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 15, 2024

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.)

111 S. Wood Avenue, Unit #100 **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 (see General Instructions A.2. below):

☐ 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 registered 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 15, 2024, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its second fiscal quarter ended March 31, 2024. 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 15, 2024
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 15, 2024

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

Exhibit 99.1

Outlook Therapeutics® Reports Financial Results for Second Quarter Fiscal Year 2024 and Provides Corporate Update

- **Positive opinion received from Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for ONS-5010/LYTENAVA™ (bevacizumab gamma)**
- **United Kingdom (UK) Marketing Authorization Application (MAA) submitted**
- **NORSE EIGHT fully underway in the US; Topline readout expected in Q4 CY2024**
- **Resubmission of the ONS-5010 Biologics License Application (BLA) planned by the end of CY2024**
- **Company to host inaugural quarterly update conference call and webcast on Thursday, May 16th at 8:30 AM ET**

ISELIN, N.J., May 15, 2024 — Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve regulatory approval for the first authorized use of an ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced financial results for the second quarter of fiscal year 2024 and provided a corporate update. As previously announced, the Company will host its inaugural quarterly conference call and live audio webcast, on Thursday, May 16, 2024, at 8:30 AM ET (details below).

"We are extremely pleased with our corporate, clinical, and regulatory progress. On the regulatory front, we continue to drive toward anticipated marketing authorization of ONS-5010 in the EU and have also submitted our marketing application for authorization in the UK. In the US, we are executing on our NORSE EIGHT clinical trial and advancing toward a topline data readout expected in the fourth quarter of calendar year 2024. On the financial front, assuming full exercise of the warrants issued in our recent private placement transactions, we believe we now have access to sufficient capital to take ONS-5010 through potential FDA approval and funding of the commercial launch," commented Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics. "We remain steadfast in our mission to enhance the standard of care in the retinal anti-VEGF space. On behalf of the entire team, I would like to thank all our partners and stakeholders for their continued support and look forward to what we believe will be an exciting remainder of the year for Outlook Therapeutics."

Lawrence Kenyon, Chief Financial Officer of Outlook Therapeutics, added, "Our adjusted financial results for the quarter met our expectations as we initiated the NORSE EIGHT clinical trial and began enrolling patients. We believe we are well positioned financially to continue executing on NORSE EIGHT enrollment, resubmission of the ONS-5010 BLA by the end of calendar 2024, and launch of ONS 5010 in 2025, if approved."

Upcoming Anticipated Milestones

- MAA decision in the European Union (EU) for ONS-5010 anticipated in Q2 CY2024;
- Full enrollment of NORSE EIGHT clinical trial in the US expected in Q3 CY2024;
- Topline readout of NORSE EIGHT clinical trial planned in Q4 CY2024;
- Resubmission of the ONS-5010 BLA targeted for the end of CY2024;
- Planning underway for potential commercial launches in the EU and UK to begin in first quarter of CY2025; and
- Potential for US FDA approval of ONS-5010 in 2025.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Regulatory Update

As previously announced, following Type A meetings with the FDA in Q4 CY2023, the FDA informed Outlook Therapeutics that it can conduct a non-inferiority study evaluating ONS-5010 versus ranibizumab in a 3-month study of treatment naïve patients with a primary efficacy endpoint at 2 months (NORSE EIGHT). In January 2024, Outlook Therapeutics announced that it received written agreement on the NORSE EIGHT trial protocol and statistical analysis plan from the FDA under a SPA for NORSE EIGHT. The SPA also confirms in writing that if the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to fully address the clinical deficiency identified in the Complete Response Letter (CRL). In addition, through a Type A meeting and additional interactions, Outlook Therapeutics has identified the approaches needed to resolve the Chemistry, Manufacturing and Controls (CMC) comments in the CRL. Outlook Therapeutics has scheduled a series of Type C and Type D meetings with the FDA to address the open CMC items in the CRL and expects to resolve these comments prior to the expected completion of NORSE EIGHT.

NORSE EIGHT is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet age-related macular degeneration (wet AMD) subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010 or 0.5 mg ranibizumab intravitreal injections. Subjects will receive injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint is mean change in BCVA from baseline to week 8. Currently, over 30% of the required subjects have been enrolled in the study. Outlook Therapeutics continues to plan NORSE EIGHT enrollment completion in Q3 CY2024, with topline results expected to be reported, and the planned resubmission of the ONS-5010 BLA to occur, by the end of calendar year 2024.

In March 2024, the CHMP issued a positive opinion concerning the EU Marketing Authorization Application (MAA) of ONS-5010/LYTENAVA™ (bevacizumab gamma), an investigational ophthalmic formulation of bevacizumab for the treatment of wet AMD in the EU. The CHMP positive opinion was based on results from Outlook Therapeutics' wet AMD clinical program for ONS-5010, which consists of three completed registration clinical trials - NORSE ONE, NORSE TWO and NORSE THREE, as well as studies and peer reviewed literature substituting or supporting certain tests and studies.

This positive opinion supports the grant of marketing authorization by the European Commission for Outlook Therapeutics' application for ONS-5010 in the EU. The European Commission is expected to make a decision on approval within approximately 67 days following the CHMP opinion. The decision will apply automatically in all 27 EU Member States, and, within 30 days, also to Iceland, Norway and Liechtenstein. If approved, an initial ten years of market exclusivity in the EU is expected for ONS-5010/LYTENAVA™.

Additionally, the Company recently announced the submission of its MAA to the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK seeking authorization of ONS-5010/LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD. The submission was completed under the new International Recognition Procedure (IRP), which allows the MHRA to rely on a positive opinion by the CHMP concerning an application for grant of marketing authorization for the same product in the EU. The IRP is available for new UK MAAs of a medicinal product (having the same qualitative and quantitative composition, and the same pharmaceutical form) that has previously been authorized by a Reference Regulator (RR). In this case this is the EMA.

If ONS-5010/LYTENAVA™ (bevacizumab-vikg or bevacizumab gamma) is approved, Outlook Therapeutics expects to commercialize it as the first and only European Commission, MHRA or FDA approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the EU, UK, and United States. Authorization may also be sought in other European markets, Japan, and elsewhere. If approved, Outlook Therapeutics plans to commercialize ONS-5010/LYTENAVA™ (bevacizumab-vikg) directly in the US and is assessing both direct commercialization and partnering for ONS-5010/LYTENAVA™ (bevacizumab gamma) in Europe and other regions outside of the US.

Financial Highlights for the Fiscal Second Quarter Ended March 31, 2024

For the fiscal second quarter ended March 31, 2024, Outlook Therapeutics reported a net loss attributable to common stockholders of $114.3 million, or $8.01 per basic and diluted share, compared to a net loss attributable to common stockholders of $6.7 million, or $0.52 per basic and diluted share, for the same period last year. For the fiscal second quarter ended March 31, 2024, Outlook Therapeutics also reported an adjusted net loss attributable to common stockholders[1] of $22.1 million, or $1.55 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $6.7 million, or $0.52 per basic and diluted share, for fiscal second quarter 2023.

Adjusted net loss attributable to common stockholders for the fiscal second quarter ended March 31, 2024 includes $34.1 million of warrant related expenses, $49.6 million of increase in fair value of warrant liability and $8.5 million of increase in fair value of convertible promissory notes. Adjusted net loss attributable to common stockholders was not materially different than net loss attributable to common stockholders for the fiscal second quarter ended March 31, 2023.

[1] Adjusted net loss attributable to common stockholders and adjusted net loss attributable to common stockholders per share of common stock – basic and diluted are non-U.S. GAAP financial measures. See “Non-GAAP Financial Measures” below.

In March and April 2024, the Company closed its previously announced private placements of common stock and accompanying warrants. In addition to the upfront gross proceeds of $65 million, the Company has the potential to receive additional gross proceeds of up to $107 million upon the full cash exercise of the warrants issued in the private placements, before deducting placement agent fees and offering expenses.

As of March 31, 2024, Outlook Therapeutics had cash and cash equivalents of $47.2 million.

Conference Call and Webcast

Outlook Therapeutics management will host its inaugural quarterly conference call and live audio webcast for investors, analysts, and other interested parties on Thursday, May 16, 2024 at 8:30 AM ET.

Interested participants and investors may access the conference call by dialing (877) 407-8291 (domestic) or (201) 689-8345 (international) and referencing the Outlook Therapeutics Conference Call. The live webcast will be accessible on the Events page of the Investors section of the Outlook Therapeutics website, outlooktherapeutics.com, and will be archived for 90 days**.**

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

ONS-5010/LYTENAVA™ is an investigational ophthalmic formulation of bevacizumab under development as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Because no FDA or European Commission approved ophthalmic formulations of bevacizumab are currently available, clinicians wishing to treat retinal patients with bevacizumab have had to use repackaged IV bevacizumab authorized for a different therapeutic indication and provided by compounding pharmacies—products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010/LYTENAVA™ would provide an authorized option for physicians to treat wet AMD in the United States, EU and the UK.

Bevacizumab-vikg (bevacizumab gamma in the EU and UK) 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 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 biopharmaceutical company working to achieve FDA, European Commission and MHRA approval for the launch of ONS-5010/LYTENAVA™ (bevacizumab-vikg or bevacizumab gamma) as the first approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010/LYTENAVA™ is approved, Outlook Therapeutics expects to commercialize it as the first and only European Commission, MHRA or FDA approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, EU, and UK. Authorization may also be sought in other European markets, Japan, and other markets. As part of the Outlook Therapeutics multi-year commercial planning process, Outlook Therapeutics and Cencora have entered into a strategic commercialization agreement to expand Outlook Therapeutics' reach for connecting to retina specialists and their patients. Cencora will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance services and other services in the United States, EU and UK.

Non-GAAP Financial Measures

Outlook Therapeutics prepares its consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP) and pursuant to accounting requirements of the Securities and Exchange Commission (SEC). In an effort to provide investors with additional information regarding the results and to provide a meaningful period-over-period comparison of Outlook Therapeutics' financial performance, Outlook Therapeutics sometimes uses non-U.S. GAAP financial measures (NGFM) as defined by the SEC. In this press release, Outlook Therapeutics uses "adjusted net loss attributable to common stockholders," which is defined as net loss attributable to common stockholders excluding warrant related expenses (i.e., the excess of the fair value of the warrants upon issuance over the proceeds of the private placement that closed on March 18, 2024) and changes in fair value of warrants and convertible promissory notes, as well as "adjusted net loss attributable to common stockholders per share of common stock – basic and diluted," which is defined as net loss attributable to common stockholders per share of common stock – basic and diluted excluding warrant related expenses and changes in fair value of warrants and convertible promissory notes. Management uses these NGFMs because they adjust for certain non-cash items that impact financial results but not cash flows and that management believes are not related to its core business. Management uses these NGFMs to evaluate Outlook Therapeutics financial performance against internal budgets and targets. Management believes that these NGFMs are useful for evaluating Outlook Therapeutics' core operating results and facilitating comparison across reporting periods. Outlook Therapeutics believes these NGFMs should be considered in addition to, and not in lieu of, GAAP financial measures. Outlook Therapeutics' NGFMs may be different from the same NGFMs used by other companies. Reconciliations to the closest U.S. GAAP financial measures are provided in the tables below.

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," "expect," "may," "plan," "potential," "target," "will," or "would" the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include, among others, expectations concerning decisions of regulatory bodies, including the European Commission, the MHRA and the FDA, and the timing thereof, expectations concerning Outlook Therapeutics' ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, including with respect to an additional clinical trial and CMC issues, expectations concerning NORSE EIGHT enrollment, the timing for completion of NORSE EIGHT and resubmission of the BLA for ONS-5010, the expected proceeds from the full exercise of warrants issued in recent private placement transactions, the sufficiency of Outlook Therapeutics' resources, including funds from the full exercise of the warrants, to fund its operations through various milestones, ONS-5010's potential as the first and only European Commission, MHRA or FDA-approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the EU, UK, and United States, plans for potential commercial launch of ONS-5010, expectations concerning the relationship with Cencora and the benefits and potential expansion thereof, 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, the content and timing of decisions by the European Commission, MHRA and FDA, 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, 2023, filed with the SEC on December 22, 2023, and future quarterly reports Outlook Therapeutics files with the SEC, which include uncertainty of market conditions and future impacts related to macroeconomic factors, including as a result of the ongoing overseas conflicts, high interest rates, inflation and potential future bank failures on the global business environment. 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.

Investor Inquiries:

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

	Three months ended March 31,		Six months ended March 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 13,509	$ 545	$ 18,038	$ 10,407
General and administrative	5,431	6,293	11,225	12,119
	18,940	6,838	29,263	22,526
Loss from operations	(18,940)	(6,838)	(29,263)	(22,526)
Income on equity method investment	30	17	28	(5)
Interest (income) expense, net	3,084	(188)	2,895	2,261
Loss on extinguishment of debt	—	—	—	578
Change in fair value of promissory notes	8,519	3	9,512	3
Warrant related expenses	34,098	—	34,098	—
Change in fair value of warrant liability	49,615	(19)	49,668	(49)
Loss before income taxes	(114,286)	(6,651)	(125,464)	(25,314)
Income tax expense	3	3	3	3
Net loss attributable to common stockholders	$ (114,289)	$ (6,654)	$ (125,467)	$ (25,317)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (8.01)	$ (0.52)	$ (9.20)	$ (2.09)
Weighted average shares outstanding, basic and diluted	14,270	12,833	13,638	12,094

Consolidated Balance Sheet Data
(Amounts in thousands)

	March 31, 2024	September 30, 2023
Cash and cash equivalents	$ 47,229	$ 23,392
Total assets	$ 59,029	$ 32,301
Current liabilities	$ 54,080	$ 46,732
Total stockholders' deficit	$ (134,236)	$ (14,438)

Reconciliation Between Reported Net Loss (GAAP) and Adjusted Net Loss (Non-GAAP), in each case Attributable to Common Stockholders

(Amounts in thousands, except per share data)

	Three months ended March 31,		Six months ended March 31,	
	2024	**2023**	**2024**	**2023**
Net loss attributable to common stockholders, as reported (GAAP)	$ (114,289)	$ (6,654)	$ (125,467)	$ (25,317)
Adjustments for reconciled items:				
Warrant related expenses	34,098	—	34,098	—
Change in fair value of warrant liability	49,615	(19)	49,668	(49)
Change in fair value of promissory notes	8,519	3	9,512	3
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (22,057)	$ (6,670)	$ (32,189)	$ (25,363)
Net loss attributable to common stockholders per share of common stock - basic and diluted, as reported (GAAP)	$ (8.01)	$ (0.52)	$ (9.20)	$ (2.09)
Adjustments for reconciled items:				
Warrant related expenses	2.39	—	2.50	—
Change in fair value of warrant liability	3.48	—	3.64	(0.01)
Change in fair value of promissory notes	0.59	—	0.70	—
Adjusted net loss attributable to common stockholders per share of common stock - basic and diluted (non-GAAP)	$ (1.55)	$ (0.52)	$ (2.36)	$ (2.10)