Outlook Therapeutics, Inc. Logo

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

May 14, 2021

- **Topline efficacy and safety data from pivotal Phase 3 NORSE TWO study on target to report in calendar Q3 2021**
- **Recently reported topline data from the NORSE THREE open-label safety study reinforce positive safety profile of ONS-5010 seen in the earlier clinical experience trial (NORSE ONE)**

ISELIN, N.J., May 14, 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 for use in retinal indications, today announced recent corporate highlights and financial results for its fiscal second quarter ended March 31, 2021.

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

"Outlook Therapeutics continues to advance ONS-5010 towards a BLA filing for wet AMD. Having reported promising results from two of the three clinical trials for our planned BLA, we are now in the home stretch and focused on the topline data readout next quarter from NORSE TWO, our pivotal Phase 3 study," commented Lawrence A. Kenyon, President, CEO and CFO of Outlook Therapeutics. "Additionally, with the funds raised in February, we are well positioned to complete NORSE TWO and prepare the BLA. We are excited about the upcoming clinical milestones and look forward to providing future updates as we continue to advance ONS-5010."

Recent Corporate Highlights

- Reported positive topline results from the open-label safety study (NORSE THREE), which demonstrated that ONS-5010 showed no unexpected safety trends and had a safety profile consistent with that of prior published data on the use of bevacizumab for ophthalmic conditions, such as the 2011 CATT study undertaken by the National Eye Institute; and
- Received aggregate gross proceeds of $46.2 million from public offerings and private placements of common stock plus warrant exercises in February 2021.

Financial Highlights for the Fiscal Second Quarter Ended March 31, 2021

For the fiscal second quarter ended March 31, 2021, Outlook Therapeutics reported a net loss attributable to common stockholders of $13.1 million, or $0.09 per basic and diluted share, compared to a net loss attributable to common stockholders of $17.5 million, or $0.36 per basic and diluted share for the same period last year.

At March 31, 2021, Outlook Therapeutics had cash and cash equivalents of $37.2 million, compared to $5.6 million at December 31, 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 November 2021.

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

In March 2021, Outlook Therapeutics announced topline results from its NORSE THREE open-label safety study evaluating ONS-5010 to treat retinal diseases. Topline results from that study demonstrated that ONS-5010 showed no unexpected safety trends and had a safety profile consistent with that of prior published data on the use of bevacizumab for ophthalmic conditions, such as the 2011 CATT study undertaken by the National Eye Institute. The safety endpoints for NORSE THREE were the frequency and incidence of treatment-emergent adverse events and an evaluation of changes in safety parameters. In the study, 20 out of 197 patients (10%) experienced an adverse event in the study eye that were most commonly associated with the injection procedure and not ONS-5010. There were no serious adverse events associated with treatment. Notably, there were zero cases of ocular inflammation, a concern that has emerged for some other anti-VEGF (Vascular Endothelial Growth Factor) therapies used to treat retinal conditions.

Outlook Therapeutics completed patient enrollment for its pivotal Phase 3 clinical trial (NORSE TWO) 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 quarter of calendar 2021.

Following the data readout of the pivotal NORSE TWO safety and efficacy study next quarter, Outlook Therapeutics plans to submit a new biologics license application (BLA) filing under the PHSA 351(a) regulatory pathway in the first quarter of calendar 2022. If the BLA is approved, it will result in 12 years of marketing exclusivity for ONS-5010 as the first and only ophthalmic formulation of bevacizumab to treat wet AMD approved by the U.S. Food and Drug Administration (FDA).

Commercial launch planning for ONS-5010 has begun, including manufacturing, distribution, physician and patient outreach, and engagement with key opinion leaders and the payor community. With potential for an enhanced safety and cost-effectiveness profile, ONS-5010, if approved, is well positioned to become the first-line drug of choice in the United States for retinal indications and to be widely adopted by payors and clinicians

worldwide in the $13.1 billion global anti-VEGF market.

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 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). Outlook Therapeutics expects to initiate registration clinical trials for ONS-5010 for DME and BRVO later in calendar 2021 or in early calendar 2022.

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

ONS-5010 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) as the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. 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 a range of retinal diseases in the United States, United Kingdom, Europe, Japan, China and other markets. Outlook Therapeutics expects to file ONS-5010 ophthalmic bevacizumab 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.

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 topline data from, NORSE TWO, , Outlook Therapeutics’ cash runway, plans for BLA submission, , statements about Outlook Therapeutics’ other planned clinical trials for ONS-5010, ONS-5010’s potential as the first FDA-approved ophthalmic formulation of bevacizumab, 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 March 31,		Six months ended March 31,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 8,529	$ 4,383	$ 20,478	$ 10,231
General and administrative	4,096	1,958	6,338	4,294
Impairment of property and equipment	-	423	-	423
	12,625	6,764	26,816	14,948
Loss from operations	(12,625)	(6,764)	(26,816)	(14,948)
Interest expense, net	251	696	410	1,294
Loss on extinguishment of debt	-	-	-	8,060
Change in fair value of redemption feature	-	(1,759)	-	(1,797)
Change in fair value of warrant liability	229	(1)	334	(202)
Loss before income taxes	(13,105)	(5,700)	(27,560)	(22,303)
Income tax expense	2	-	2	-
Net loss	(13,107)	(5,700)	(27,562)	(22,303)
Series A-1 convertible preferred stock dividends and related settlement	-	-	-	(166)
Deemed dividend upon modification of warrants	-	(1,432)	-	(3,140)
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	$ (13,107)	$ (17,460)	$ (27,562)	$ (35,937)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.09)	$ (0.36)	$ (0.20)	$ (0.93)
Weighted average shares outstanding, basic and diluted	150,730	47,896	136,081	38,849

Consolidated Balance Sheet Data

(Amounts in thousands)

	March 31, 2021	September 30, 2020
Cash	$ 37,169	$ 12,536
Total assets	$ 45,112	$ 19,733
Current liabilities	$ 23,898	$ 15,889
Total stockholders' equity (deficit)	$ 20,651	$ 2,826

OUTLOOK THERAPEUTICS

Source: Outlook Therapeutics, Inc.