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 13, 2021**

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.)

485 Route 1 South **Building F, Suit 320** **Iselin, New Jersey**	**08830**
(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 2.02 Results of Operations and Financial Condition

On August 13, 2021, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its third fiscal quarter ended June 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 2.02 and in the accompanying Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press Release dated August 13, 2021.

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 13, 2021

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

Exhibit 99.1

Outlook Therapeutics Reports Financial Results for Third Quarter of Fiscal Year 2021 and Provides Corporate Update

- **Reported positive, statistically significant top-line efficacy and safety data from pivotal Phase 3 NORSE TWO trial of ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the treatment of wet age-related macular degeneration (wet AMD)**

- **On track to submit new U.S. BLA for ONS-5010 in the first quarter of calendar 2022 and pre-commercial launch planning underway**

ISELIN, N.J., August 13, 2021 — Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced recent corporate highlights and financial results for its fiscal third quarter ended June 30, 2021.

Outlook Therapeutics also provided a clinical development and pre-commercialization update on ONS-5010 / LYTENAVA™ (bevacizumab-vikg), its investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD) and other retinal indications.

Recent Corporate Highlights

- Announced positive top-line results from pivotal Phase 3 NORSE TWO safety and efficacy trial evaluating ONS-5010 for treatment of wet AMD; and
- Appointed C. Russell Trenary III as President, Chief Executive Officer and a member of the Board of Directors. Mr. Trenary brings over 35 years of experience in the life sciences industry, specifically in medical ophthalmic implant sales, marketing, and business development. Over the course of his career, he has led four major product launches in eye care medical devices. Additionally, Mr. Trenary has played a key role in seven acquisitions including, most recently, the sale of InnFocus, Inc. to Santen.

“The past quarter for Outlook Therapeutics has been truly transformative for the company. With all three of our registration clinical trials now completed, including our NORSE TWO pivotal trial, we possess positive, statistically significant results to support our plans to submit a BLA for ONS-5010 in the first calendar quarter of 2022. I believe there is a tremendous amount of opportunity ahead for Outlook Therapeutics and, since I joined as CEO at the beginning of July, the dedication of this team, and the potential of ONS-5010, have continued to reinforce my confidence in our position as an up-and-coming leader in the retina space. We are dedicated to building momentum, shareholder value, and ultimately potentially bringing the first FDA-approved ophthalmic formulation of bevacizumab to the retina community,” commented Mr. C. Russell Trenary III, President and Chief Executive Officer of Outlook Therapeutics.

ONS-5010 (bevacizumab) Clinical Program Overview

Outlook Therapeutics' wet AMD ONS-5010 clinical program for the planned BLA submission consists of three clinical trials, NORSE ONE, NORSE TWO, and NORSE THREE, all of which have now been completed. Most recently, Outlook Therapeutics reported positive topline data from its NORSE TWO pivotal Phase 3 clinical trial. The topline data from NORSE TWO demonstrated that ONS-5010 is safe and met the primary and key secondary endpoints for efficacy. In NORSE TWO, ONS-5010 achieved statistically significant and clinically relevant primary ($p = 0.0052$) and key secondary ($p = 0.0043$) efficacy endpoints with 41% of subjects gaining at least 15 letters of BVCA. ONS-5010 was also found to be safe and well tolerated in the NORSE TWO trial.

With the registration clinical trials now completed, Outlook Therapeutics plans to submit a BLA under the Public Health Service Act (PHSA) 351(a) regulatory pathway in the first quarter of calendar 2022. If the BLA is approved, it is expected to result in 12 years of marketing exclusivity for ONS-5010 as the first and only ophthalmic formulation of bevacizumab approved by the FDA to treat wet AMD.

"We couldn't be more pleased with the results from our pivotal study, and now with this added confidence in the potential of ONS-5010 backed by data, we are continuing our shift towards commercialization. The retinal anti-VEGF market represents a significant opportunity, currently estimated to be in excess of $13.1 billion worldwide, and growing annually. We are stepping into a space in need of an FDA-approved ophthalmic formulation of bevacizumab, the most frequently used treatment for wet AMD in the United States. If approved, we believe ONS-5010 would bring added assurance to physicians, patients, and payors in the retina community with a treatment for wet AMD that meets the FDA's standards and potentially eliminates issues seen with unapproved repackaged IV bevacizumab. Additionally, we believe there is opportunity beyond wet AMD and we look forward to continuing to evaluate and work towards those market expansion opportunities," added Mr. Trenary.

Pre-commercialization Planning Underway

In anticipation of potential FDA marketing approval in 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning activities, including manufacturing with drug substance manufacturer FUJIFILM Diosynth Biotechnologies and best-in-class drug product manufacturer Aji Biopharma Services, along with distribution, sales force planning, physician and payor advisory board outreach, key opinion leader support and payor community engagement. To bring ONS-5010 to market in a way that benefits all stakeholders – clinicians, patients and payors – Outlook Therapeutics has already commenced collaborative discussions with payors and the retina community. Outlook Therapeutics expects ONS-5010, if approved, to be a safe and cost-effective choice for patients, payors and clinicians worldwide for retinal indications.

Outlook Therapeutics is also developing registration documents on a parallel path for approvals in Europe and expects to submit them shortly after completing the submission to the FDA in the United States. Outlook Therapeutics continues to explore potential strategic commercialization partners, such as the existing Syntone Biopharma joint venture in China.

In addition to the clinical development program 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 a planned registration clinical trial evaluating ONS-5010 to treat branch retinal vein occlusion (BRVO, NORSE FOUR), and two planned registration clinical trials evaluating the drug candidate for the treatment of diabetic macular edema (DME, NORSE FIVE and NORSE SIX).

Financial Highlights for the Fiscal Third Quarter Ended June 30, 2021

For the fiscal third quarter ended June 30, 2021, Outlook Therapeutics reported a net loss attributable to common stockholders of $12.2 million, or $0.07 per basic and diluted share, compared to a net loss attributable to common stockholders of $3.0 million, or $0.03 per basic and diluted share, for the same period last year.

At June 30, 2021, Outlook Therapeutics had cash and cash equivalents of $19.7 million. Outlook Therapeutics' cash and cash equivalents on hand are sufficient to fund planned operations through December 2021.

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

ONS-5010 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. Because no currently approved ophthalmic formulations of bevacizumab are available, clinicians wishing to treat retinal patients with bevacizumab have had to use unapproved repackaged IV bevacizumab provided by compounding pharmacists, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 will replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacists for the treatment of wet AMD.

ONS-5010 is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (mAb) that inhibits VEGF and associated angiogenic activity. VEGF is a protein that promotes the growth of abnormal new blood vessels and promotes leakage from these vessels leading to retinal edema and hemorrhage. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Anti-VEGF injection therapy treats the vision-threatening leakage and hemorrhage as well as blocks the growth of the abnormal blood vessels. 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 biopharmaceutical company working to develop and launch 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. 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. Outlook Therapeutics expects to submit ONS-5010 ophthalmic bevacizumab to the U.S. FDA as a 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, among others, statements about ONS-5010’s potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, including benefits therefrom to patients, payors and physicians, including expectations of market exclusivity, the timing of BLA submission and commercial launch of ONS-5010, plans for regulatory approvals in other markets, and plans for future clinical trials. 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, as well as those risks detailed in Outlook Therapeutics’ filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the fiscal year ended September 30, 2020, as amended, and subsequent Quarterly Reports on Form 10-Q, 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.

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Outlook Therapeutics, Inc.
Consolidated Statements of Operations
(Amounts in thousands, except share data)

	Three months ended June 30,		Nine months ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 8,546	$ 8,488	$ 29,023	$ 18,719
General and administrative	2,930	3,287	9,268	7,581
Impairment of property and equipment	-	104	-	528
	11,476	11,879	38,291	26,828
Loss from operations	(11,476)	(11,879)	(38,291)	(26,828)
Loss on equity method investment	435	-	435	-
Interest expense, net	257	443	667	1,737
(Gain) loss on extinguishment of debt	-	(6,164)	-	1,896
Change in fair value of redemption feature	-	-	-	(1,797)
Change in fair value of warrant liability	29	128	364	(75)
Loss before income taxes	(12,197)	(6,286)	(39,757)	(28,589)
Income tax expense benefit	-	(3,271)	2	(3,271)
Net loss	(12,197)	(3,015)	(39,759)	(25,318)
Series A-1 convertible preferred stock dividends and related settlement	-	-	-	(166)
Deemed dividend upon modification of warrants	-	-	-	(3,140)
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	-	-	-	(10,328)
Net loss attributable to common stockholders	$ (12,197)	$ (3,015)	$ (39,759)	$ (38,952)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.07)	$ (0.03)	$ (0.27)	$ (0.69)
Weighted average shares outstanding, basic and diluted	168,421	90,758	146,861	56,089

Consolidated Balance Sheet Data
(Amounts in thousands)

	June 30, 2021	**September 30, 2020**
Cash	$ 19,692	$ 12,536
Total assets	$ 32,882	$ 19,733
Current liabilities	$ 19,639	$ 15,889
Total stockholders' equity	$ 12,749	$ 2,826