

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): **May 31, 2022**

Outlook Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37759
(Commission File Number)

38-3982704
(IRS Employer Identification No.)

**485 Route 1 South
Building F, Suite 320
Iselin, New Jersey**
(Address of principal executive offices)

08830
(Zip Code)

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

(Former name or former address, if changed since last report)

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 May 31, 2022, Outlook Therapeutics, Inc. issued a press release providing an update on its Biologics License Application submission for ONS-5010 as a treatment for wet age-related macular degeneration. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated May 31, 2022.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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: May 31, 2022

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



Outlook Therapeutics Provides Update on Biologics License Application (BLA) Submission for ONS-5010 as a Treatment for Wet AMD

ISELIN, N.J., May 31, 2022 — Outlook Therapeutics, Inc. (Nasdaq: OTLK), a pre-commercial biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced that the U.S. Food and Drug Administration (FDA) has requested additional information in order to complete the filing of the Company's Biologics License Application (BLA) for ONS-5010/ LYTENAVA™ (bevacizumab-vikg) for the treatment of wet age-related macular degeneration (wet AMD). Outlook Therapeutics has voluntarily withdrawn its BLA for ONS-5010 and is actively working to respond to the FDA's request. The Company plans to re-submit a revised BLA by September 2022.

Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics, commented, "We remain confident in ONS-5010 and its potential to be the first FDA-approved ophthalmic formulation of bevacizumab that avoids the public health risk to patients of off-label treatment of bevacizumab that was never approved for any ophthalmic indications. We are continuing to have productive discussions with the FDA and are committed to providing the additional information necessary to support the application. We look forward to a successful resubmission and ultimately the potential approval of ONS-5010 for the treatment of wet AMD. We also look forward to a future where virtually all retina patients treated with bevacizumab are receiving an FDA-approved ophthalmic therapy."

Based on a compilation of the data from its previously completed clinical trials – NORSE ONE, NORSE TWO and NORSE THREE – Outlook Therapeutics submitted the BLA to the FDA in March 2022. NORSE ONE, a proof-of-concept and clinical experience trial, helped validate the protocols and approach for NORSE TWO, the pivotal safety and efficacy trial. The NORSE TWO data were statistically significant and clinically relevant for the primary and all secondary endpoints. NORSE THREE was an open-label supplementary safety trial conducted to ensure that a sufficient number of patients had been dosed with ONS-5010 ophthalmic bevacizumab to support the regulatory submission.

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

ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Because no currently approved ophthalmic formulations of bevacizumab are available, clinicians wishing to treat retinal patients with bevacizumab must use unapproved repackaged IV bevacizumab provided by compounding pharmacies, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 can replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacies for the treatment of wet AMD.

Bevacizumab-vikg 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-vikg 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. VEGF is a protein that promotes the growth of abnormal new blood vessels and promotes leakage from these vessels, leading to retinal edema and hemorrhage. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Since the advent of anti-VEGF therapy, it has become the standard-of-care treatment option within the retina community globally.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a pre-commercial biopharmaceutical company working to develop and launch ONS-5010/ LYTENAVA™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 ophthalmic bevacizumab is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, United Kingdom, Europe, Japan and other markets. For more information, please visit www.outlooktherapeutics.com.

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,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “will,” the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include, among others, statements about ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, our ongoing discussions with the FDA, our ability to provide adequate information to the FDA to support a successful resubmission of the BLA, the timing of a resubmission of the BLA and commercial launch of ONS-5010 and plans for regulatory approvals in other markets. 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 pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, as well as those risks detailed in Outlook Therapeutics' filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the fiscal year ended September 30, 2021 and subsequent Quarterly Reports on Form 10-Q, which include the uncertainty of future impacts related to the ongoing COVID-19 pandemic. 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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