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): **September 30, 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 September 30, 2020, Outlook Therapeutics, Inc. issued a press release announcing certain business updates. 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 September 30, 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: September 30, 2020

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

Exhibit 99.1

Outlook Therapeutics Provides Update on Progress Towards First Approved Ophthalmic Formulation of Bevacizumab-vikg for Advanced Macular Degeneration

MONMOUTH JUNCTION, N.J., September 30, 2020 — Outlook Therapeutics, Inc. (Nasdaq: OTLK) is a late clinical-stage biopharmaceutical company developing the first FDA-approved ophthalmic formulation of bevacizumab-vikg (LYTENAVA™) for use in retinal indications (known as ONS-5010). Outlook Therapeutics is advancing on multiple fronts, including: progress on its Phase 3 clinical program, manufacturing and regulatory activities, and global strategic partnering negotiations, all leading to the planned commercial launch of ONS-5010 anticipated in 2022. In addition, Outlook Therapeutics recently completed a strategic partnership for commercialization in Greater China and is in discussions with other strategic partners for commercial launches in the United States, Asia and Europe.

Clinical Progress Drives ONS-5010 Towards U.S. and EU Filings in 2021
Outlook Therapeutics has already demonstrated both safety and efficacy through a recently reported clinical experience trial and, separately, has also completed enrollment of 227 patients in its U.S.-based Phase 3 pivotal trial. The clinical experience trial gives Outlook Therapeutics a high level of confidence in the outcome of the ongoing fully-enrolled pivotal trial. Pivotal data are expected mid-2021 followed by submission of a U.S. Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). If the BLA is approved, it will result in 12 years of marketing exclusivity. Outlook Therapeutics is on track for both U.S. BLA filing and EU Marketing Authorization Application (MAA) filings in 2021.

ONS-5010 Addresses Significant Unmet Medical Need
Although unapproved repackaged IV Avastin® from compounding pharmacists is widely used by retinal specialists, extensive marketing research has indicated that there is a significant unmet medical need for an approved ophthalmic formulation of bevacizumab that removes both the product liability and safety concerns of a repackaged product. Once approved, Outlook Therapeutics' ONS-5010 will reduce the need for use of unapproved repackaged IV Avastin® from compounding pharmacists. Upon approval, ONS-5010 will be the first ophthalmic formulation of bevacizumab-vikg approved as an anti-VEGF therapy addressing vision loss from wet age-related macular degeneration (wet AMD). Outlook Therapeutics also intends to seek approval of ONS-5010 for other approved indications, including branch retinal vein occlusion (BRVO) and diabetic macular degeneration (DME).

Commercial Planning Activities Underway
Commercial launch planning has begun, including distribution, physician and patient outreach, key opinion leader support and payor community engagement. With an enhanced safety and cost-effective profile, Outlook Therapeutics expects ONS-5010 to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated "step edit" in the United States for retinal indications.

Extensive market research indicates that ONS-5010, if approved, will be a significant therapy in the retinal anti-VEGF market, currently estimated to be in excess of $13 billion worldwide.

Manufacturing and Regulatory Progress Towards Commercialization
Outlook Therapeutics is working with FujiFilm Diosynth Biotechnologies (Fuji) and Ajinomoto Bio-pharma Services (AjiBio) to provide product manufacturing in best-in-class cGMP global manufacturing facilities. The Outlook Therapeutics strategy also provides greater safety confidence to both clinicians and patients by reducing the current practice of using compounding facilities, which have raised concerns about product quality that impact patient safety. Outlook Therapeutics has completed technology transfer and scale-up consistent with global cGMP standards with both Fuji and AjiBio.

Outlook Therapeutics also has executed a supply agreement for a best-in-class pre-filled ophthalmic syringe that will provide both ease-of-use for clinicians and add to ONS-5010's safety profile over the current unapproved therapies that have caused problems related to syringe malfunction, contamination, etc.

On the regulatory front, Outlook Therapeutics has tentatively been granted an ATC code for ophthalmic bevacizumab by the World Health Organization. Also, SME Entity Status has been granted by the EMA.

Discussions with Potential Strategic Partners Progressing
The above accomplishments and the potential of ONS-5010 have captured the attention of potential strategic partners. Outlook Therapeutics is engaged with several life sciences companies that could result in a strategic partnership and definitive agreement for ONS-5010 as soon as the end of 2020. Recently, Outlook Therapeutics announced a joint venture with Syntone Technologies for commercializing ONS-5010 in Greater China. Syntone Technologies also made a substantial equity investment in Outlook Therapeutics. Outlook Therapeutics anticipates similar interest from biologic commercial partners in other countries.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a late clinical-stage biopharmaceutical company working to develop ONS-5010 / LYTENAVA™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg for use in treating retinal diseases in the United States, United Kingdom, 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 the timing of commercial launch of ONS-5010, the timing of completion of, and safety and efficacy data from, the Phase 3 pivotal trial, the timing of BLA and MAA submission for ONS-5010, ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab, including benefits therefrom to patients, payors and physicians, the timing of entry into a strategic partnership and definitive agreement with a global ophthalmic company, including its ability to do so, plans for regulatory approvals in other markets, and interest from OUS commercial partners. 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, and risks of negotiating strategic partnership agreements, as well as those risks detailed in Outlook Therapeutics' 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. 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. For additional details on Outlook Therapeutics' financial performance during the quarter, please see the Outlook Therapeutics filings with the Securities and Exchange Commission.

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