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): August 28, 2025

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 August 28, 2025, Outlook Therapeutics, Inc (the "Company") issued a press release announcing that the U.S. Food and Drug Administration issued a complete response letter to the Company's biologics license application for ONS-5010, an investigational ophthalmic formulation of bevacizumab under development to treat wet AMD.

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 August 28, 2025
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: September 2, 2025

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

Exhibit 99.1

Outlook Therapeutics Provides Regulatory Update on U.S. Food and Drug Administration Review of ONS-5010/LYTENAVA™ (bevacizumab-vikg) for the Treatment of Wet AMD

- **FDA issues Complete Response Letter (CRL) for resubmitted ONS-5010 BLA**
- **Outlook Therapeutics plans to work with FDA to address the Agency's issues**
- **Company to host a conference call and webcast today, August 28th at 8:30 AM ET**

ISELIN, N.J., August 28, 2025 — 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 that the U.S. Food and Drug Administration (FDA) has issued a complete response letter (CRL) to its biologics license application (BLA) resubmission, indicating that the FDA cannot approve the application in its present form for the treatment of wet age-related macular degeneration (wet AMD).

The CRL included only one deficiency, for a lack of substantial evidence of effectiveness. In the CRL, the FDA advised that, because ONS-5010 did not meet the primary efficacy endpoint in NORSE EIGHT, it is recommended that confirmatory evidence of efficacy be submitted to support the application for ONS-5010. Additionally, the FDA reiterated that NORSE TWO met its primary endpoint for effectiveness.

"While we are very disappointed with this outcome, we intend to meet with the FDA to receive additional clarity on their requirements to potentially approve the first on-label bevacizumab product specifically formulated, manufactured, and packaged for intravitreal use in the United States. We remain committed to providing patients with a safe and effective alternative to compounded Avastin manufactured in the United States," commented Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "It is important to also note that the CRL identified no other outstanding deficiencies in our BLA."

In addition to requesting a meeting with the FDA to explore pathways for potential approval in the U.S., Outlook Therapeutics intends to continue its efforts to expand into additional markets in Europe. As previously announced, LYTENAVA™ (bevacizumab gamma) was granted Marketing Authorization by the European Commission in the EU and Marketing Authorization by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK for the treatment of wet AMD. In June 2025, LYTENAVA™ (bevacizumab gamma) became commercially available in Germany and the UK for the treatment of wet AMD. LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in adults in the European Union and UK.

Investor Conference Call and Webcast

Outlook Therapeutics management will host a corporate update conference call and webcast today, August 28, 2025 at 8:30 AM ET.

Interested participants and investors may access the conference call by dialing (877) 407-8291 (domestic) or (201) 689-8345 (international). The live webcast will be accessible on the Events page of the Investors section of the Outlook Therapeutics website, outlooktherapeutics.com, and will be archived there for 90 days.

About Wet AMD

Age-related macular degeneration, AMD, is a common eye condition and a leading cause of vision loss among people aged 50 and older. It causes damage to the macula, a small spot near the center of the retina and the part of the eye needed for sharp, central vision, which lets us see objects that are straight ahead. Wet AMD, a form of late-stage AMD, is also called neovascular AMD.

In wet AMD, abnormal blood vessels grow underneath the retina. These vessels leak fluid and blood, which may lead to swelling and damage to the macula, causing vision loss. Additionally, with wet AMD, abnormally high levels of vascular endothelial growth factor (VEGF) are secreted in the eyes. VEGF is a protein that promotes the growth of new abnormal blood vessels; anti-VEGF injection therapy blocks this growth and has become the standard-of-care treatment for wet AMD and other retinal diseases, such as diabetic macular edema and branch retinal vein occlusion.

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

ONS-5010/LYTENAVA™ is an ophthalmic formulation of bevacizumab 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 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," "continue," "expect," "intend," "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 to meet with the FDA and to work to address the deficiency identified in the CRL, the potential to obtain FDA approval for ONS-5020, plans to expand the commercial availability of LYTENAVA in other markets in Europe, the potential of ONS-5010/LYTENAVA™ as a treatment for wet AMD and to mitigate certain risks associated with the current off-label use of repackaged bevacizumab, 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 Outlook Therapeutics is unable to address the issues identified in the CRL and ultimately obtain FDA approval, 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, 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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