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): June 1, 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 8.01 Other Events.

On June 1, 2026, Outlook Therapeutics, Inc (the "Company") issued a press release announcing that it has resubmitted the Biologics License Application for ONS-5010 to the U.S. Food and Drug Administration.

The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated June 1, 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: June 1, 2026

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

Exhibit 99.1

Outlook Therapeutics Announces Resubmission of Biologics License Application to U.S. FDA for ONS-5010/LYTENAVA™ (bevacizumab-vikg)

ISELIN, N.J., June 1, 2026 — Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company focused on the development and commercialization of ONS-5010/LYTENAVA™ (bevacizumab-vikg, bevacizumab gamma) for the treatment of retinal diseases, today announced the resubmission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ONS-5010/LYTENAVA™ for the treatment of neovascular age-related macular degeneration (nAMD).

As previously announced, Outlook Therapeutics successfully appealed the December 2026 Complete Response Letter (CRL) related to the ONS-5010 Biologics License Application reviewed by the FDA. In their decision, the FDA Office of New Drugs concluded that substantial evidence of effectiveness has been established for LYTENAVA™ for the treatment of neovascular age-related macular degeneration (nAMD), therefore additional trials are not required.

The FDR decision directed the Division of Ophthalmology and Office of Specialty Medicine to work with Outlook Therapeutics to focus on reaching an agreement on final product labeling. Additionally, as indicated in the formal decision, this will be a Class 1 resubmission with a PDUFA date and decision expected within 60 days of FDA's receipt of the resubmission.

Dr. Baruch Kuppermann, Steinert Endowed Professor, Chair, Dept of Ophthalmology and Visual Sciences, Director, Gavin Herbert Eye Institute University of California, Irvine, stated, "ONS-5010/LYTENAVA™ has the potential to offer clinicians and patients an important additional option for treating wet AMD. If approved as the first on-label ophthalmic formulation of bevacizumab, ONS-5010 will enable patients to benefit from wider access and provide an attractive alternative for anti-VEGF treatment of wet AMD."

"We are incredibly pleased to reach this important milestone. This resubmission represents the strength of our application and the tremendous dedication of our entire organization," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "Our team worked through an extensive and rigorous review and appeal process, maintaining close collaboration with the FDA. We are encouraged with the Class 1 review designation. We remain committed to bringing ONS-5010/LYTENAVA™ to patients who deserve FDA-approved options for the treatment of nAMD."

When approved, ONS-5010/LYTENAVA™ will be the first and only FDA-approved ophthalmic formulation of bevacizumab supported by standardized manufacturing, FDA-approved labeling, and robust pharmacovigilance.

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 certain European Union Member States, ONS-5010/LYTENAVA™ must receive pricing and reimbursement approval before it can be sold.

In the United States, ONS-5010/LYTENAVA ™ (bevacizumab-vikg) is investigational. When approved, it will be the first ophthalmic formulation approved by the FDA.

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). 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, Austria, and the UK as a treatment for wet AMD.

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, plans for continued engagement with the FDA and the potential to agree on a regulatory pathway for ONS-5010, the potential of ONS-5010/LYTENAVA™ as a treatment for wet AMD, the potential for ONS-5010 to receive approval from the FDA, 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 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 the Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 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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