Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Financial Results for First Quarter Fiscal Year 2021 and Provides Corporate Update

February 16, 2021

- **Topline data from pivotal Phase 3 safety and efficacy study (NORSE TWO) on target to report in Q3 2021**
- **Topline data from the open-label safety study (NORSE THREE) on target to report in Q2 2021**
- **Recent funding significantly enhances financial position, extends cash runway through BLA filing and provides strategic optionality to maximize stockholder value**

MONMOUTH JUNCTION, N.J., Feb. 16, 2021 (GLOBE NEWSWIRE) -- 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 recent corporate highlights and financial results for its fiscal first quarter ended December 31, 2020.

Outlook Therapeutics also provided a clinical development and pre-commercialization 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.

"As we look forward to what we believe will be an exciting year at Outlook Therapeutics, I am proud of our team and the tremendous progress we have made, despite the challenges from the current pandemic. Outlook Therapeutics continues to advance ONS-5010 on multiple fronts as we work towards a BLA filing for ONS-5010 for wet AMD. On the clinical side, two of the three clinical trials for our planned BLA for wet AMD are now completed. With the cash proceeds received from our successful recent capital raise, we are now focused on the topline data readouts expected over the next two quarters, and completing the CMC work for the BLA submission, expected in December of this year," commented Lawrence A. Kenyon, President, CEO and CFO of Outlook Therapeutics. "We believe we now have the necessary resources to support our continued development efforts as we evaluate our options for the best path forward to commercialize ONS-5010 and provide the greatest value to our stockholders."

Recent Corporate Highlights

- Secured aggregate gross proceeds in February 2021 of $42.6 million to support ONS-5010 / LYTENAVA ™ providing funding through planned Biologics License Application (BLA) submission;
- Reported final visit for last patient in open-label safety study (NORSE THREE) of ONS-5010 / LYTENAVA™ (bevacizumab-vikg) in February 2021; and
- Announced the formation of a Global Retina Advisory Council in November 2020 to collaborate on outreach to retinal clinicians to support development and commercialization of ONS-5010 / LYTENAVA ™ .

Financial Highlights for the Fiscal First Quarter Ended December 31, 2020

For the fiscal first quarter ended December 31, 2020, Outlook Therapeutics reported a net loss attributable to common stockholders of $14.5 million, or $0.12 per basic and diluted share, compared to a net loss attributable to common stockholders of $18.5 million, or $0.62 per basic and diluted share for the same period last year. For the fiscal first quarter ended December 31, 2020, Outlook Therapeutics also reported an adjusted net loss attributable to common stockholders of $13.7 million, or $0.11 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $8.2 million, or $0.28 per basic and diluted share for the same period last year.

Adjusted net loss attributable to common stockholders in the fiscal first quarter ended December 31, 2020 excludes $1.2 million of stock-based compensation expense, $0.1 million of depreciation and amortization, $0.1 million of non-cash interest expense, a $0.1 million change in the fair value of warrant liability, and $0.7 million gain on settlement of lease termination obligation. For the fiscal first quarter ended December 31, 2019, adjusted net loss attributable to common stockholders excludes $0.4 million of stock-based compensation expense, $0.2 million of depreciation and amortization, $8.1 million loss on extinguishment of debt, $0.2 million change in the fair value of warrant liability, $0.2 million of Series A-1 Convertible Preferred Stock dividends and $1.7 million of deemed dividend from modification of warrants.

At December 31, 2020, Outlook Therapeutics had cash and cash equivalents of $5.6 million, compared to $12.5 million at September 30, 2020. With the $42.6 million in gross proceeds received from the public offerings and private placements of common stock in February 2021, plus an additional $3.6 million received from warrant exercises also in February 2021, Outlook Therapeutics cash and cash equivalents on hand are sufficient to fund operations through the planned ONS-5010 BLA submission for wet AMD in late 2021.

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

Outlook Therapeutics completed patient enrollment in its pivotal Phase 3 (NORSE TWO) clinical trial in July 2020, enrolling a total of 228 patients at 39 clinical trial sites in the United States. Patients in the trial are being treated for 12 months. The primary endpoint for the study 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.

Outlook Therapeutics recently announced the final visit of the last patient for its open-label safety study (NORSE THREE). The study enrolled a total of 197 subjects with a range of retinal diseases for which an anti-VEGF drug is a therapeutic option, including wet AMD, diabetic macular edema (DME) and branch retinal vein occlusion (BRVO). Subjects enrolled in the study received three monthly intravitreal doses of ONS-5010 / LYTENAVA™. The

data from this study are expected to be reported in the second quarter of calendar 2021 and will be included in the complete data package to support the planned BLA for wet AMD, on schedule for submission to the U. S. Food and Drug Administration (FDA) in the fourth quarter of calendar 2021.

Following the data readout from both the open-label safety study and the pivotal safety and efficacy study, Outlook Therapeutics plans to submit a new BLA filing to the FDA under the PHSA 351(a) regulatory pathway. If the BLA is approved, it will result in 12 years of marketing exclusivity for ONS-5010.

Commercial launch planning has begun, including distribution, physician and patient outreach, key opinion leader support and payor community engagement. With an enhanced safety and cost-effectiveness profile, Outlook Therapeutics expects ONS-5010, if approved, to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated "step edit" in the United States for retinal indications.

In addition to the clinical development plan 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 BRVO (NORSE FOUR), and two planned registration clinical trials evaluating ONS-5010 for the treatment of DME (NORSE FIVE and NORSE SIX). Outlook Therapeutics expects to initiate registration clinical trials for ONS-5010 for DME and BRVO later in 2021.

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. 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 pharmacists, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 will reduce the need for use of unapproved repackaged IV bevacizumab from compounding pharmacists for retinal disease.

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 lead to loss of vision. 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 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 a range of retinal diseases in the United States, United Kingdom, Europe, Japan, China 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, initially for wet AMD. 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 gains on lease terminations, or losses on extinguishment of debt, as well as significant non-cash items that impact financial results but not cash flows, such as stock-based compensation expense, depreciation and amortization expense, interest expense, fair value measurements for equity and debt securities, stock dividends on the Series A-1 Convertible Preferred Stock and deemed dividends upon warrant modifications. Management uses 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 "expect," "plan," "anticipate," "may," "might," "will," "should," "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 TWO, timing of topline data from NORSE THREE, the cash runway and the timing of BLA submission, including completion of CMC work, plans for the Global Retina Advisory Council, statements about Outlook Therapeutics' 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, including expectations regarding market exclusivity, as well as 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 December 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 11,949	$ 5,847
General and administrative	2,242	2,337
	14,191	8,184
Loss from operations	(14,191)	(8,184)
Interest expense, net	160	598
Loss on extinguishment of debt	-	8,060
Change in fair value of redemption feature	-	(38)
Change in fair value of warrant liability	105	(201)
Net loss	(14,456)	(16,603)
Series A-1 convertible preferred stock dividends and related settlement	-	(166)
Deemed dividend upon modification of warrants	-	(1,709)
Net loss attributable to common stockholders	$ (14,456)	$ (18,478)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.12)	$ (0.62)
Weighted average shares outstanding, basic and diluted	121,750	29,901

Consolidated Balance Sheet Data
(Amounts in thousands)

	December 31, 2020	**September 30, 2020**
Cash	$ 5,568	$ 12,536
Total assets	$ 12,518	$ 19,733
Current liabilities	$ 12,123	$ 15,889
Total stockholders' equity (deficit)	$ (10,475)	$ 2,826

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 December 31,	
	2020	**2019**
Net loss attributable to common stockholders, as reported (GAAP)	$ (14,456)	$ (18,478)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	1,155	359
Depreciation and amortization	81	175
Non-cash interest expense	149	16
Loss on extinguishment of debt	-	8,060
Change in fair value of redemption feature	-	(38)
Change in fair value of warrant liability	105	(201)
Gain on settlement of lease termination obligation	(732)	-
Series A-1 convertible preferred stock dividends and related settlement	-	166
Deemed dividend upon modification of warrants	-	1,709
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (13,698)	$ (8,232)
Net loss attributable to common stockholders per share of common stock - basic and diluted, as reported (GAAP)	$ (0.12)	$ (0.62)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	0.01	0.01
Depreciation and amortization	-	0.01
Non-cash interest expense	0.01	-
Loss on extinguishment of debt	-	0.26
Change in fair value of warrant liability	-	(0.01)
Gain on settlement of lease termination obligation	(0.01)	-
Series A-1 convertible preferred stock dividends and related settlement	-	0.01
Deemed dividend upon modification of warrants	-	0.06
Adjusted net loss attributable to common stockholders per share of common stock - basic and diluted (non-GAAP)	$ (0.11)	$ (0.28)

OUTLOOK THERAPEUTICS

Source: Outlook Therapeutics, Inc.