

Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Provides Business Update and Reports Financial Results for the First Quarter of Fiscal Year 2020

February 14, 2020

First clinical trial results from the Phase 3 development program for ONS-5010 expected in six months

CRANBURY, N.J., Feb. 14, 2020 (GLOBE NEWSWIRE) -- 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 business highlights and financial results for its fiscal first quarter ended December 31, 2019.

"This will be an exciting year for our company as we continue to advance towards our goal of a new BLA submission to the FDA for ONS-5010 in 2021 and, if approved, a commercial launch in 2022. Once achieved, these milestones will allow us to move forward with our priority to provide patients with the safety and efficacy of the first and only FDA-approved, responsibly priced ophthalmic formulation of bevacizumab," said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer. "We are pleased to report that our Phase 3 development program for ONS-5010 continues to make progress, including ongoing patient recruitment for the NORSE 2 study, which is expected to be completed by the end of May 2020. In addition, we plan to announce the topline data for the NORSE 1 study in August 2020."

Recent ONS-5010 Highlights

The Phase 3 clinical development program for ONS-5010 consists of two ongoing clinical trials, NORSE 1 and NORSE 2, to evaluate ONS-5010 against ranibizumab (LUCENTIS®) for wet age-related macular degeneration (wet AMD).

The Company expects to announce a readout of the topline results from NORSE 1 in August 2020. The NORSE 1 study, which completed enrollment in August 2019, includes a total of 61 patients at nine sites in Australia. The endpoint for the study is the difference in mean change from baseline visual acuity at 11 months for ONS-5010 dosed on a monthly basis compared to LUCENTIS dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing. NORSE 1 will provide initial safety and efficacy data for ONS-5010 in wet AMD patients.

The Company is currently enrolling patients in the NORSE 2 trial, and is expected to enroll a total of approximately 220 patients at more than 40 clinical trial sites in the United States. Patients in the trial will be treated for 11 months. In agreement with the FDA, the primary outcome of the study has been changed to 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, from the mean change in baseline in visual acuity. The new study endpoint had previously been included in NORSE 2 as the key secondary endpoint, and is a standard measure of success for the treatment of wet AMD that is expected to further enhance the probability for a positive outcome in the trial.

In addition, the Company has received agreements from the FDA on three Special Protocol Assessments (SPAs) for three additional registration clinical trials for its ongoing Phase 3 program for ONS-5010. These SPAs cover the protocols for NORSE 4, a registration clinical trial to treat branch retinal vein occlusion (BRVO), and NORSE 5 and NORSE 6, two registration clinical trials to treat diabetic macular edema (DME).

The Company intends to complete development of ONS-5010 for submission to the FDA as a new Biologics License Application (BLA) for the treatment of wet AMD, DME and BRVO. If successful, the ONS-5010 clinical program will support Outlook Therapeutics' plan to submit for regulatory approvals in the United States, France, United Kingdom, Italy, Germany, Spain and Japan, as well as other countries. If approved, ONS-5010 would be the first and only on-label ophthalmic formulation of bevacizumab for treating retinal diseases.

Recent Corporate Highlights

The Company recently announced entering into agreements with BioLexis Pte. Ltd. (BioLexis), its largest stockholder, and MTTR, LLC (MTTR), 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. Details of these agreements can be found in the Company's current report on Form 8-K, which was filed with the Securities and Exchange Commission on January 31, 2020. The Company intends to seek the requisite stockholder approvals under these agreements at its 2020 Annual Meeting of Stockholders scheduled to be held on March 19, 2020.

The Company believes that these agreements will better align the interests of all parties with the Company's common stockholders and support the continued development of ONS-5010.

Financial Highlights for the Fiscal First Quarter Ended December 31, 2019

For the fiscal first quarter ended December 31, 2019, the Company reported a net loss attributable to common stockholders of \$18.5 million, or \$0.62 per basic and diluted share, compared to a net loss attributable to common stockholders of \$9.9 million, or \$1.00 per basic and diluted share, for the same period last year. For the fiscal first quarter ended December 31, 2019, the Company reported an adjusted net loss attributable to common stockholders of \$8.2 million, or \$0.28 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of \$6.9 million, or \$0.70 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, 2019 includes \$0.4 million of stock-based compensation expense, \$0.2 million of depreciation and amortization, \$8.1 million of loss on extinguishment of debt, a \$0.2 million decrease in the fair value of warrant liability, \$0.2 million stock dividend for the Company's Series A-1 convertible preferred stock, and \$1.7 million of deemed dividend upon modification of warrants. For the first quarter of fiscal 2019, adjusted net loss attributable to common stockholders includes \$0.9 million of stock-based compensation expense, \$0.8 million of depreciation and amortization, \$0.5 million of non-cash interest expense, a \$1.6 million decrease in the fair value of warrant liability, \$2.3 million of impairment loss on property and equipment, and a \$0.2 million stock dividend for the Company's Series A-1 convertible preferred stock.

At December 31, 2019, the Company had cash of \$1.3 million, compared to \$8.0 million at September 30, 2019.

Important Additional Information Will be Filed with the SEC

This communication may be deemed to be solicitation material. The Company intends to file a definitive proxy statement for the 2020 Annual Meeting of Stockholders with the SEC, which will be mailed to stockholders. The Company may file other documents with the SEC in connection with the 2020 Annual Meeting and the proposed transactions. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND STOCKHOLDERS OF THE COMPANY ARE URGED TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY BECAUSE THEY CONTAIN, OR WILL CONTAIN, IMPORTANT INFORMATION ABOUT THE COMPANY, THE PROPOSED TRANSACTIONS, THE 2020 ANNUAL MEETING OF STOCKHOLDERS AND RELATED MATTERS. Investors and stockholders may obtain free copies of the documents filed with the SEC through the website maintained by the SEC at www.sec.gov or at the Company's website at www.outlooktherapeutics.com. Investors and stockholders may also obtain free copies of the documents filed by the Company with the SEC by contacting the Company by mail at Outlook Therapeutics, Inc., 7 Clarke Drive, Cranbury, NJ 08512, Attention: Corporate Secretary. Investors and stockholders are urged to read the proxy statement and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transactions.

Participants in the Solicitation

Outlook Therapeutics, Inc. and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of the Company in connection with the proposed transactions described above. Information regarding the interests of the directors and executive officers in the proposed transactions will be included in the proxy statement that Outlook Therapeutics, Inc. intends to file for its 2020 Annual Meeting of Stockholders. These documents are available free of charge from the sources indicated above.

About ONS-5010

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. ONS-5010 is currently being evaluated in two adequate and well-controlled registration clinical trials for wet AMD (NORSE 1 and 2) and, if successful, is expected to be submitted to the FDA as a new BLA for this ophthalmic indication. If approved, ONS-5010 would 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.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (or 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, its investigational ophthalmic formulation of bevacizumab, is approved, Outlook Therapeutics expects to commercialize it as the first and only on-label approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, Europe, Japan and other markets. Outlook Therapeutics is listed on the Nasdaq Capital Market (NASDAQ: OTLK). 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 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, timing of announcement of topline data for NORSE 1 and the effects of recent agreements with BioLexis and MTTR, including ability to obtain necessary stockholder approvals. 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. 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
Chief Executive Officer and Chief Financial Officer

LawrenceKenyon@outlooktherapeutics.com

Media Inquiries:

Emmie Twombly
Media Relations Specialist
LaVoie Health Science

M: 857.389.6042

etwombly@lavoiehealthscience.com

Investor Inquiries:

Jeremy Feffer
Managing Director
LifeSci Advisors, LLC

T: 212.915.2568

jeremy@lifesciadvisors.com

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

	Three months ended December	
	31,	
	2019	2018
	\$	\$
Collaboration revenues	-	1,068
Operating expenses:		
Research and development	5,847	6,072
General and administrative	2,337	2,904
Impairment of property and equipment	-	2,349
	<u>8,184</u>	<u>11,325</u>
Loss from operations	(8,184)	(10,257)
Interest expense, net	598	1,121
Loss on extinguishment of debt	8,060	-
Change in fair value of redemption feature	(38)	-
Change in fair value of warrant liability	(201)	(1,636)
Net loss	(16,603)	(9,742)
Series A-1 convertible preferred stock dividends and related settlement	(166)	(150)
Deemed dividend upon modification of warrants	(1,709)	-
Net loss attributable to common stockholders	<u>\$ (18,478)</u>	<u>\$ (9,892)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (0.62)</u>	<u>\$ (1.00)</u>
Weighted average shares outstanding, basic and diluted	<u>29,901</u>	<u>9,844</u>

Consolidated Balance Sheet Data
(Amounts in thousands)

December 31, September 30,

	2019	2019
Cash	\$ 1,334	\$ 8,016
Total assets	\$ 10,423	\$ 17,135
Current liabilities	\$ 20,100	\$ 20,290
Series A-1 convertible preferred stock	\$ 5,526	\$ 5,359
Total stockholders' deficit	\$ (30,932)	\$ (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 December 31,	
	2019	2018
Net loss attributable to common stockholders, as reported (GAAP)	\$ (18,478)	\$ (9,892)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	359	872
Depreciation and amortization	175	823
Non-cash interest expense	16	450
Loss on extinguishment of debt	8,060	—
Change in fair value of redemption feature	(38)	—
Change in fair value of warrant liability	(201)	(1,636)
Impairment of property and equipment	—	2,349
Series A-1 convertible preferred stock dividends	166	150
Deemed dividend upon modification of warrants	1,709	—
Adjusted net loss attributable to common stockholders (non-GAAP)	<u>\$ (8,232)</u>	<u>\$ (6,884)</u>
Net loss attributable to common stockholders per share of common stock - basic and diluted, as reported (GAAP)	\$ (0.62)	\$ (1.00)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	0.01	0.08
Depreciation and amortization	0.01	0.08
Non-cash interest expense	—	0.05
Loss on extinguishment of debt	0.26	—
Change in fair value of redemption feature	—	—
Change in fair value of warrant liability	(0.01)	(0.17)
Impairment of property and equipment	—	0.24
Series A-1 convertible preferred stock dividends	0.01	0.02
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)	<u>\$ (0.28)</u>	<u>\$ (0.70)</u>



Source: Outlook Therapeutics, Inc.