

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, 2020**

Outlook Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37759
(Commission File Number)

38-3982704
(IRS Employer Identification No.)

4260 U.S. Route 1
Monmouth Junction, New Jersey
(Address of principal executive offices)

08852
(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 May 15, 2020, Outlook Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for its second fiscal quarter ended March 31, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 15, 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: May 15, 2020

By: /s/ Lawrence A. Kenyon

Lawrence A. Kenyon

Chief Executive Officer and Chief Financial Officer



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

- **Company remains on track to report topline data results from NORSE 1, its first registration clinical trial evaluating ONS-5010, an investigational ophthalmic formulation of bevacizumab to treat wet AMD, in August 2020**
- **Enrollment in NORSE 2 registration clinical trial remains ongoing and is expected to be completed in calendar Q3 2020**

MONMOUTH JUNCTION, N.J., May 15, 2020 — Outlook Therapeutics, Inc. (Nasdaq: OTLK) (the Company), a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced its corporate highlights and financial results for its fiscal second quarter ended March 31, 2020.

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

“Over the course of the last quarter, we made notable progress amidst navigating the uncertainties of the evolving COVID-19 pandemic. Our team remains focused on advancing our ONS-5010 development program as efficiently and rapidly as possible while focusing on the safety, health and welfare of our employees, clinical trial site providers and the patients in our trials,” said Lawrence A. Kenyon, President, CEO and CFO of the Company. “With the execution of the strategic approach that we took at the beginning of the fiscal year to streamline our capital structure and regain 100% ownership of any future net profits for ONS-5010, coupled with the regulatory approach towards potential approval of ONS-5010 that we continue to advance, I believe Outlook is well-positioned to build stockholder value in the near- and long-term.”

FY Q2 2020 Corporate Highlights

- 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;
 - Closed \$10.2 million equity capital raise through a registered direct offering priced at-the-market and two concurrent private placements; and
 - Entered into strategic agreements with BioLexis Pte. Ltd., its largest stockholder, and MTTR, LLC, its development partner for ONS-5010, to streamline the Company’s capital structure and regain 100% ownership of any future net profits for ONS-5010 to better align the interests of all parties with the Company’s common stockholders and support the continued development of ONS-5010.
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“Through the hard work of our team and the commitment of the medical professionals at our clinical sites, we have been fortunate to be minimally affected by the COVID-19 pandemic,” added Mr. Kenyon. “Our ongoing NORSE 1 registration clinical trial for ONS-5010 remains on track for topline data readout in August of this year, as previously announced. Additionally, enrollment in our ongoing NORSE 2 registration clinical trial has regained momentum at an encouraging rate and we have nearly returned to pre-COVID-19 enrollment rates. We expect to complete enrollment in NORSE 2 in the third calendar quarter of this year and remain focused on successfully executing the milestones ahead, including the data readout of NORSE 1 later this year.”

Recent ONS-5010 / LYTENATM (bevacizumab-vikg) Development Updates

The Company recently announced it received U.S. Food and Drug Administration (FDA) tentative approval of the trade name for ONS-5010 as LYTENATM (bevacizumab-vikg). The trade name is conditionally approved by FDA and will be subject to further review at the time of the Company’s planned filing of a new biologics license application (BLA) with the FDA under the 351(a) PHSA regulatory pathway for LYTENATM (bevacizumab-vikg) in 2021.

The NORSE 1 registration clinical trial completed enrollment in August 2019 and is on pace to report topline data in August 2020. NORSE 1 enrolled a total of 61 patients at nine sites in Australia. NORSE 1 will provide initial safety and efficacy data for ONS-5010 in wet AMD patients for ONS-5010 dosed monthly compared to LUCENTIS® dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing. The Company anticipates reporting data during the third calendar quarter of 2020. At this time, the COVID-19 pandemic is not expected to affect the completion of NORSE 1 and anticipated data readout date.

The NORSE 2 registration clinical trial commenced patient enrollment in July 2019 and is expected to enroll a total of approximately 220 patients at more than 40 clinical trial sites in the United States. NORSE 2 continues to screen, enroll and treat patients, subject to additional COVID-19 safety protocols for both patients and staff at trial sites. Patients in the trial will be treated for 11 months. The primary outcome of the study is a statistically significant difference in the proportion of patients who gain at least 15 letters in the best corrected visual acuity for ONS-5010 over LUCENTIS®. Outlook Therapeutics estimates that, subject to local conditions which have varying degrees of “shelter-in-place” and other similar government orders mandating various restrictions due to COVID-19, enrollment will be completed no later than August of 2020.

The Company intends to complete development of ONS-5010 for submission to the FDA as a new BLA under the 351(a) PHSA regulatory pathway for the treatment of wet AMD. The Company also has plans to submit for regulatory approvals in France, United Kingdom, Italy, Germany, Spain and Japan, as well as other countries. If approved, ONS-5010 will be the first and only on-label ophthalmic formulation of bevacizumab for treating retinal diseases.

Financial Highlights for the Fiscal Second Quarter Ended March 31, 2020

For the fiscal second quarter ended March 31, 2020, the Company reported a net loss attributable to common stockholders of \$17.5 million, or \$0.36 per basic and diluted share, compared to a net loss attributable to common stockholders of \$11.3 million, or \$0.98 per basic and diluted share, for the same period last fiscal year. For the fiscal second quarter ended March 31, 2020, the Company also reported an adjusted net loss attributable to common stockholders of \$6.4 million, or \$0.13 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of \$6.7 million, or \$0.58 per basic and diluted share, for the same period last fiscal year.

Adjusted net loss attributable to common stockholders in the fiscal second quarter ended March 31, 2020 includes \$0.3 million of stock-based compensation expense, \$0.2 million of depreciation and amortization, \$0.1 million of non-cash interest expense, a \$1.8 million decrease in the fair value of redemption feature on convertible notes, \$0.4 million impairment loss on property and equipment, \$1.4 million of deemed dividend upon modification of warrants, and \$10.3 million of deemed dividend upon amendment of terms to Series A-1 convertible preferred stock. For the second quarter of fiscal 2019, adjusted net loss attributable to common stockholders includes \$0.3 million of stock-based compensation expense, \$0.8 million of depreciation and amortization, \$0.4 million of non-cash interest expense, \$0.2 million of loss on extinguishment of debt, a \$1.3 million increase in the fair value of warrant liability, \$0.6 million of impairment loss on property and equipment, \$0.1 million of beneficial conversion feature of Series A-1 convertible preferred stock, a \$0.2 million stock dividend for the Company's Series A-1 convertible preferred stock, and \$0.8 million of deemed dividend upon modification of warrants.

At March 31, 2020, the Company had cash and cash equivalents of \$4.7 million, compared to \$8.0 million at September 30, 2019.

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

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab 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 adequate and well-controlled 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. If approved, ONS-5010 will be the first and only FDA-approved ophthalmic formulation of bevacizumab to treat retinal diseases. The Company currently intends to commercialize ONS-5010 in both vials and single-use pre-filled syringes.

ONS-5010 is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (mAb) that inhibits VEGF and associated angiogenic activity. With wet AMD, abnormally high levels of VEGF are secreted in the eye. VEGF is a protein that promotes the growth of new abnormal blood vessels. 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.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 / LYTENAVA™ (bevacizumab vkg), its investigational ophthalmic formulation of bevacizumab, is approved, Outlook Therapeutics expects to commercialize it as the first and only approved ophthalmic formulation of bevacizumab for use in treating approved retinal diseases in the United States, Europe, Japan and other markets. Outlook Therapeutics expects to file ONS-5010 with the U.S. FDA as a new BLA under the PHS 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 the Company’s core business, such as impairment losses on property and equipment 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 to BioLexis, deemed dividends upon warrant or convertible note modifications, stock-based compensation expense, depreciation and amortization expense, interest expense, and fair value measurements for the Company’s 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 BLA submission and commercial launch of ONS-5010, the ability of ONS-5010 to provide benefits to patients, payors and physicians, and the benefits of having an FDA approved bevacizumab, completion of enrollment in NORSE 2 and any impacts related to the COVID-19 pandemic, timing of announcement of topline data for NORSE 1, timing of the final approval for ONS-5010’s conditionally approved trade name, and the future impacts, if any, of the ongoing COVID-19 pandemic. Although the Company believes that it has a reasonable basis for forward-looking statements contained herein, they are based on current expectations about future events affecting the Company 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 the Company’s 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. The Company 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 the Company’s financial performance during the quarter, please see the Company’s filings with the [Securities and Exchange Commission](#).

CONTACTS:

Outlook Therapeutics:

Lawrence A. Kenyon

LawrenceKenyon@outlooktherapeutics.com

Investor Inquiries:

Jenene Thomas

Chief Executive Officer

JTC Team, LLC

T: 833.475.8247

OTLK@jtcir.com

Media Inquiries:

Emmie Twombly

Media Relations Specialist

LaVoie Health Science

M: 857.389.6042

etwombly@lavoiehealthscience.com

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

	<u>Three months ended March 31,</u>		<u>Six Months Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Collaboration revenues	\$ -	\$ 641	\$ -	\$ 1,709
Operating expenses:				
Research and development	4,383	5,935	10,231	12,008
General and administrative	1,958	1,849	4,294	4,753
Impairment of property and equipment	423	562	423	2,911
	<u>6,764</u>	<u>8,346#</u>	<u>14,948#</u>	<u>19,672</u>
Loss from operations	(6,764)	(7,705)	(14,948)	(17,963)
Interest expense, net	696	1,054	1,294	2,175
Loss on extinguishment of debt	-	184	8,060	184
Change in fair value of redemption feature	(1,759)	-	(1,797)	-
Change in fair value of warrant liability	(1)	1,302	(202)	(335)
Net loss	(5,700)	(10,245)	(22,303)	(19,987)
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	(61)	-	(61)
Series A-1 convertible preferred stock dividends and related settlement	-	(154)	(166)	(305)
Deemed dividend upon modification of warrants	(1,432)	(830)	(3,140)	(830)
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	(10,328)	-	(10,328)	-
Net loss attributable to common stockholders	<u>\$ (17,460)</u>	<u>\$ (11,290)</u>	<u>\$ (35,937)</u>	<u>\$ (21,183)</u>
Per share information:				
Net loss per share of common stock, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.98)</u>	<u>\$ (0.93)</u>	<u>\$ (1.98)</u>
Weighted average shares outstanding, basic and diluted	<u>47,896</u>	<u>11,529</u>	<u>38,849</u>	<u>10,677</u>

Consolidated Balance Sheet Data
(Amounts in thousands)

	<u>March 31,</u>	<u>September 30,</u>
	<u>2020</u>	<u>2019</u>
Cash	\$ 4,653	\$ 8,016
Total assets	\$ 13,170	\$ 17,135
Current liabilities	\$ 23,706	\$ 20,290
Series A-1 convertible preferred stock	\$ -	\$ 5,359
Total stockholders' deficit	\$ (20,525)	\$ (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)

	<u>Three months ended March 31,</u>		<u>Six Months Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net loss attributable to common stockholders, as reported (GAAP)	\$ (17,460)	\$ (11,290)	\$ (35,937)	\$ (21,183)
Adjustments for reconciled items:				
Stock-based compensation, non-cash	305	268	664	1,140
Depreciation and amortization	177	817	352	1,640
Non-cash interest expense	120	445	136	895
Loss on extinguishment of debt	-	184	8,060	184
Change in fair value of redemption feature	(1,759)	-	(1,797)	-
Change in fair value of warrant liability	(1)	1,302	(202)	(335)
Impairment of property and equipment	423	562	423	2,911
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	61	-	61
Series A-1 convertible preferred stock dividends and related settlement	-	154	166	305
Deemed dividend upon modification of warrants	1,432	830	3,140	830
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	10,328	-	10,328	-
Adjusted net loss attributable to common stockholders (non-GAAP)	<u>\$ (6,435)</u>	<u>\$ (6,667)</u>	<u>\$ (14,667)</u>	<u>\$ (13,552)</u>
Net loss attributable to common stockholders per share of common stock - basic and diluted, as reported (GAAP)	\$ (0.36)	\$ (0.98)	\$ (0.93)	\$ (1.98)
Adjustments for reconciled items:				
Stock-based compensation, non-cash	0.01	0.02	0.02	0.11
Depreciation and amortization	-	0.07	0.01	0.15
Non-cash interest expense	-	0.04	-	0.08
Loss on extinguishment of debt	-	0.02	0.21	0.02
Change in fair value of redemption feature	(0.04)	-	(0.05)	-
Change in fair value of warrant liability	-	0.11	(0.01)	(0.03)
Impairment of property and equipment	0.01	0.05	0.01	0.27
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	0.01	-	0.01
Series A-1 convertible preferred stock dividends and related settlement	-	0.01	-	0.03
Deemed dividend upon modification of warrants	0.03	0.07	0.08	0.08
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	0.22	-	0.27	-
Adjusted net loss attributable to common stockholders per share of common stock - basic and diluted (non-GAAP)	<u>\$ (0.13)</u>	<u>\$ (0.58)</u>	<u>\$ (0.39)</u>	<u>\$ (1.26)</u>