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): **February 14, 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, 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 February 14, 2022, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its first fiscal quarter ended December 31, 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 February 14, 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: February 14, 2022

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

Exhibit 99.1

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

- **Outlook Therapeutics remains on track to submit new U.S. FDA Biologics License Application (BLA) for first ophthalmic formulation of bevacizumab**

- **Commercial launch planning underway**

- **Financed through the anticipated approval of the ONS-5010 BLA**

ISELIN, N.J., February 14, 2022 — 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 first quarter ended December 31, 2021.

Recent Corporate Highlights

- Expanded commercial team with appointment of SVP, Commercial Operations;
- Closed a $57.5 million gross proceeds equity offering, including full exercise of underwriter's option to purchase additional shares;
- Presented data at scientific conferences including the Retina Subspecialty Day, American Academy of Ophthalmology (AAO) 2021 Annual Conference, the Eyecelerator@AAO 2021 Conference Retina Showcases, the 2021 American Society of Retina Specialists (ASRS) Annual Meeting, the Ophthalmology Innovation Summit (OIS) Retina Innovation Showcase, the EURETINA Virtual 2021 Medical Conference, the Asia-Pacific Vitreo-Retina Society (APVRS) Congress and the International Congress on OCT and OCT Angiography in Rome (ICOOR/ FLORetina) Symposia; and
- Reported positive 12-month safety data from pivotal Phase 3 NORSE TWO trial, which reinforce strong safety profile consistent with previous trials of ONS-5010 ophthalmic bevacizumab and with prior published data on ophthalmic use of bevacizumab.

"We continue to build on the solid foundation laid over the course of the past year to position Outlook Therapeutics for a transformational year ahead. With the targeted submission of our BLA just around the corner, we are ramping up our commercial launch planning and expertise as we look to optimize the benefit and potential positive impact ONS-5010 which, if approved, will provide to the retina community a differentiated anti-VEGF offering. Additionally, with a strong balance sheet coupled with the encouraging data amassed for our BLA submission, we look forward to driving this exciting opportunity forward," commented Mr. 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 for the planned BLA submission consists of three clinical trials, NORSE ONE, NORSE TWO, and NORSE THREE, all of which have been completed. In early August, Outlook Therapeutics reported positive top-line data from its NORSE TWO pivotal Phase 3 clinical trial. In NORSE TWO, ONS-5010 achieved statistically significant and clinically relevant primary endpoint results with 41.7% of subjects gaining at least 15 letters of best corrected visual acuity (BCVA). Additionally, key secondary endpoint results were achieved including an average gain of 11.2 letters of BCVA from baseline to month 11. In November 2021, these positive results were also reported at the Retina Subspecialty Day at the AAO 2021 Annual Conference, together with the remaining secondary endpoints, with 56.5% of ONS-5010 subjects gaining ≥ 10 letters of vision and 68.5% of ONS-5010 subjects gaining ≥ 5 letters of vision. ONS-5010 was also found to be safe and well tolerated in the NORSE TWO trial.

With the registration clinical trials completed, Outlook Therapeutics plans to submit a new BLA under the Public Health Service Act (PHSA) 351(a) regulatory pathway in the first quarter of calendar 2022. If the BLA is approved as planned in the first quarter of calendar 2023, 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 file a supplementary application for approval to provide the product in a pre-filled, silicone oil-free syringe that meets the FDA's strict specifications for ophthalmic use. In anticipation of potential approval, 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 been completed.

Pre-Commercialization Planning Underway

Per 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 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning, including a partnership with FUJIFILM Diosynth Biotechnologies for our drug substance and best-in-class drug product manufacturer Aji Biopharma Services for our drug product, plus 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 – patients, clinicians and payors – Outlook Therapeutics is 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 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. Outlook Therapeutics currently expects to initiate registration clinical trials for ONS-5010 for DME and BRVO in 2023 if FDA approval is received for the wet AMD indication.

Upcoming Milestones

- Planned submission of new BLA to the FDA in the first calendar quarter of 2022;
- Ongoing pre-launch commercial planning underway in anticipation of potential approval for ONS-5010 within the next 12 months;
- Completion of the NORSE SEVEN study evaluating Outlook Therapeutics' vial delivery system versus a pre-filled syringe of ONS-5010 in calendar 2022; and
- Continued preparation for NORSE FOUR (BRVO) and NORSE FIVE and NORSE SIX (DME) evaluating ONS-5010 for additional ophthalmic indications in calendar 2023.

Financial Highlights for the Fiscal First Quarter Ended December 31, 2021

For the fiscal first quarter ended December 31, 2021, Outlook Therapeutics reported a net loss attributable to common stockholders of $14.5 million, or $0.08 per basic and diluted share, compared to a net loss attributable to common stockholders of $14.5 million, or $0.12 per basic and diluted share, for the same period last year.

In November 2021, Outlook Therapeutics closed a $57.5 million gross proceeds equity offering, including full exercise of underwriter's option to purchase additional shares, which is expected to provide funding to the anticipated approval of the ONS-5010 BLA expected in the first calendar quarter of 2023.

At December 31, 2021, Outlook Therapeutics had cash and cash equivalents of $70.2 million.

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 may replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacies 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, potential approval and commercial launch of ONS-5010, expectations about the sufficiency of our capital, 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 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 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.

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

	Three months ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 9,872	$ 11,949
General and administrative	3,277	2,242
	13,149	14,191
Loss from operations	(13,149)	(14,191)
Loss on equity method investment	24	-
Interest expense, net	352	160
Loss on extinguishment of debt	1,026	-
Change in fair value of convertible promissory note	162	
Change in fair value of warrant liability	(250)	105
Net loss attributable to common stockholders	$ (14,463)	$ (14,456)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.12)
Weighted average shares outstanding, basic and diluted	188,158	121,750

Consolidated Balance Sheet Data
(Amounts in thousands)

	December 31, 2021	**September 30, 2021**
Cash and cash equivalents	$ 70,151	$ 14,477
Total assets	$ 78,678	$ 22,811
Current liabilities	$ 19,949	$ 6,752
Total stockholders' equity	$ 48,823	$ 4,607