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): **May 13, 2022**

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, Suite 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

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 May 13, 2022, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its second fiscal quarter ended March 31, 2022. 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 May 13, 2022.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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: May 13, 2022

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

Exhibit 99.1

Outlook Therapeutics Reports Financial Results for Second Quarter Fiscal Year 2022 and Provides Corporate Update

- **ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Biologics License Application (BLA) submitted to U.S. Food and Drug Administration (FDA); PDUFA date expected to be announced in June 2022**
- **Advancing ONS-5010 toward potential marketing approval in early 2023**
- **U.S. pre-launch commercial planning continues to ramp up**
- **Operations supported by access to funding expected to be sufficient to launch LYTENAVA, if approved**

ISELIN, N.J., May 13, 2022 — Outlook Therapeutics, Inc. (Nasdaq: OTLK), a pre-commercial 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 second quarter ended March 31, 2022.

Recent Corporate Highlights

- Successfully submitted a BLA for ONS-5010, an investigational therapy which, if approved, will be branded as LYTENAVA™ (bevacizumab-vikg), for the treatment of wet age-related macular degeneration (wet AMD);
- Expanded commercial team with the appointment of Joel Prieve as Senior Vice President, Commercial Operations, in February 2022; and
- Further expanded commercial team with appointment of Alicia Tozier as Senior Vice President, Marketing and Market Access, in March 2022.

“This past quarter was marked by the achievement of the most important milestone to date for Outlook Therapeutics – the submission of our BLA for ONS-5010. In anticipation of potentially providing an on-label, FDA-approved alternative for wet AMD patients in the United States, we are ramping up our pre-commercial launch activities. To support these efforts, we have continued to add to the expertise of our commercial team to build momentum among partners, payors and the retina community. We are focused on positioning ourselves to unlock the full potential of ONS-5010,” commented C. Russell Trenary III, President and Chief Executive Officer of Outlook Therapeutics.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Development Updates

Outlook Therapeutics’ wet AMD clinical program for ONS-5010 consists of three completed clinical trials, NORSE ONE, NORSE TWO, and NORSE THREE. With the successful completion of these clinical trials, Outlook Therapeutics submitted its BLA under the Public Health Service Act (PHSA) 351(a) regulatory pathway in March 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.

As previously announced, if ONS-5010 receives FDA approval, Outlook Therapeutics plans to submit a supplementary application (sBLA) for approval to provide the product in a pre-filled, silicone oil-liquid free syringe that meets the FDA's strict specifications for ophthalmic use. To support the anticipated submission of this sBLA, Outlook Therapeutics is conducting its NORSE SEVEN clinical trial to compare the safety of ONS-5010 in vials versus pre-filled syringes. NORSE SEVEN is expected to enroll approximately 120 subjects with visual impairment due to retinal disorders. Patients will be treated for three months and the enrollment of patients in the arm of the study receiving ONS-5010 in vials has already been completed.

Pre-Launch Commercial Planning Underway

According to the National Eye Institute (NEI), use of unapproved repackaged IV bevacizumab from compounding pharmacies is estimated to account for at least 50% of all wet AMD injections in the United States each year. Globally, the nine major markets account for an estimated $13.1 billion market for anti-VEGF drugs to treat retina diseases.

In anticipation of potential FDA marketing approval in early 2023, Outlook Therapeutics has begun commercial launch planning, including best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance, and with drug product manufacturer Aji Biopharma Services for finished drug product. The Company also is actively building out its distribution and commercial team structures.

To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians and payors – Outlook Therapeutics has been in collaborative discussions with payors and the retina community. Outlook Therapeutics is also developing registration documents on a parallel path for approvals in Europe and expects to submit them in the fourth quarter of calendar 2022. Outlook Therapeutics continues to explore potential strategic commercialization partners, such as the current partnership with Syntone Biopharma JV in China. Outlook Therapeutics expects ONS-5010, if approved, to be a safe and cost-effective choice for patients, clinicians, and payors worldwide for retinal indications.

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.

Upcoming Anticipated Milestones

- Receive PDUFA date from FDA;
- Continued progress with ongoing pre-launch commercial preparations in anticipation of potential approval for ONS-5010 in early 2023; and
- Completion in calendar 2022 of the NORSE SEVEN study evaluating Outlook Therapeutics' vial delivery system versus a pre-filled syringe of ONS-5010.

Financial Highlights for the Fiscal Second Quarter Ended March 31, 2022

For the fiscal second quarter ended March 31, 2022, Outlook Therapeutics reported a net loss attributable to common stockholders of $19.7 million, or $0.09 per basic and diluted share, compared to a net loss attributable to common stockholders of $13.1 million, or $0.09 per basic and diluted share, for the same period last year.

At March 31, 2022, Outlook Therapeutics had cash and cash equivalents of $58.4 million, compared to $70.2 million at December 31, 2021. Outlook Therapeutics' cash and cash equivalents on hand are expected to provide funding into the first calendar quarter of 2023.

"We believe Outlook Therapeutics is in a strong financial position," stated Lawrence A. Kenyon, Chief Financial Officer of Outlook Therapeutics. "We have successfully accessed capital via our ATM program and plan to continue using this financing option, subject to market conditions. Also, we have initiated discussions with the holders of our unsecured notes to extend the maturity of these notes until 2024 after we begin generating revenue from LYTENAVA, if approved. With these steps, we believe we have charted a path that would allow Outlook Therapeutics to launch LYTENAVA without the need to raise significant additional capital."

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 pharmacies, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 can replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacies for the treatment of wet AMD.

Bevacizumab-vikg is a recombinant humanized monoclonal antibody (mAb) that selectively binds with high affinity to all isoforms of human vascular endothelial growth factor (VEGF) and neutralizes VEGF's biologic activity through a steric blocking of the binding of VEGF to its receptors Flt-1 (VEGFR-1) and KDR (VEGFR-2) on the surface of endothelial cells. Following intravitreal injection, the binding of bevacizumab-vikg to VEGF prevents the interaction of VEGF with its receptors on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation in the retina.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a pre-commercial biopharmaceutical company working to develop and launch ONS-5010/ LYTENAVA™ (bevacizumab-vikg), an investigational therapy, as the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. Outlook Therapeutics has submitted its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ONS-5010 to treat wet AMD. The submission is supported by Outlook Therapeutics' wet AMD registration clinical program, which consists of three clinical trials: NORSE ONE, NORSE TWO, and NORSE THREE. 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. 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 "anticipate," "believe," "continue," "could," "estimate," "expect," "may," "might," "intend," "potential," "predict," should," or "will," 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, potential approval and commercial launch of ONS-5010 and the timing thereof, including the expectation of timing for a PDUFA date, expectations about the sufficiency of our capital to fund our operations through commercial launch, our ability to extend the maturity date of our unsecured notes, potential financing sources, plans for and the timing of potential future clinical trials, including the expected completion of NORSE SEVEN and the expected commencement of NORSE FOUR, NORSE FIVE and NORSE SIX, potential strategic partners, plans for regulatory approvals and commercialization of ONS-5010 in other markets and other statements that are not historical fact. 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 (the "SEC"), including the Annual Report on Form 10-K for the fiscal year ended September 30, 2021 filed with the SEC, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 and future quarterly reports we file with the SEC, 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.

CONTACTS:

Media Inquiries:
Harriet Ullman
Vice President
LaVoie Health Science
T: 617-669-3082
hullman@lavoiehealthscience.com

Investor Inquiries:
Jenene Thomas
Chief Executive Officer
JTC Team, LLC
T: 833.475.8247
OTLK@jtcir.com

# # #

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

	Three months ended March 31,		Six months ended March 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 12,220	$ 8,529	$ 22,092	$ 20,478
General and administrative	6,690	4,096	9,967	6,338
	18,910	12,625	32,059	26,816
Loss from operations	(18,910)	(12,625)	(32,059)	(26,816)
Loss on equity method investment	6	-	30	-
Interest expense, net	418	251	770	410
Loss on extinguishment of debt	-	-	1,026	-
Change in fair value of convertible promissory note	344	-	506	-
Change in fair value of warrant liability	25	229	(225)	334
Loss before income taxes	(19,703)	(13,105)	(34,166)	(27,560)
Income tax expense (benefit)	2	2	2	2
Net loss attributable to common stockholders	$ (19,705)	$ (13,107)	$ (34,168)	$ (27,562)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.09)	$ (0.09)	$ (0.17)	$ (0.20)
Weighted average shares outstanding, basic and diluted	219,068	150,730	203,443	136,081

Consolidated Balance Sheet Data
(Amounts in thousands)

	March 31, 2022	September 30, 2021
Cash and cash equivalents	$ 58,424	$ 14,477
Total assets	$ 67,686	$ 22,811
Current liabilities	$ 31,411	$ 6,752
Total stockholders' equity	$ 35,963	$ 4,607