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, 2020**

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.)

4260 U.S. Route 1 **Monmouth Junction, New Jersey**	**08852**
(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 August 14, 2020, Outlook Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for its third fiscal quarter ended June 30, 2020. 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, 2020.

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, 2020

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

Outlook Therapeutics Reports Financial Results for the Third Quarter of Fiscal Year 2020 and Provides Corporate Update

- **Successfully completed NORSE 2 enrollment in July 2020**

- **NORSE 1 topline results to be reported in August 2020**

MONMOUTH JUNCTION, N.J., August 14, 2020 — Outlook Therapeutics, Inc. (Nasdaq: OTLK), a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, today announced its corporate highlights and financial results for its fiscal third quarter ended June 30, 2020.

Outlook Therapeutics also provided a clinical development update on ONS-5010 / LYTENAVA™ (bevacizumab-vikg), its investigational ophthalmic formulation of bevacizumab-vikg for the treatment of wet age-related macular degeneration (wet AMD) and other retinal indications.

“I am extremely proud of the progress we have made over the last few months. In addition to successfully completing two strategic financings during the last quarter that helped provide a meaningful cash runway as we advance ONS-5010 towards a BLA submission, we continued to achieve important clinical milestones,” said Lawrence A. Kenyon, President, CEO and CFO of Outlook Therapeutics. “This month we are on track to report topline safety and efficacy results from our NORSE 1 study in wet AMD. The data from this study in addition to the pivotal NORSE 2 data and the results of NORSE 3, which we expect in the third calendar quarter of next year, should be sufficient to support our BLA filing in the second half of 2021.”

Recent Corporate Highlights

- Announced the completion of patient enrollment in NORSE 2 clinical trial for ONS-5010;
- Closed a registered direct offering and a private placement, each priced at-the-market under Nasdaq rules, for aggregate gross proceeds of approximately $11.2 million;
- Closed a private placement of $16.0 million of common stock at a price per share representing a 34% premium at signing to Syntone Ventures LLC, a U.S.-based affiliate of Syntone Technologies Group Co. Ltd.;
- Converted all senior secured convertible notes into common stock; and
- Appointed internationally renowned ophthalmologist, Gerd Auffarth, MD, and former President of the North American Pharmaceutical division of Allergan, Inc., Julian Gangolli, to the Company’s Board of Directors.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Development Updates

The NORSE 1 clinical trial is a small 30-subject-per-arm clinical experience trial designed to provide an initial safety and efficacy readout for ONS-5010. LUCENTIS® (ranibizumab) in treating patients with wet AMD, and to provide the initial safety data necessary to open an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration (FDA). The first of two registration clinical trials evaluating ONS-5010 in treating wet AMD, NORSE 1 completed enrollment in August 2019 and enrolled a total of 61 treatment-naïve and previously treated patients diagnosed with wet AMD at nine sites in Australia. Patients on ONS-5010 were dosed monthly compared to those on ranibizumab, who were dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing. Outlook Therapeutics expects to report the topline safety and efficacy data later in August 2020.

Outlook Therapeutics completed patient enrollment in its NORSE 2 clinical trial in July 2020, enrolling a total of 227 patients at 39 clinical trial sites in the United States. Patients in the trial are being treated for 12 months. The primary endpoint for NORSE 2 is the difference in proportion of patients who gain at least 15 letters in the best corrected visual acuity (BCVA) at 11 months for ONS-5010 dosed on a monthly basis, compared to LUCENTIS®, which is being dosed quarterly per the PIER regimen. Outlook Therapeutics expects to report pivotal safety and efficacy data in the third calendar quarter of 2021.

The NORSE 3 open-label safety study will be conducted to ensure the adequate number of safety exposures to ONS-5010 are available for the initial regulatory filings. In total, NORSE 3 is expected to enroll approximately 180 patients in several different vascular and inflammatory retinal diseases where an anti-VEGF drug can be used as a therapeutic option. Patients in NORSE 3 will receive three doses of ONS-5010 over three months.

In addition to NORSE 1 and NORSE 2 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 NORSE 4, a planned registration clinical trial evaluating ONS-5010 to treat branch retinal vein occlusion (BRVO), and NORSE 5 and NORSE 6, two planned registration clinical trials evaluating ONS-5010 for the treatment of diabetic macular edema (DME).

Outlook Therapeutics intends to complete development of ONS-5010 for submission to the FDA as a new biologics license application (BLA) under the 351(a) PHSA regulatory pathway for the treatment of wet AMD and also has plans to submit for regulatory approvals in Europe, the United Kingdom and Japan, as well as other countries. If approved, ONS-5010 will be the first and only on-label ophthalmic formulation of bevacizumab-vikg for treating retinal diseases with the potential to address a $9.1 billion anti-VEGF market.

Financial Highlights for the Fiscal Third Quarter Ended June 30, 2020

For the fiscal third quarter ended June 30, 2020, Outlook Therapeutics reported a net loss attributable to common stockholders of $3.0 million, or $0.03 per basic and diluted share, compared to a net loss attributable to common stockholders of $4.6 million, or $0.20 per basic and diluted share, for the same period last fiscal year. For the fiscal third quarter ended June 30, 2020, Outlook Therapeutics also reported an adjusted net loss attributable to common stockholders of $10.0 million, or $0.11 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $5.5 million, or $0.24 per basic and diluted share, for the same period last fiscal year.

Adjusted net loss attributable to common stockholders in the fiscal third quarter ended June 30, 2020 includes $1.4 million of stock-based compensation expense, $0.1 million of depreciation and amortization, $0.1 million of non-cash interest expense, a $6.2 million gain on the extinguishment of debt, $0.7 million loss on lease termination, $0.1 million impairment of property and equipment, $0.1 million increase in the fair value of warrant liability, and $3.3 million of income tax benefit from sale of state tax net operating losses (NOLs). For the third quarter of fiscal 2019, adjusted net loss attributable to common stockholders includes $0.8 million of depreciation and amortization, $0.4 million of non-cash interest expense, $0.4 million of loss on extinguishment of debt, a $1.9 million decrease in the fair value of warrant liability, $0.8 million of income tax benefit from the sale of state tax NOLs, $0.1 million impairment of property and equipment, and $0.2 million stock dividend for the Series A-1 convertible preferred stock.

At June 30, 2020, Outlook Therapeutics had cash and cash equivalents of $24.0 million, compared to $4.7 million at March 31, 2020.

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

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab-vikg under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. ONS-5010 is currently being evaluated in two registration clinical trials for wet AMD (NORSE 1 and NORSE 2) and, if successful, is expected to be submitted to the FDA as a new BLA for this ophthalmic indication under the 351(a) regulatory pathway. Because no currently approved ophthalmic formulations of bevacizumab are available, clinicians wishing to treat retinal patients with bevacizumab use unapproved repackaged bevacizumab provided by compounding pharmacists, products that have known risks of contamination and inconsistent potency and availability.

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 new abnormal blood vessels. With wet AMD, abnormally high levels of VEGF are secreted in the eye and can lead to vision loss. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it has become the standard-of-care treatment option within the retina community globally.

If approved, ONS-5010 will be the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg to treat retinal diseases. Outlook Therapeutics currently intends to commercialize ONS-5010 in both vials and single-use pre-filled syringes.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a late clinical-stage biopharmaceutical company working to develop ONS-5010 / LYTENAVA™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg for use in treating retinal diseases in the United States, United Kingdom, Europe, Japan and other markets. Outlook Therapeutics expects to file ONS-5010 with the U.S. FDA as a new BLA under the PHSA 351(a) regulatory pathway. For more information, please visit www.outlooktherapeutics.com.

Non-GAAP Financial Measure – Adjusted Net Loss Attributable to Common Stockholders

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. 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 Securities and Exchange Commission. In this press release, Outlook Therapeutics uses the NGFM, “adjusted net loss attributable to common stockholders.” Management uses this NGFM because it adjusts for certain transactions management believes are not related to its core business, such as income tax benefits from the sale of state NOLs, impairment losses on property and equipment, losses on lease terminations, or gains or losses on extinguishment of debt, as well as significant non-cash items that impact financial results but not cash flows, such as stock dividends on the Series A-1 Convertible Preferred Stock, deemed dividends upon warrant or convertible note modifications, stock-based compensation expense, depreciation and amortization expense, interest expense, and fair value measurements for equity and debt securities. Management used this NGFM to evaluate Outlook Therapeutics financial performance against internal budgets and targets. Management believes that this NGFM is useful for evaluating Outlook Therapeutics core operating results and facilitating comparison across reporting periods. Outlook Therapeutics believes this NGFM should be considered in addition to, and not in lieu of, GAAP financial measures. Outlook Therapeutics NGFM may be different from the same NGFM used by other companies.

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 statements about the timing of completion of, and pivotal safety and efficacy data from, NORSE 2, statements about Outlook’s other planned clinical trials for ONS-5010, ONS-5010’s potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, including benefits therefrom to patients, payors and physicians, the timing of BLA submission and commercial launch of ONS-5010, and plans for regulatory approvals in other markets. 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, 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.

For additional details on Outlook Therapeutics’ financial performance during the quarter, please see the Outlook Therapeutics filings with the Securities and Exchange Commission.

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

	Three months ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenues	$ -	$ 584	$ -	$ 2,293
Operating expenses:				
Research and development	8,488	4,342	18,719	16,350
General and administrative	3,287	1,835	7,581	6,588
Impairment of property and equipment	104	51	528	2,962
	11,879	6,228#	26,828#	25,900
Loss from operations	(11,879)	(5,644)	(26,828)	(23,607)
Interest expense, net	444	1,082	1,737	3,257
(Gain) loss on extinguishment of debt	(6,164)	424	1,896	607
Change in fair value of redemption feature	-	-	(1,797)	-
Change in fair value of warrant liability	127	(1,931)	(75)	(2,266)
Loss before income taxes	(6,286)	(5,219)	(28,589)	(25,205)
Income tax benefit	(3,271)	(778)	(3,271)	(778)
Net loss	(3,015)	(4,441)	(25,318)	(24,427)
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	-	-	(61)
Series A-1 convertible preferred stock dividends and related settlement	-	(158)	(166)	(463)
Deemed dividend upon modification of warrants	-	-	(3,140)	(830)
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	-	-	(10,328)	-
Net loss attributable to common stockholders	$ (3,015)	$ (4,599)	$ (38,952)	$ (25,781)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.03)	$ (0.20)	$ (0.69)	$ (1.74)
Weighted average shares outstanding, basic and diluted	90,758	23,007	56,089	14,787

Consolidated Balance Sheet Data
(Amounts in thousands)

	June 30, 2020	September 30, 2019
Cash	$ 23,953	$ 8,016
Total assets	$ 30,243	$ 17,135
Current liabilities	$ 18,454	$ 20,290
Series A-1 convertible preferred stock	$ -	$ 5,359
Total stockholders' equity (deficit)	$ 10,965	$ (16,129)

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

	Three months ended June 30,		Nine Months Ended June 30,	
	2020	2019	2020	2019
Net loss attributable to common stockholders, as reported (GAAP)	$ (3,015)	$ (4,599)	$ (38,952)	$ (25,781)
Adjustments for reconciled items:				
Stock-based compensation, non-cash	1,359	(31)	2,023	1,109
Depreciation and amortization	122	833	474	2,473
Non-cash interest expense	100	419	236	1,314
(Gain) loss on extinguishment of debt	(6,164)	423	1,896	607
Change in fair value of redemption feature	-	-	(1,797)	-
Change in fair value of warrant liability	127	(1,931)	(75)	(2,266)
Income tax benefit from sale of New Jersey NOLs	(3,271)	(778)	(3,271)	(778)
Impairment of property and equipment	105	51	528	2,962
Loss on lease termination	680	-	680	-
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	-	-	61
Series A-1 convertible preferred stock dividends and related settlement	-	158	166	463
Deemed dividend upon modification of warrants	-	-	3,140	830
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	-	-	10,328	-
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (9,957)	$ (5,455)	$ (24,624)	$ (19,006)
Net loss attributable to common stockholders per share of common stock - basic and diluted, as reported (GAAP)	$ (0.03)	$ (0.20)	$ (0.69)	$ (1.74)
Adjustments for reconciled items:				
Stock-based compensation, non-cash	0.01	-	0.04	0.07
Depreciation and amortization	0.01	0.04	0.01	0.16
Non-cash interest expense	-	0.01	-	0.09
(Gain) loss on extinguishment of debt	(0.07)	0.02	0.03	0.04
Change in fair value of redemption feature	-	-	(0.03)	-
Change in fair value of warrant liability	-	(0.08)	-	(0.15)
Income tax benefit from sale of New Jersey NOLs	(0.04)	(0.04)	(0.06)	(0.05)
Impairment of property and equipment	-	-	0.01	0.20
Loss on lease termination	0.01	-	0.01	-
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	-	-	-
Series A-1 convertible preferred stock dividends and related settlement	-	0.01	-	0.03
Deemed dividend upon modification of warrants	-	-	0.06	0.06
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	-	-	0.18	-
Adjusted net loss attributable to common stockholders per share of common stock - basic and diluted (non-GAAP)	$ (0.11)	$ (0.24)	$ (0.44)	$ (1.29)