

**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 30, 2023**

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 August 30, 2023, 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.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release dated August 30, 2023.
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: August 30, 2023

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



Outlook Therapeutics® Provides Regulatory Update on FDA Review of ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the Treatment of Wet AMD

FDA issues Complete Response Letter (CRL) for ONS-5010 BLA based on CMC and need for further confirmatory clinical evidence

Outlook Therapeutics working with FDA to address the Agency's issues

Company to host conference call and webcast, today, August 30 at 8:30 AM ET

ISELIN, N.J., August 30, 2023 — (GLOBE NEWSWIRE) Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve FDA approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced the U.S. Food and Drug Administration (FDA) has issued a CRL to the Company's BLA for ONS-5010, an investigational ophthalmic formulation of bevacizumab under development to treat wet AMD. While the FDA acknowledged the NORSE TWO pivotal trial met its safety and efficacy endpoints, the Agency concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence.

"We continue to believe in the public health need to provide the retina community with an FDA-approved bevacizumab treatment option for wet AMD. We will request a formal meeting as soon as possible with the FDA to further understand the BLA deficiencies and how best to resolve them. Following this meeting with the FDA, the Company will be able to discuss next steps and the expected timing for resolution," said Russell Trenary, President and CEO of Outlook Therapeutics.

Julia A. Haller, MD, Ophthalmologist-in-Chief at Wills Eye Hospital and an Outlook Therapeutics Board member, commented, "The retina community needs an FDA-approved ophthalmic bevacizumab to deliver an alternative targeted on-label treatment for patients with wet AMD."

Investor Conference Call and Webcast

Outlook Therapeutics management will host a corporate update conference call and webcast today, August 30, 2023 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 ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Because no FDA-approved ophthalmic formulations of bevacizumab are available currently, clinicians wishing to treat retinal patients with bevacizumab have had to 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 would provide an FDA-approved option for physicians that currently have no choice but to prescribe unapproved repackaged oncologic 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.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company working to achieve FDA approval for the launch of 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. The FDA accepted Outlook Therapeutics' BLA submission for ONS-5010 to treat wet AMD with an initial PDUFA goal date of August 29, 2023; FDA did not approve the BLA during this review cycle and the Company is working with the FDA to address the issues that have been raised so that the BLA may be re-submitted. The submission is supported by Outlook Therapeutics' wet AMD clinical program, which consists of three clinical trials: NORSE ONE, NORSE TWO, and NORSE THREE. 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. As part of the Company's multi-year commercial planning process, Outlook Therapeutics and AmerisourceBergen entered into a strategic commercialization agreement to expand the Company's reach for connecting to retina specialists and their patients. AmerisourceBergen will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance services and other services in the United States. 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,” “believe,” “continue,” “could,” “estimate,” “expect,” “may,” “might,” “intend,” “potential,” “predict,” “should,” or “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, expectations concerning our ability to remediate or otherwise resolve deficiencies identified in the CRL, expectations concerning a formal meeting with the FDA and the outcome thereof, our plans to discuss next steps and timing for resolution of deficiencies identified in the CRL, expectations concerning decisions of regulatory bodies, including the FDA, and the timing thereof, expectations concerning our relationship with AmerisourceBergen and the benefits and potential expansion thereof 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 pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, the content and timing of the expected follow up meeting with the FDA, the content and timing of decisions by the FDA, 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, 2022 as supplemented by the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, in each case as filed with the SEC and future quarterly reports we file with the SEC, which include the uncertainty of future impacts related to macroeconomic factors, including as a result of the ongoing conflict between Russia and Ukraine, high interest rates, 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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