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): **April 1, 2019**

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.)

7 Clarke Drive **Cranbury, New Jersey**	**08512**
(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))

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 April 1, 2019, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing the U.S. Food and Drug Administration's acceptance and activation of the investigational new drug application for the Company's lead product candidate, ONS-5010, which press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated April 1, 2019.

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: April 5, 2019

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

Exhibit 99.1

Outlook Therapeutics Announces FDA Acceptance of IND for ONS-5010

Enrollment of U.S. patients in the ONS-5010-002 Phase 3 clinical trial expected to be initiated in calendar Q2 2019

CRANBURY, N.J., April 1, 2019 – Outlook Therapeutics, Inc. (NASDAQ:OTLK) (the "Company") announced today the U.S. Food and Drug Administration (FDA) acceptance and activation of the Investigational New Drug (IND) application for the Company's lead product candidate, ONS-5010, an innovative monoclonal antibody (mAb) therapeutic product candidate being developed for wet age related macular degeneration (wet AMD), diabetic macular edema (DME) and branch retinal vein occlusion (BRVO). The Company is now able to begin enrolling patients with wet AMD in the U.S. portion of its ONS-5010-002 Phase 3 clinical trial.

"We look forward to initiating the enrollment of U.S. patients for our Phase 3 ONS-5010-002 trial now that the FDA has accepted our IND. Patient enrollment for the study is already underway in Australia and New Zealand, which was initiated earlier this month," said Lawrence A. Kenyon, President and Chief Executive Officer. "We remain on track with our plan to submit ONS-5010 for regulatory approval in multiple markets in 2020."

ONS-5010-002 is the second of two adequate and well controlled Phase 3 clinical trials evaluating ONS-5010 against ranibizumab (Lucentis®) for wet AMD and will enroll approximately 180 patients (90 in each arm). Patients enrolled in the ONS-5010-002 study will be treated for 11 months. The primary outcome of the study is a statistically significant improvement in mean visual acuity of five letters or more for ONS-5010 over ranibizumab.

If approved by regulators, ONS-5010 has the potential to mitigate the risks associated with off-label use of Avastin® or other drugs. Off label use of Avastin® is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States.

About ONS-5010
ONS-5010 is a proprietary ophthalmic formulation of bevacizumab to be administered as an intravitreal injection for the treatment of wet AMD and other retina diseases. Bevacizumab is a full length humanized anti-VEGF (Vascular Endothelial Growth Factor) antibody that inhibits VEGF and associated angiogenic activity. The Company's proprietary ophthalmic bevacizumab product candidate is an anti-VEGF recombinant humanized monoclonal antibody (or mAb) formulated as a single use vial for IVT injection. By inhibiting the VEGF receptor from binding, bevacizumab prevents the growth and maintenance of tumor blood vessels.

About Outlook Therapeutics, Inc.
Outlook Therapeutics is a clinical-stage biopharmaceutical company focused on developing its lead clinical program, ONS-5010, a proprietary ophthalmic bevacizumab product candidate for the treatment of wet age related macular degeneration (wet AMD) and other retina diseases. ONS-5010 is currently in Phase 3 clinical trials outside the United States for patients suffering from wet AMD. 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 the Company’s plans for regulatory approval of ONS-5010, its ongoing Phase 3 clinical trials for ONS-5010, including enrollment in such trials and the outcome of such clinical trials, as well as the ability of ONS-5010 to mitigate off-label use of Avastin® or other drugs if approved. 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. 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.

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