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 14, 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 August 14, 2024, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its third fiscal quarter ended June 30, 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 August 14, 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: August 14, 2024

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

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

- **Received European Union (EU) and United Kingdom (UK) Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD**
- **NORSE EIGHT current enrollment pace supports topline readout target of Q4 CY2024**
- **Resubmission of the ONS-5010 Biologics License Application (BLA) on track for Q1 CY2025**
- **Quarterly update conference call and webcast today, Wednesday, August 14th at 8:30 AM ET**

ISELIN, N.J., August 14, 2024 — Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company that has achieved regulatory approval in the EU and UK for the first authorized use of an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD), today announced financial results for the third quarter of fiscal year 2024 and provided a corporate update. As previously announced, Outlook Therapeutics will host its quarterly conference call and live audio webcast, today, Wednesday, August 14, 2024, at 8:30 AM ET (details below).

"This quarter we achieved two major milestones with receipt of Marketing Authorization in both the European Union and the United Kingdom. Additionally, we made significant progress with our primary focus, which remains the successful completion of enrollment in our ongoing NORSE EIGHT clinical trial. Based on our enrollment progress, we expect to report those results in the fourth calendar quarter of 2024 with the anticipated resubmission of our BLA in the first calendar quarter of 2025," commented Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics. "Meanwhile, we continue commercial preparations to launch the first, and only, ophthalmic approved bevacizumab for the treatment of wet AMD in the EU and UK, either directly or with a partner, anticipated in the first half of calendar year 2025."

Upcoming Anticipated Milestones

- 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 Q1 CY2025;
- Initial commercial launches in Europe planned to commence in first half of CY2025; and
- Potential for US FDA approval of ONS-5010 in second half of CY2025.

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

As previously announced, following Type A meetings with the US Food and Drug Administration (FDA) in Q4 CY2023 to address the ONS-5010 Complete Response Letter (CRL), the FDA informed Outlook Therapeutics that it could conduct a non-inferiority study evaluating ONS-5010 versus ranibizumab in a 12 week study of treatment naïve patients with a primary efficacy endpoint at 8 weeks (NORSE EIGHT) to support the resubmission of the ONS-5010 BLA to the FDA. In January 2024, Outlook Therapeutics received written agreement on the NORSE EIGHT trial protocol and statistical analysis plan from the FDA under a Special Protocol Assessment (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 CRL. In addition, Outlook Therapeutics has completed 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 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. As of the date of this release, 359 subjects have been enrolled in the study. Outlook Therapeutics remains on track for NORSE EIGHT enrollment completion in Q3 CY2024, with topline results expected to be reported in Q4 CY2024. The resubmission of the ONS-5010 BLA is planned for Q1 CY2025.

In May 2024, the European Commission granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD in the EU. Additionally, in July 2024, the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the same indication in the UK.

LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK. Authorization may also be sought in other European countries, Japan, and elsewhere. Outlook Therapeutics expects its anticipated commercial launch of LYTENAVA™ (bevacizumab gamma) in the EU and UK in the first half of calendar year 2025. As part of a multi-year planning process, Outlook Therapeutics entered a strategic collaboration with Cencora (NYSE: COR) (formerly AmerisourceBergen) to support the commercial launch of LYTENAVA™ globally following regulatory approvals.

Cencora will provide comprehensive launch support in the EU and the UK including pharmacovigilance, regulatory affairs, quality management, market access support, importation, third-party logistics (3PL), distribution and field solutions. The collaboration and integrated approach is designed to support market access and efficient distribution of LYTENAVA™ to benefit all stakeholders, including retina specialists, providers and patients.

Additionally, if approved by the FDA, Outlook Therapeutics plans to commercialize ONS-5010/LYTENAVA™ (bevacizumab-vikg) directly in the US, but is also assessing partnering options for LYTENAVA™ (bevacizumab gamma) in the EU and the UK and other regions outside of the US.

Financial Highlights for the Fiscal Third Quarter Ended June 30, 2024

For the fiscal third quarter ended June 30, 2024, Outlook Therapeutics reported net income attributable to common stockholders of $44.4 million, or $1.91 per basic share, and net loss attributable to common stockholders of $0.89 per diluted share, compared to a net loss attributable to common stockholders of $20.7 million, or $1.61 per basic and diluted share, for the same period last year. For the fiscal third quarter ended June 30, 2024, Outlook Therapeutics also reported an adjusted net loss attributable to common stockholders[1] of $19.2 million, or $0.83 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $17.8 million, or $1.38 per basic and diluted share, for fiscal third quarter 2023.

Adjusted net loss attributable to common stockholders for the fiscal third quarter ended June 30, 2024 includes $3.4 million of warrant related expenses, $59.5 million of decrease in fair value of warrant liability and $7.6 million of decrease in fair value of convertible promissory notes. Adjusted net loss attributable to common stockholders for the fiscal third quarter ended June 30, 2023 includes $2.9 million of increase in fair value of convertible promissory notes.

In March and April 2024, Outlook Therapeutics closed its previously announced private placements of common stock and accompanying warrants. In addition to the upfront gross proceeds of $65 million, Outlook Therapeutics 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 June 30, 2024, Outlook Therapeutics had cash and cash equivalents of $32.0 million.

Conference Call and Webcast

Outlook Therapeutics management will host its quarterly conference call and live audio webcast for investors, analysts, and other interested parties on Wednesday, August 14, 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 ophthalmic formulation of bevacizumab for the treatment of wet AMD. LYTENAVA™ (bevacizumab gamma) is the subject of a centralized Marketing Authorization granted by the European Commission in the European Union (EU) and Marketing Authorization granted by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) for the treatment of wet age-related macular degeneration (wet AMD).

[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-GAAP financial measures. See “Non-GAAP Financial Measures” below.

In the United States, ONS-5010/LYTENAVA™ (bevacizumab-vikg) is investigational and is being evaluated in an ongoing non-inferiority study for the treatment of wet AMD.

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 focused on the development and commercialization of ONS-5010/LYTENAVA™ (bevacizumab-vikg; bevacizumab gamma), for the treatment of retina diseases, including wet AMD. LYTENAVA™ (bevacizumab gamma) is the first ophthalmic formulation of bevacizumab to receive European Commission and MHRA Marketing Authorization for the treatment of wet AMD. Outlook Therapeutics is working to initiate its commercial launch of LYTENAVA™ (bevacizumab gamma) in the EU and the UK as a treatment for wet AMD, expected in the first half of calendar 2025. In the United States, ONS-5010/LYTENAVA™ is investigational, is being evaluated in an ongoing non-inferiority study for the treatment of wet AMD, and if successful, the data may be sufficient for Outlook to resubmit a BLA application to the FDA in the United States. If approved in the United States, ONS-5010/LYTENAVA™, would be the first approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD.

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 placements that closed on March 18, 2024 and April 15, 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 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, plans for commercial launch of ONS-5010 in the UK and EU and the timing thereof, including the potential to launch with a partner, 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, the expected proceeds from the full exercise of warrants issued in recent private placement transactions, 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 and commercializing pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, the content and timing of decisions by regulatory bodies, the sufficiency of Outlook Therapeutics' resources, 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.

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

	Three months ended June 30,		Nine months ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 11,202	$ 11,101	$ 29,240	$ 21,509
General and administrative	8,361	7,040	19,586	19,158
	19,563	18,141	48,826	40,667
Loss from operations	(19,563)	(18,141)	(48,826)	(40,667)
Loss on equity method investment	57	7	85	2
Interest income	(404)	(395)	(666)	(665)
Interest expense	—	—	3,157	2,531
Loss on extinguishment of debt	—	—	—	578
Change in fair value of promissory notes	(7,563)	2,910	1,949	2,913
Warrant related expenses	3,392	—	37,490	—
Change in fair value of warrant liability	(59,454)	12	(9,786)	(37)
Income (loss) before income taxes	44,409	(20,675)	(81,055)	(45,989)
Income tax expense	—	—	3	3
Net income (loss) attributable to common stockholders	$ 44,409	$ (20,675)	$ (81,058)	$ (45,992)
Per share information:				
Net income (loss) per share of common stock, basic	$ 1.91	$ (1.61)	$ (4.82)	$ (3.73)
Net loss per share of common stock, diluted	$ (0.89)	$ (1.61)	$ (4.82)	$ (3.73)
Weighted average shares outstanding, basic	23,277	12,844	16,823	12,344
Weighted average shares outstanding, diluted	25,476	12,844	16,823	12,344

Consolidated Balance Sheet Data
(Amounts in thousands)

	June 30, 2024	**September 30, 2023**
Cash and cash equivalents	$ 32,024	$ 23,392
Total assets	$ 47,092	$ 32,301
Current liabilities	$ 42,554	$ 46,732
Total stockholders' deficit	$ (83,673)	$ (14,438)

Reconciliation Between Reported Net Income (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 June 30,		Nine months ended June 30,	
	2024	2023	2024	2023
Net income (loss) attributable to common stockholders, as reported (GAAP)	$ 44,409	$ (20,675)	$ (81,058)	$ (45,992)
Adjustments for reconciled items:				
Warrant related expenses	3,392	-	37,490	-
Change in fair value of warrant liability	(59,454)	12	(9,786)	(37)
Change in fair value of promissory notes	(7,563)	2,910	1,949	2,913
Adjusted net income (loss) attributable to common stockholders (non-GAAP)	$ (19,216)	$ (17,753)	$ (51,405)	$ (43,116)
Net income (loss) attributable to common stockholders per share of common stock - basic as reported (GAAP)	$ 1.91	$ (1.61)	$ (4.82)	$ (3.73)
Adjustments for reconciled items:				
Warrant related expenses	0.15	-	2.23	-
Change in fair value of warrant liability	(2.56)	-	(0.58)	-
Change in fair value of promissory notes	(0.33)	0.23	0.12	0.24
Adjusted net loss attributable to common stockholders per share of common stock - basic (non-GAAP)	$ (0.83)	$ (1.38)	$ (3.05)	$ (3.49)
Net loss attributable to common stockholders per share of common stock - diluted as reported (GAAP)	$ (0.89)	$ (1.61)	$ (4.82)	$ (3.73)
Adjustments for reconciled items:				
Warrant related expenses	0.15	-	2.23	-
Change in fair value of warrant liability	(0.06)	-	(0.58)	-
Change in fair value of promissory notes	(0.03)	0.23	0.12	0.24
Adjusted net loss attributable to common stockholders per share of common stock - diluted (non-GAAP)	$ (0.83)	$ (1.38)	$ (3.05)	$ (3.49)