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, 2025**

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**

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 August 14, 2025, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its third fiscal quarter ended June 30, 2025. 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, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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, 2025

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

Exhibit 99.1

Outlook Therapeutics Reports Financial Results for Third Quarter Fiscal Year 2025 and Provides Corporate Update

- **First commercial sales of LYTENAVA™ (bevacizumab gamma) achieved in Europe**
- **ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Prescription Drug User Fee Act (PDUFA) goal date of August 27, 2025 in the United States**

ISELIN, N.J., August 14, 2025 — Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company focused on enhancing the standard of care for bevacizumab for the treatment of retina diseases, today reported financial results for the third quarter of fiscal year 2025 and provided a corporate update.

Financial Highlights for the Fiscal Third Quarter Ended June 30, 2025

For the fiscal third quarter ended June 30, 2025, Outlook Therapeutics reported net loss attributable to common stockholders of $20.2 million, or $0.55 per basic and diluted share, and $1.5 million of revenue. Revenue consisted of the initial sales into Germany and the UK for LYTENAVA™ where title to the product has transferred to the distributor. This compares with net loss attributable to common stockholders of $0.89 per basic and diluted share for the same period last year, and no revenue.

For the fiscal third quarter ended June 30, 2025, Outlook Therapeutics also reported an adjusted net loss attributable to common stockholders of $15.8 million, or $0.44 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $19.2 million, or $0.83 per basic and diluted share, for fiscal third quarter 2024.

Adjusted net loss attributable to common stockholders for the fiscal third quarter ended June 30, 2025 excludes $2.3 million of loss from change in fair value of promissory notes and $2.0 million of loss from change in fair value of warrant liability. Adjusted net loss attributable to common stockholders for the fiscal third quarter ended June 30, 2024 excludes $3.4 million of warrant related expenses, $59.5 million of gain from change in fair value of warrant liability and $7.6 million of gain from change in fair value of convertible promissory notes.

As of June 30, 2025, Outlook Therapeutics had cash and cash equivalents of $8.9 million.

Upcoming Near-term Milestone

- U.S. Food and Drug Administration (FDA) PDUFA goal date for ONS-5010 is August 27, 2025.

“With the first commercial sales of LYTENAVA™ (bevacizumab gamma) in Europe for the treatment of wet AMD, the transformation of Outlook Therapeutics into a commercial company has begun,” commented Bob Jahr, Chief Executive Officer of Outlook Therapeutics. “We are proud to report that the first patients have already been dosed in both Germany and the UK, and we are pushing ahead with our efforts to enhance the addition of this important therapy to the standard treatment regimen as quickly as possible in these key markets. We continue to execute on our commercial pathway forward and have preparations underway in advance of potential U.S. FDA approval later this month.”

LYTENAVA™ (bevacizumab gamma) European Commercial Update

LYTENAVA™ (bevacizumab gamma) is now commercially available in Germany and the UK for the treatment of wet age-related macular degeneration (wet AMD). LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in adults in the European Union and UK.

Off-label repackaged bevacizumab is one of the most frequently used first-line anti-VEGF treatments in Europe (approximately 2.8 million injections annually) and the United States (approximately 2.7 million injections annually) for the treatment of retinal diseases. ONS-5010/LYTENAVA™ has potential to mitigate certain risks associated with the current off-label use of repackaged bevacizumab.

As previously announced, Outlook Therapeutics has entered into a strategic collaboration with Cencora to support the commercial launch of LYTENAVA™ globally following regulatory approvals. 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 in the European Union and UK and, if approved, in the United States.

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

In April 2025, Outlook Therapeutics announced that the FDA acknowledged receipt of the resubmission of the Biologics License Application (BLA) for ONS-5010 (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab for the treatment of wet AMD. The FDA has determined that the BLA is a Class 2 review, which results in a six-month review period from the date of resubmission. The FDA set a PDUFA goal date of August 27, 2025. ONS-5010, if approved, will be branded as LYTENAVA™ (bevacizumab-vikg) in the United States for the treatment of wet AMD and is expected to receive 12 years of regulatory exclusivity.

The ONS-5010 BLA resubmission was based on the efficacy and safety demonstrated in NORSE EIGHT, as well as additional chemistry, manufacturing and controls (CMC) information requested by the FDA. As previously announced, following Type A meetings with the FDA in Q4 CY2023 to address the ONS-5010 Complete Response Letter (CRL), the FDA informed Outlook Therapeutics that, in order to meet the FDA’s requirement for a second adequate and well-controlled clinical trial of ONS-5010, 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). Outlook Therapeutics believes that the complete data set for NORSE EIGHT and the additional CMC information in the BLA resubmission, combined with the data from the other NORSE clinical trials, provides the required evidence to support approval of the ONS-5010 BLA in the United States.

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 EU and Marketing Authorization granted by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK for the treatment of wet AMD.

In the United States, ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) is investigational. In certain European Union Member States ONS-5010/LYTENAVA™ must receive pricing and reimbursement approval before it can be sold.

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) to enhance the standard of care for bevacizumab for the treatment of retina diseases. 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 commenced commercial launch of LYTENAVA™ (bevacizumab gamma) in Germany and the UK as a treatment for wet AMD.

In the United States, ONS-5010/LYTENAVA™ (bevacizumab-vikg) is investigational, and a BLA has been resubmitted to the FDA. 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 inducement expenses 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 inducement 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," "on track," "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, plans for commercial launch of LYTENAVA™ in additional markets 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 decisions of regulatory bodies and the timing thereof, including market exclusivity, the potential to receive approval from the FDA and the timing thereof, the potential of ONS-5010/LYTENAVA™ as a treatment for wet AMD and to mitigate certain risks associated with the current off-label use of repackaged bevacizumab, the market opportunity for LYTENAVA™ in Europe and the United States, , 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, including the risk that the data from the NORSE EIGHT trial does not support the approval by the FDA of the ONS-5010 BLA, 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, 2024, filed with the SEC on December 27, 2024, as supplemented by the Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2025 and future 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, tariffs and trade tensions, fluctuations in interest rates and 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 June 30,		Nine months ended June 30,	
	2025	2024	2025	2024
Revenues, net	$ 1,505	$ —	$ 1,505	$ —
Cost of revenues	440	—	440	—
Gross profit	1,065	—	1,065	—
Operating expenses:				
Research and development	$ 7,135	$ 11,202	$ 21,202	$ 29,240
Selling, general and administrative	9,679	8,361	29,610	19,586
Loss from operations	(15,749)	(19,563)	(49,747)	(48,826)
Loss on equity method investment	30	57	100	85
Interest expense (income), net	49	(404)	19	2,491
Loss (gain) from change in fair value of promissory notes	2,324	(7,563)	5,739	1,949
Warrant related expenses	—	3,392	—	37,490
Warrant inducement expenses	—	—	33,857	—
Loss (gain) from change in fair value of warrant liability	2,000	(59,454)	(40,333)	(9,786)
(Loss) income before income taxes	(20,152)	44,409	(49,129)	(81,055)
Income tax expense	—	—	3	3
Net (loss) income	$ (20,152)	$ 44,409	$ (49,132)	$ (81,058)
Per share information:				
Net (loss) income per share of common stock, basic	$ (0.55)	$ 1.91	$ (1.60)	$ (4.82)
Net loss per share of common stock, diluted	$ (0.55)	$ (0.89)	$ (1.60)	$ (4.82)
Weighted average shares outstanding, basic	36,957	23,227	30,664	16,823
Weighted average shares outstanding, diluted	36,957	25,476	30,664	16,823

Condensed Consolidated Balance Sheet Data
(Amounts in thousands)

	June 30, 2025	September 30, 2024
Cash and cash equivalents	$ 8,901	$ 14,928
Total assets	$ 22,392	$ 28,823
Current liabilities	$ 31,489	$ 42,554
Total stockholders' deficit	$ (37,190)	$ (73,077)

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 June 30,		Nine months ended June 30,	
	2025	2024	2025	2024
Net (loss) income attributable to common stockholders, as reported (GAAP)	$ (20,152)	$ 44,409	$ (49,132)	$ (81,058)
Adjustments for reconciled items:				
Loss (gain) from change in fair value of promissory notes	2,324	(7,563)	5,739	1,949
Warrant related expenses	—	3,392	—	37,490
Warrant inducement expenses	—	—	33,857	—
Loss (gain) from change in fair value of warrant liability	2,000	(59,454)	(40,333)	(9,786)
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (15,828)	$ (19,216)	$ (49,869)	$ (51,405)
Net (loss) income attributable to common stockholders per share of common stock - basic as reported (GAAP)	$ (0.55)	$ 1.91	$ (1.60)	$ (4.82)
Adjustments for reconciled items:				
Loss (gain) from change in fair value of promissory notes	0.06	(0.33)	0.19	0.12
Warrant related expenses	—	0.15	—	2.23
Warrant inducement expenses	—	—	1.10	—
Loss (gain) from change in fair value of warrant liability	0.05	(2.56)	(1.32)	(0.58)
Adjusted net loss attributable to common stockholders per share of common stock - basic (non-GAAP)	$ (0.44)	$ (0.83)	$ (1.63)	$ (3.05)
Net loss attributable to common stockholders per share of common stock - diluted as reported (GAAP)	$ (0.55)	$ (0.89)	$ (1.60)	$ (4.82)
Adjustments for reconciled items:				
Loss (gain) from change in fair value of promissory notes	0.06	(0.03)	0.19	0.12
Warrant related expenses	—	0.15	—	2.23
Warrant inducement expenses	—	—	1.10	—
Loss (gain) from change in fair value of warrant liability	0.05	(0.06)	(1.32)	(0.58)
Adjusted net loss attributable to common stockholders per share of common stock - diluted (non-GAAP)	$ (0.44)	$ (0.83)	$ (1.63)	$ (3.05)
Weighted average shares outstanding, basic	36,956,582	23,227,069	30,663,988	16,822,774
Weighted average shares - diluted	36,956,582	25,476,438	30,663,988	16,822,774