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 14, 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.)

7 Clarke Drive **Cranbury, New Jersey**	**08512**
(Address of principal executive offices)	(Zip Code)

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

N/A
(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 Information

On April 14, 2020, Outlook Therapeutics, Inc. (the "Company") issued a press release providing an update on the COVID-19 Impact on its ongoing NORSE 1 and NORSE 2 clinical trials. The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Also, in light of the rapidly evolving COVID-19 pandemic and recent notification from Nasdaq, the Company is also filing this Current Report on Form 8-K for the purpose of supplementing the risk factors disclosed in Item 1A of its Annual Report on Form 10-K for the fiscal year ended September 30, 2019. Accordingly, the Company's risk factor disclosure is hereby updated as follows:

Our business could be adversely affected by the effects of health pandemics or epidemics, including the recent outbreak of COVID-19, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations, including at our headquarters in New Jersey, which is currently subject to a state executive order mandating shelter-in-place, and at our clinical trial sites, as well as the business or operations of our manufacturers, CROs or other third parties with whom we conduct business.

Our business could be adversely affected by the effects of health pandemics or epidemics, including the recent outbreak of COVID-19, which was declared by the World Health Organization as a global pandemic, and is resulting in travel and other restrictions to reduce the spread of the disease, including a New Jersey executive order, and several other state and local orders across the country, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. As a result of these recent developments, we have implemented work-from-home policies for all our employees. The effects of these orders, government-imposed quarantines and our work-from-home policies may negatively impact productivity, disrupt our business and could delay our ONS-5010 clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which could disrupt our supply chain.

In addition, our ongoing clinical trials are being affected by the recent COVID-19 outbreak. Patient enrollment and recruitment is delayed due to local clinical trial site protocols designed to protect staff and patients from COVID-19 infection, and some patients may not be able to comply with clinical trial protocols if quarantines or other restrictions impede patient movement or interrupt healthcare services. Similarly, our ability to retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be disrupted, which would adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic, may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the recent COVID-19 outbreak or a similar health pandemic or epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Our common stock may be delisted from Nasdaq and begin trading in the over-the-counter markets if we are not successful in regaining compliance with Nasdaq's continued listing standards, which may negatively impact the price of our common stock and our ability to access the capital markets.

On March 27, 2020, we received written notification from The Nasdaq Stock Market LLC, or Nasdaq, indicating that as of March 27, 2020, we were not in compliance with Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market, as the minimum bid price of our listed securities was less than $1.00 per share for the previous 30 consecutive business days. Under Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days (plus such additional time as may be accorded under temporary relief from Nasdaq), or until September 23, 2020, to regain compliance with the rule (without taking into account any additional time as a result of temporary relief from Nasdaq in light of COVID-19). To regain compliance, during this 180-day compliance period (plus such additional time as may be accorded under temporary relief from Nasdaq), the minimum bid price of our listed securities must close at $1.00 per share or more for a minimum of 10 consecutive business days. If we are unable to regain compliance during the 180-day period (plus such additional time as may be accorded under temporary relief from Nasdaq), we anticipate that we will receive a delisting determination from Nasdaq, following which we anticipate requesting a hearing to remain on The Nasdaq Capital Market. If granted, such request will ordinarily suspend such delisting determination until a decision by Nasdaq subsequent to the hearing. We intend to actively monitor the minimum bid price of our listed securities and, as appropriate, will consider available options to resolve the deficiencies and regain compliance with the Nasdaq Listing Rules, including effecting a reverse stock split.

If we are not successful in regaining compliance, we anticipate that our common stock would begin trading on the over-the-counter market. Delisting from Nasdaq and trading on the over-the-counter market could adversely affect the liquidity of our common stock. Stocks traded on the over-the-counter market generally have limited trading volume and exhibit a wider spread between the bid/ask quotation, as compared to securities listed on a national securities exchange. Consequently, you may not be able to liquidate your investment in the event of an emergency or for any other reason.

If our common stock is delisted from the Nasdaq, we could face significant material adverse consequences, including:

- A limited availability of market quotations for our common stock;
- A reduced amount of news and analyst coverage for our company;
- A decreased ability to issue additional securities or obtain additional financing in the future;
- Reduced liquidity for our stockholders;
- Potential loss of confidence by partners and employees; and
- Loss of institutional investor interest and fewer business development opportunities.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated April 14, 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: April 17, 2020

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

Exhibit 99.1

Outlook Therapeutics Provides COVID-19 Impact Update on Ongoing Clinical Trials NORSE 1 and NORSE 2

- **Company reports no anticipated COVID-19 impact on NORSE 1, its first registration clinical trial evaluating ONS-5010, an investigational ophthalmic formulation of bevacizumab, to treat wet AMD**

- **Risk mitigation strategies being developed for possible one- to three-month delay related to COVID-19 for NORSE 2, the Company's second registration clinical trial for ONS-5010 to treat wet AMD, depending on local emergency conditions**

CRANBURY, N.J., April 14, 2020 (GLOBE NEWSWIRE) — 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 on the impact of the COVID-19 pandemic on the status of NORSE 1 and NORSE 2, its ongoing registration clinical trials for ONS-5010 / LYTENAVA™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab.

All clinical and chemistry, manufacturing and control (CMC) activities are currently active for both NORSE 1 and NORSE 2, registration clinical trials evaluating ONS-5010 for treatment of wet age-related macular degeneration (wet AMD). The Company has confirmed with the Ophthalmic Division of the U.S. Food and Drug Administration (FDA) that it considers both approved and investigational treatments for sight-threatening conditions such as wet AMD not to be elective, and that as such they should continue during the COVID-19 restrictions.

NORSE 1 completed enrollment in August 2019 and is on pace to meet its schedule as expected. The Company anticipates reporting data during the third calendar quarter of 2020. At this time, COVID-19 is not expected to affect the completion of NORSE 1 and anticipated data readout date.

NORSE 2, which commenced enrollment in July 2019 and is being conducted in the United States, continues to screen, enroll and treat patients, subject to additional COVID-19 safety protocols for both patients and staff at trial sites. Due to these additional safety protocols, some sites have temporarily shut down and patient enrollment has slowed. Outlook estimates that final enrollment could be delayed by one to three months, depending on local conditions, which have varying degrees of "shelter-in-place" and other type of executive orders mandating various restrictions.

"In these unprecedented times across the globe, the safety of the patients and medical staff engaged in our NORSE 1 and NORSE 2 clinical trials is our top priority. We are fortunate enough not to expect any delay in our NORSE 1 clinical trial and anticipate reporting data from the study in August of this year, as planned. We want to share our deepest appreciation to all medical staff and patients for their ongoing participation in this important clinical work," said Lawrence A. Kenyon, President, CEO and CFO, Outlook Therapeutics. "While the full impact of COVID-19 remains uncertain, we are confident that the statistical analysis plans we have built into the NORSE 2 clinical trial will mitigate potential missed visits and the slower pace of enrollment we are currently experiencing. Our team remains dedicated to advancing the program efficiently while minimizing delays as much as possible."

About ONS-5010 / LYTENAVA™

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 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 approved 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 (or 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 age-related macular degeneration (wet AMD), diabetic macular edema (DME) and branch retinal vein occlusion (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. 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 its plans for filing a BLA for ONS-5010 / LYTENAVA™ (bevacizumab-vikg), its commercialization plans for ONS-5010, expected data read-out dates for NORSE 1, and the impact of the COVID-19 pandemic on its ongoing ONS-5010 clinical trials. 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, the uncertainty regarding the COVID-19 pandemic and its duration, 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.

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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