTENAVA (bevacizumab-vikg (U.S.), bevacizumab gamma (E.U.)). LYTENAVA is the only ophthalmic formulation of bevacizumab to receive U.S. FDA approval and European Commission and MHRA Marketing Authorization for the treatment of wet AMD. Outlook Therapeutics commenced commercial launch of LYTENAVA ™ (bevacizumab gamma) in Germany, Austria, and the UK as a treatment for 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 loss 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 loss 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 may or are considered "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," "can," "could," "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, express or implied discussions regarding the Company's planned launch of LYTENAVA in the United States and other jurisdictions and the timing thereof; expectations concerning potential revenue generation from sales of LYTENAVA; expectations surrounding market adoption of LYTENAVA; potential additional marketing approvals; expectations regarding the potential impact of LYTENAVA in the retina community; new indications or labeling for LYTENAVA; Outlook Therapeutics development or future revenue plans for LYTENAVA generally; 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 in obtaining necessary regulatory approvals, the content and timing of decisions by regulatory bodies, as well as those risks detailed in Outlook Therapeutics' filings with the Securities and Exchange Commission (the SEC), including the Current Report on Form 8-K filed with the SEC on August 12, 2026, 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 June 30,		Nine months ended June 30,	
	2026	2025	2026	2025
Revenues, net	$ 9	$ 1,505	$ (1,071)	$ 1,505
Cost of revenues	17	440	196	440
Gross profit	(8)	1,065	(1,267)	1,065
Operating expenses:				
Research and development	$ 3,251	$ 7,135	11,386	21,202
Selling, general and administrative	7,551	9,679	25,668	29,610
Loss from operations	(10,810)	(15,749)	(38,321)	(49,747)
Loss on equity method investment	41	30	125	100
Interest expense	—	49	—	19
Loss from change in fair value of promissory notes	1,103	2,324	5,351	5,739
Warrant inducement expenses	—	—	—	33,857
Loss (gain) from change in fair value of warrant liability	7,036	2,000	2,990	(40,333)
Loss on extinguishment of debt	1,329	—	1,043	—
Net loss before income tax	$ (20,319)	$ (20,152)	(47,830)	$ (49,129)

Income tax expense	—	—	—	3
Net loss	(20,319)	(20,152)	(47,830)	(49,132)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.15)	$ (0.55)	$ (0.51)	$ (1.60)
Weighted average shares outstanding, basic and diluted	136,743	36,957	93,232	30,664

Condensed Consolidated Balance Sheet Data

(Amounts in thousands)

	June 30, 2026	September 30, 2025
Cash and cash equivalents	$ 11,242	$ 8,083
Total assets	$ 26,185	$ 18,584
Current liabilities	$ 28,679	$ 45,815
Total stockholders' deficit	$ (10,393)	$ (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 June 30,		Nine months ended June 30,	
	2026	2025	2026	2025
Net loss attributable to common stockholders, as reported (GAAP)	$ (20,319)	$ (20,152)	$ (47,830)	$ (49,132)
Adjustments for reconciled items:				
Loss from change in fair value of promissory notes	1,102	2,324	5,351	5,739
Warrant inducement expenses	—	—	—	33,857
Loss (gain) from change in fair value of warrant liability	7,036	2,000	2,990	(40,333)
Loss on extinguishment of debt	1,329	—	1,043	—
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (10,852)	$ (15,828)	$ (38,446)	$ (49,869)
Net loss attributable to common stockholders per share of common stock - basic as reported (GAAP)	$ (0.15)	$ (0.55)	$ (0.51)	$ (1.60)
Adjustments for reconciled items:				
Loss from change in fair value of promissory notes	0.01	0.06	0.06	0.19
Warrant inducement expenses	—	—	—	1.10
Loss (gain) from change in fair value of warrant liability	0.05	0.05	0.03	(1.32)
Loss on extinguishment of debt	0.01	-	0.01	-
Adjusted net loss attributable to common stockholders per share of common stock - basic (non-GAAP)	$ (0.09)	$ (0.44)	$ (0.42)	$ (1.63)

OUTLOOK THERAPEUTICS

Source: Outlook Therapeutics, Inc.