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 17, 2020**

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.)

4260 U.S. Route 1 **Monmouth Junction, New Jersey**	**08852**
(Address of principal executive offices)	(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
Series A Warrants	OTLKW	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 17, 2020, Outlook Therapeutics, Inc. issued a press release providing a clinical update on ONS-5010 / LYTENAVA™ (bevacizumab-vikg). 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 June 17, 2020.

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 17, 2020

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

Exhibit 99.1

Outlook Therapeutics Provides Clinical Update on ONS-5010 / LYTENAVA™
(bevacizumab-vikg)

- **Lead product candidate ONS-5010 / LYTENAVA™ (bevacizumab-vikg) has potential to be first FDA-approved ophthalmic formulation of bevacizumab for use in multiple retinal indications**
- **Topline results from NORSE 1, the Company's first registration clinical trial evaluating ONS-5010 and providing clinical experience and initial safety and efficacy data, are expected in August 2020**
- **NORSE 2 has enrolled 204 of 220 planned patients and is expected to complete enrollment no later than August 2020**
- **NORSE 3 open-label safety study designed to support planned BLA is expected to commence in Q4 2020**

MONMOUTH JUNCTION, N.J., June 17, 2020 — Outlook Therapeutics, Inc. (Nasdaq: OTLK) (the Company), a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today provided a clinical update for ONS-5010 / LYTENAVA™ (bevacizumab-vikg), the Company's investigational ophthalmic formulation of bevacizumab.

Outlook Therapeutics is currently conducting two registration clinical trials for ONS-5010. At an End-of-Phase 2 meeting in April 2018, the U.S. Food and Drug Administration (FDA) accepted the study design / size for the NORSE 1 and NORSE 2 trials and confirmed that each of them is acceptable and may support a new biologics license application (BLA) under the 351(a) regulatory pathway toward approval for the treatment of wet age-related macular degeneration (wet AMD).

"The remainder of 2020 is poised to be an exciting year for Outlook Therapeutics and ONS-5010 as we approach multiple major milestones in the coming quarter," said Lawrence A. Kenyon, President, CEO and CFO of the Company. "The agreed-upon regulatory strategy with the FDA that includes the two registration trials provides us with a streamlined and significantly de-risked pathway towards approval. The first key milestone towards filing our new BLA begins with the topline safety and efficacy results from our NORSE 1 trial, which we expect to report in August, just two months away. This study is expected to provide us with valuable insight as to the safety of ONS-5010 dosed monthly in comparison to the PIER quarterly dosing regimen of ranibizumab. We also will be able to assess the first human efficacy data for ONS-5010 in wet AMD. Although not pivotal data, these study results will help to set the stage for NORSE 2."

The NORSE 1 clinical trial completed enrollment in August 2019 and is on pace to report topline data in August 2020. NORSE 1 enrolled a total of 61 treatment naïve and previously treated patients at nine sites in Australia. NORSE 1 will provide initial safety and efficacy data for ONS-5010 in wet AMD patients for ONS-5010 dosed monthly compared to LUCENTIS® dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing.

“The next key element in our streamlined regulatory pathway for ONS-5010 is our ongoing pivotal clinical trial, NORSE 2, which remains on track to complete enrollment within the next two months, with topline results expected in the third calendar quarter of 2021,” added Mr. Kenyon. “Additionally, we are preparing to initiate the NORSE 3 open-label study, which is meant to ensure enough patients have been exposed to ONS-5010 to meet the requirements for our planned BLA submission next year. We expect to commence NORSE 3 in the fourth calendar quarter of 2020.”

The NORSE 2 clinical trial commenced patient enrollment in July 2019 and is expected to enroll a total of approximately 220 treatment naïve patients at more than 40 clinical trial sites in the United States. NORSE 2 has currently enrolled 204 of the 220 patients. Patients in the trial will be treated for 12 months. The primary outcome of the study at Month 11 is a statistically significant difference in the proportion of patients who gain at least 15 letters in the best corrected visual acuity for ONS-5010 over LUCENTIS®, which is being dosed quarterly per the PIER regimen. The Company expects to report pivotal safety and efficacy data in the third calendar quarter of 2021.

The NORSE 3 open-label safety study will be conducted to ensure the adequate number of safety exposures to ONS-5010 are available for the initial regulatory filings. In total, approximately 180 patients are expected to be enrolled in several different vascular and inflammatory retinal diseases where an anti-VEGF drug can be used as a therapeutic option. Patients in NORSE 3 will receive three doses of ONS-5010 over three months.

In addition to NORSE 1 and NORSE 2 evaluating ONS-5010 for wet AMD, Outlook Therapeutics has received agreements from the FDA on three Special Protocol Assessments (SPAs), for three additional registration clinical trials. These SPAs cover the protocols for NORSE 4, a planned registration clinical trial evaluating ONS-5010 to treat branch retinal vein occlusion or BRVO, and NORSE 5 and NORSE 6, two planned registration clinical trials evaluating ONS-5010 for the treatment of diabetic macular edema, or DME.

“We believe there is a sizeable market opportunity for ONS-5010 which, if approved, will be a cGMP-produced, responsibly priced, on-label ophthalmic formulation of bevacizumab to treat retinal diseases – an option that is not currently available. We are dedicated to bringing ONS-5010 to market as quickly and efficiently as possible so that patients can benefit from the safety and reliability of an FDA-approved product, and we look forward to providing you with additional updates in the coming months,” concluded Mr. Kenyon.

The Company intends to complete development of ONS-5010 for submission to the FDA as a new BLA under the 351(a) PHSA regulatory pathway for the treatment of wet AMD. The Company also has plans to submit for regulatory approvals in France, the United Kingdom, Italy, Germany, Spain and Japan, as well as other countries.

If approved, ONS-5010 will be the first and only on-label ophthalmic formulation of bevacizumab for treating retinal diseases and has the potential to address a $9.1 billion anti-VEGF market.

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

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) 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. ONS-5010 is currently being evaluated in two adequate and well-controlled registration clinical trials for wet AMD (NORSE 1 and NORSE 2) and, if successful, is expected to be submitted to the FDA as a new BLA for this ophthalmic indication. If approved, ONS-5010 will be the first and only FDA-approved ophthalmic formulation of bevacizumab to treat retinal diseases. The Company currently intends to commercialize ONS-5010 in both vials and single-use pre-filled syringes.

ONS-5010 is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (mAb) that inhibits VEGF and associated angiogenic activity. With wet AMD, abnormally high levels of VEGF are secreted in the eye. VEGF is a protein that promotes the growth of new abnormal blood vessels. Anti-VEGF injection therapy blocks this growth. 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 late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 / LYTENAVA™ (bevacizumab vikg), its investigational ophthalmic formulation of bevacizumab, is approved, Outlook Therapeutics expects to commercialize it as the first and only approved ophthalmic formulation of bevacizumab for use in treating approved retinal diseases in the United States, Europe, Japan and other markets. Outlook Therapeutics expects to file ONS-5010 with the U.S. FDA as a new BLA under the PHSA 351(a) regulatory pathway. 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 “may,” “might,” “will,” “should,” “expect,” “plan,” “anticipate,” “project,” “believe,” “estimate,” “predict,” “potential,” “intend” or “continue,” the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include statements about ONS-5010’s potential, the timing of topline results from NORSE 1, expected completion of NORSE 2 enrollment and timing of topline results therefrom, commencement of NORSE 3 safety study and anticipated enrollment, the timing of BLA submission and commercial launch of ONS-5010, the ability of ONS-5010 to provide benefits to patients, payors and physicians, and the benefits of having an FDA approved bevacizumab, and plans for regulatory approvals in other markets. Although the Company believes that it has a reasonable basis for forward-looking statements contained herein, they are based on current expectations about future events affecting the Company 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 the Company’s filings with the Securities and Exchange Commission, 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. The Company 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.

For additional details on the Company's financial performance during the quarter, please see the Company's filings with the Securities and Exchange Commission.

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