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, 2023**

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 February 14, 2023, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its first fiscal quarter ended December 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 February 14, 2023.
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, 2023

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

Outlook Therapeutics® Reports Financial Results for First Quarter Fiscal Year 2023 and Provides Corporate Update

- **Pre-launch commercial activities underway as Company advances toward U.S. Food and Drug Administration (FDA) Prescription Drug User Fee Act (PDUFA) goal date of August 29, 2023 for ONS-5010 / LYTENAVA™ (bevacizumab-vikg), an investigational ophthalmic formulation for the treatment of wet age-related macular degeneration (wet AMD)**

- **Cash runway through the anticipated FDA approval of ONS-5010 in the third calendar quarter of 2023 and into the fourth calendar quarter of 2023**

ISELIN, N.J., February 14, 2023 — 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, 2022.

Recent Corporate Highlights

- **Strengthened Medical Affairs and Commercial Expertise with Appointments of Surendra Sharma, MD, Senior Vice President of Medical Affairs, and Glen Olsheim, Executive Director of Commercial Excellence.**
- **Closed on approximately $54 million in net proceeds from two financings to support pre-launch commercial activities through anticipated FDA approval of ONS-5010 in third calendar quarter of 2023 and into the fourth calendar quarter of 2023.**
  - **Approximately $24 million registered direct equity offering priced at-the-market under Nasdaq rules.**
  - **Approximately $30 million net proceeds from issuance of an unsecured convertible promissory note with an initial conversion price of $2.00 per share.**
- **Received validation of Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) for ONS-5010/ LYTENAVA™ (bevacizumab-vikg).**
- **Announced that the FDA accepted its Biologics License Application (BLA) for ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the treatment of wet AMD and set a PDUFA goal date of August 29, 2023.**

“Our first fiscal quarter of 2023 continued to demonstrate solid execution toward the potential commercialization of ONS-5010. With the accepted FDA filing of our BLA for ONS-5010 and PDUFA date set for August 29, 2023, and review of our MAA in the EU underway with a decision date expected in early 2024, we are well on our way toward our goal of becoming a commercial-stage company,” commented Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics. “Looking ahead, we remain focused on execution and positioning ourselves for a commercial launch of ONS-5010 to enhance the standard of care in the retinal anti-VEGF space.”

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Pre-Launch Commercial Planning Underway

According to GlobalData, the use of unapproved repackaged IV bevacizumab from compounding pharmacies is estimated to account for approximately 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 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 Bio-pharma Services for the finished drug product.

Outlook Therapeutics is actively building out its sales and commercial team, and in September 2022, Outlook Therapeutics entered into a strategic partnership with AmerisourceBergen in preparation for the anticipated commercial launch in the United States of ONS-5010. As Outlook Therapeutics moves toward a potential launch in the United States, AmerisourceBergen's commercialization support will expand to include additional services. Through the agreement with AmerisourceBergen, Outlook Therapeutics expects to significantly increase market access and efficient distribution of ONS-5010, if approved by the FDA. Moreover, working with AmerisourceBergen will help to provide Outlook Therapeutics with an accelerated pathway to deliver a high-quality customer experience to retina specialists. To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians, and payors – Outlook Therapeutics has also 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 submitted them in December 2022. The formal review process of the MAA by the EMA's Committee for Medicinal Products for Human Use (CHMP) is underway with an estimated decision date expected in early 2024. In addition to pursuing potential strategic partnering opportunities in the EU and other regions, such as the current partnership with Syntone Biopharma JV in China, Outlook Therapeutics is also exploring an expanded relationship with AmerisourceBergen to support the launch of ONS-5010 in international markets. AmerisourceBergen increased its global distribution capabilities in 2021 with the acquisition of Alliance Healthcare, a leading wholesaler of healthcare products in Europe.

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

- Continued progress with ongoing pre-launch commercial preparations in anticipation of potential approval for ONS-5010 in 2023;
- PDUFA goal date of August 29, 2023;
- Completion of enrollment in the NORSE SEVEN clinical trial assessing the safety of ONS-5010 in a pre-filled syringe; and
- Estimated decision date from the EMA's CHMP on the Company's submitted MAA in EU for ONS-5010 expected in early 2024.

Financial Highlights for the Fiscal First Quarter Ended December 31, 2022

For the fiscal first quarter ended December 31, 2022, Outlook Therapeutics reported a net loss attributable to common stockholders of $18.7 million, or $0.08 per basic and diluted share, compared to a net loss attributable to common stockholders of $14.5 million, or $0.08 per basic and diluted share, for the same period last year.

In December 2022, the Company closed a registered direct equity offering priced at-the-market under Nasdaq rules, resulting in net proceeds of approximately $24.0 million. Additionally, the Company closed on an unsecured convertible promissory note (the "Note") with a face amount of $31.8 million and net proceeds of approximately $30.0 million after original issue discount and after deducting the lender's transaction costs. The net proceeds from these transactions are expected to provide sufficient capital to support operations past the anticipated FDA approval of ONS-5010 in the third calendar quarter of 2023 and into the fourth calendar quarter of 2023.

At December 31, 2022, Outlook Therapeutics had cash and cash equivalents of $52.3 million.

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

ONS-5010 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 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 oncologic 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 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. The FDA accepted Outlook Therapeutics' BLA submission for ONS-5010 to treat wet AMD with a PDUFA goal date of August 29, 2023. The submission is supported by Outlook Therapeutics' wet AMD 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. As part of the Company's multi-year commercial planning process, and in anticipation of potential FDA approval in August 2023, Outlook Therapeutics and AmerisourceBergen have entered into a strategic commercialization agreement to expand the Company's reach for connecting to retina specialists and their patients. AmerisourceBergen will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance services in the United States. 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, expectations about the sufficiency of our capital, upcoming anticipated milestones, expectations concerning decisions of regulatory bodies, including the FDA and the EMA, and the timing thereof, our estimated market, expectations concerning our relationship with AmerisourceBergen and the benefits thereof, 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 submissions, 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, 2022 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 and the impacts of the pandemic and other macroeconomic factors, including as a result of the ongoing conflict between Russia and Ukraine, 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.

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

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

	Three months ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 9,862	$ 9,872
General and administrative	5,826	3,277
Loss from operations	(15,688)	(13,149)
(Income) loss on equity method investment	(22)	24
Interest expense, net	2,449	352
Loss on extinguishment of debt	578	1,026
Change in fair value of promissory notes	-	162
Change in fair value of warrant liability	(30)	(250)
Net loss attributable to common stockholders	$ (18,663)	$ (14,463)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.08)	$ (0.08)
Weighted average shares outstanding, basic and diluted	227,411	188,158

Consolidated Balance Sheet Data
(Amounts in thousands)

	December 31, 2022	September 30, 2022
Cash and cash equivalents	$ 52,341	$ 17,397
Total assets	$ 62,688	$ 28,528
Current liabilities	$ 15,082	$ 19,730
Total stockholders' equity	$ 15,759	$ 8,737