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): July 24, 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 July 24, 2026, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) approved the Company's biologics license application for ONS-5010/LYTENAVA™ (bevacizumab-vikg), an ophthalmic formulation of bevacizumab, for the treatment of neovascular (wet) age-related macular degeneration (wet AMD). LYTENAVA™ is the first and only FDA-approved ophthalmic formulation of bevacizumab for the treatment of wet AMD in the United States.

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 July 24, 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: July 24, 2026

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

Exhibit 99.1

Outlook Therapeutics Announces LYTENAVA™ FDA Approval as the First and Only FDA-Approved Ophthalmic Bevacizumab for the Treatment of Wet AMD

Landmark FDA Approval Is an Important Milestone in Retina Care, Bringing Patients and Physicians an Ophthalmic Bevacizumab Developed Specifically for the Eye Following Years of Rigorous Clinical and Regulatory Evaluation

Company Launches Commercial Franchise Positioned to Establish a New Standard as an FDA-Approved Bevacizumab Therapy Across the Approximately $8.5 Billion U.S. Retina Market

Anticipated 12 Years of Market Exclusivity Under the Biologics Price Competition and Innovation Act (BPCIA)

ISELIN, N.J., July 24, 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 that the U.S. Food and Drug Administration (FDA) has approved LYTENAVA™ (bevacizumab-vikg) for the treatment of neovascular age-related macular degeneration (nAMD), commonly known as wet AMD.

The approval establishes LYTENAVA™ as the first and only FDA-approved ophthalmic formulation of bevacizumab for the treatment of wet AMD in the United States. For the first time, retina specialists and patients have access to an FDA-approved ophthalmic bevacizumab developed specifically for the eye and supported by rigorous clinical evidence, validated manufacturing, approved labeling, comprehensive quality systems, and ongoing FDA regulatory oversight. Additionally, the Company anticipates that the approval will provide LYTENAVA™ with 12 years of Reference Product Exclusivity under the BPCIA.

Outlook Therapeutics believes this FDA approval establishes a new benchmark for ophthalmic bevacizumab and positions LYTENAVA™ to become the new FDA-approved standard for bevacizumab therapy in patients with wet AMD. Bevacizumab already accounts for the majority of first-line anti-VEGF treatment in wet AMD, underscoring its important role in retina care.[1]

“For more than two decades, bevacizumab has served as one of the most widely utilized anti-VEGF therapies in retina care despite the absence of an FDA-approved ophthalmic formulation. LYTENAVA™ fundamentally changes that landscape. Rather than relying on repackaged formulations originally intended for intravenous use, physicians now have access to a purpose-built ophthalmic formulation of bevacizumab designed specifically for intravitreal administration that delivers the manufacturing consistency, product quality, and regulatory oversight patients deserve.” said Bob Jahr, Chief Executive Officer of Outlook Therapeutics.

Mr. Jahr continued by saying, "Today's approval represents a defining moment for Outlook Therapeutics and, more importantly, for the physicians and patients we have been working to serve. With the approval of LYTENAVA™, physicians now have access to the first FDA-approved ophthalmic bevacizumab developed specifically for the eye. We believe this approval has the potential to meaningfully advance patient care and establish LYTENAVA™ as an important new treatment option for retina specialists and wet AMD patients across the United States."

“The retina community has been waiting a long time for access to an FDA-approved, ophthalmic formulation of bevacizumab to treat patients suffering from wet AMD in the United States,” added Firas M. Rahhal, MD, Chairman of Ophthalmology at Good Samaritan Hospital, Los Angeles, California. “It is exciting news that LYTENAVA™ will soon be an option for patients suffering from this disease.”

Wet AMD is a chronic, progressive retinal disease and one of the leading causes of severe vision loss among older adults worldwide.[2] Patients often require treatment over many years to preserve vision, making manufacturing consistency, product quality, and long-term reliability especially important throughout treatment.

LYTENAVA™ enters one of the world's largest ophthalmology markets. The U.S. anti-VEGF retina market is estimated at approximately $8.5 billion annually, with millions of intravitreal injections administered every year.[2]

The Company is now executing the commercial launch of LYTENAVA™, including expanding reimbursement and patient support access, building an industry-leading, specialized retina commercial organization, supporting physicians nationwide, and establishing LYTENAVA™ as the trusted FDA-approved ophthalmic bevacizumab across the United States.

"FDA approval is the outcome we have been waiting for. Immediate commercial execution is our next mission," added Mr. Jahr. "Everything we do from this point forward is focused on delivering LYTENAVA™ to physicians and patients, expanding access, and building what we believe can become the leading retina care franchise. We are incredibly excited about the opportunity ahead, not only for Outlook Therapeutics, but most importantly for the patients whose vision we strive to protect."

Outlook Therapeutics expects to make LYTENAVA™ available to eligible patients in the United States before year-end. The Company is committed to providing broad patient access support services through comprehensive reimbursement and patient assistance programs designed to help physicians integrate LYTENAVA™ into routine clinical practice for wet AMD.

1. Citeline (2023), Global Data (2023) and Market Scope (2022).
2. National Eye Institute. *Age-Related Macular Degeneration (AMD).* National Institutes of Health.

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 the United States, ONS-5010/LYTENAVA™ (bevacizumab-vikg) is the first 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 for 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 US 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 first 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.

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 potential marketing approvals, Outlook Therapeutics plans to launch ONS-5010/LYTENAVA; 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 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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