UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 17, 2026

Outlook Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37759**	**38-3982704**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

111 S. Wood Avenue, **Unit #100** **Iselin, New Jersey**	**08830**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(609) 619-3990**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock	OTLK	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On February 17, 2026, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its first fiscal quarter ended December 31, 2025. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 17, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Outlook Therapeutics, Inc.

Date: February 17, 2026

By: /s/ Lawrence A. Kenyon
Lawrence A. Kenyon
Chief Financial Officer

Exhibit 99.1

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

- ***Continued expansion of LYTENAVA™ (bevacizumab gamma) in Europe underway, including commercial launch in Austria in January 2026***
- ***Additional European launches expected in 2026***
- ***Type A meeting request submitted to the U.S. Food and Drug Administration for ONS-5010***

ISELIN, N.J., February 17, 2026 — 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 first quarter fiscal year 2026 and provided a corporate update.

"LYTENAVA™ (bevacizumab gamma) is demonstrating increasing adoption in Europe following our initial launches, with growing demand and quarter-over-quarter unit sales growth," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "Building on this momentum, we are actively working towards launching into additional EU markets in the near term, following our January launch into Austria, as part of a broader regional expansion strategy."

In addition to the planned launches of LYTENAVA in Ireland and the Netherlands in 2026, followed by France, Italy and Spain in 2027, Outlook Therapeutics also continues with its efforts to potentially partner with established companies in other countries in Europe, Latin America and Asia.

Financial Highlights for the Fiscal First Quarter Ended December 31, 2025

For the fiscal first quarter ended December 31, 2025, Outlook Therapeutics reported net loss attributable to common stockholders of $23.1 million, or $ 0.38 per basic and diluted share. This compares with net income attributable to common stockholders of $17.4 million, or $0.72 per basic and diluted share for the same period last year.

For the fiscal first quarter ended December 31, 2025, Outlook Therapeutics reported an adjusted net loss attributable to common stockholders of $13.5 million, or $0.22 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $21.6 million, or $0.89 per basic and diluted share for the first fiscal quarter of 2025.

Adjusted net loss attributable to common stockholders for the fiscal quarter ended December 31, 2025 excludes $6.7 million of loss from change in fair value of promissory notes and $2.8 million of loss from change in fair value of warrant liability. Adjusted net loss attributable to common stockholders for the fiscal quarter ended December 31, 2024 excludes $40.3 million of gain from change in fair value of warrant liability and $1.3 million of loss from change in fair value of promissory notes.

Revenue in the fiscal quarter ended December 31, 2025 was negatively impacted by an increase in the returns reserve for estimated product returns from the UK distributor resulting from short dated product used for the initial shipments into the distribution channel in June 2025 to support the launch of LYTENAVA in Europe. No further adjustments for these batches are anticipated for the remainder of fiscal year 2026. Overall, unit sales of LYTENAVA in Europe more than doubled in the quarter ended December 31, 2025, as compared to the previous three months.

As of December 31, 2025, Outlook Therapeutics had cash and cash equivalents of $8.7 million, which does not include $2.4 million of net proceeds from sales under its at-the-market offering program after December 31, 2025.

ONS-5010 U.S. Regulatory Update

Outlook Therapeutics has requested a Type A meeting with the U.S. Food and Drug Administration to discuss the Complete Response Letter (CRL) dated December 30, 2025, regarding the Company's Biologics License Application (BLA) for ONS-5010, an investigational ophthalmic bevacizumab formulation for the treatment of wet age-related macular degeneration (wet AMD). The Company submitted the Type A meeting request to work with the FDA on a path forward to resolving the FDA's request for additional confirmatory evidence. The timing of the Type A meeting is subject to FDA scheduling, and further updates will be provided as appropriate.

"Outlook Therapeutics remains fully committed to advancing ONS-5010 in the United States," Mr. Jahr continued. "Our ongoing discussions with the FDA beginning in September 2025 have confirmed alignment on CMC, safety, and the positive results from NORSE TWO, and we look forward to constructive discussions with the FDA as we seek guidance on confirmatory evidence that will withstand current dynamics."

The CRL identified a single deficiency based on a purported lack of substantial evidence of effectiveness, and recommended submission of additional confirmatory evidence. Outlook Therapeutics believes this determination is inconsistent with the totality of evidence submitted in the BLA, including data from an adequate and well-controlled study and confirmatory evidence of effectiveness. Prior to submitting the Type A meeting request, Outlook Therapeutics conducted informal meetings with the FDA to discuss the CRL.

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.

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 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, plans for commercial launch of LYTENAVA™ in additional markets, either directly or with a partner, and the timing thereof, expectations concerning Outlook Therapeutics' plans to conduct a Type A meeting with the FDA and the ability to remediate or otherwise resolve deficiency identified in the CRL, expectations concerning decisions of regulatory bodies and the timing thereof, the potential to receive approval from the FDA, 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 Outlook Therapeutics is not able to provide sufficient evidence to 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, 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 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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Consolidated Statements of Operations
(Amounts in thousands, except per share data)

	Three months ended December 31,	
	2025	**2024**
Revenues, net	$ (1,208)	$ —
Cost of revenues	30	—
Gross profit	(1,238)	—
Operating expenses:		
Research and development	3,634	9,660
Selling, general and administrative	8,612	11,947
Loss from operations	(13,484)	(21,607)
Loss on equity method investment	38	33
Interest income	—	(49)
Loss from change in fair value of promissory notes	6,744	1,304
Loss (gain) from change in fair value of warrant liability	2,792	(40,273)
Net (loss) income	$ (23,058)	$ 17,378
Per share information:		
Net (loss) income per share of common stock, basic and diluted	$ (0.38)	$ 0.72
Weighted average shares outstanding, basic and diluted	60,205	24,234

Condensed Consolidated Balance Sheet Data
(Amounts in thousands)

	December 31, 2025	September 30, 2025
Cash and cash equivalents	$ 8,677	$ 8,083
Total assets	$ 18,239	$ 18,584
Current liabilities	$ 49,056	$ 45,815
Total stockholders' deficit	$ (38,549)	$ (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 December 31,	
	2025	2024
Net loss attributable to common stockholders, as reported (GAAP)	$ (23,058)	$ 17,378
Adjustments for reconciled items:		
Loss from change in fair value of promissory notes	6,744	1,304
Loss (gain) from change in fair value of warrant liability	2,792	(40,273)
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (13,522)	$ (21,591)
Net loss attributable to common stockholders per share of common stock - basic as reported (GAAP)	$ (0.38)	$ 0.72
Adjustments for reconciled items:		
Loss from change in fair value of promissory notes	0.11	0.05
Loss (gain) from change in fair value of warrant liability	0.05	(1.66)
Adjusted net loss attributable to common stockholders per share of common stock - basic (non-GAAP)	$ (0.22)	$ (0.89)