

Outlook Therapeutics Provides Business Update and Reports Financial Results for Fiscal Year 2019

December 19, 2019

- *Topline results from the NORSE 1 study of ONS-5010 expected to be announced in the third quarter of calendar 2020*
- *Enrollment in the NORSE 2 study underway*
- *SPA agreement reached with FDA for NORSE 4, 5 and 6 studies*

CRANBURY, N.J., Dec. 19, 2019 (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 year ended September 30, 2019.

Recent Highlights:

- Completed patient enrollment in the NORSE 1 study for ONS-5010, an investigational ophthalmic formulation of bevacizumab, in wet age-related macular degeneration (wet AMD); topline results expected to be announced in the third quarter of calendar 2020
- Initiated dosing of patients in the NORSE 2 study for ONS-5010 in wet AMD; topline results expected to be announced in the first quarter of calendar 2021
- Announced agreement with U.S. Food and Drug Administration ("FDA") on Special Protocol Assessments ("SPAs") for clinical trial protocols for NORSE 4 for branch retinal vein occlusion ("BRVO") and NORSE 5 and NORSE 6 for diabetic macular edema ("DME")

"We continue to execute against our Phase 3 clinical program for ONS-5010, and remain on track with our goal of a commercial launch in 2022, pending the successful outcome of our trials and approval by FDA," said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer. "We saw great progress in 2019. As we continue to make progress, 2020 will also be an important year for Outlook Therapeutics and the ONS-5010 program as we continue our efforts to provide patients and their physicians with an FDA-approved, responsibly priced, ophthalmic formulation of bevacizumab."

Recent ONS-5010 Highlights

In the fourth quarter of fiscal 2019, the Company announced that the NORSE 1 study completed enrollment with a total of 61 patients at nine sites in Australia. The study is the first of two ongoing adequate and well-controlled registration clinical trials evaluating ONS-5010 against ranibizumab (LUCENTIS[®]) for wet AMD. The endpoint for the study is a mean change in baseline visual acuity at 11 months for ONS-5010 dosed on a monthly basis compared to ranibizumab dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing. The Company expects to announce a readout of the topline results from NORSE 1 in the third quarter of calendar 2020.

During the quarter, the Company began dosing patients in the NORSE 2 trial, the second of the two ongoing adequate and well-controlled registration clinical trials evaluating ONS-5010 against ranibizumab for wet AMD. The study is expected to enroll a total of approximately 220 patients at more than 40 clinical trial sites in the United States. Patients enrolled in the trial will be treated for 11 months. The primary outcome of the study is a statistically significant improvement in mean visual acuity of five letters or more for ONS-5010 over ranibizumab.

Outlook Therapeutics recently received an agreement from the FDA on three SPAs for three additional registration clinical trials for the ongoing Phase 3 program for ONS-5010. The agreements reached with the FDA on these SPAs cover the protocols for NORSE 4, a registration clinical trial to treat BRVO, and NORSE 5 and NORSE 6, two registration clinical trials to treat DME.

The Company intends to complete development of ONS-5010 for submission to the FDA as a 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. If approved, ONS-5010 would be the first and only on-label ophthalmic formulation of bevacizumab for treating retinal diseases.

Financial Highlights for the Fiscal Year Ended September 30, 2019

For the fiscal year ended September 30, 2019, the Company reported a net loss attributable to common stockholders of \$36.0 million, or \$1.98 per basic and diluted share, compared to a net loss attributable to common stockholders of \$48.0 million, or \$9.74 per basic and diluted share, for fiscal year 2018. For the fiscal year ended September 30, 2019, the Company reported an adjusted net loss attributable to common stockholders of \$22.5 million, or \$1.24 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of \$29.9 million, or \$6.06 per basic and diluted share, in fiscal year 2018.

Adjusted net loss attributable to common stockholders in fiscal year 2019 includes \$1.3 million of stock-based compensation expense, \$3.4 million of depreciation and amortization, \$1.3 million of non-cash interest expense, \$0.6 million of loss on extinguishment of debt, a \$2.4 million decrease in the fair value of warrant liability, \$11.3 million of impairment loss on property and equipment, \$3.4 million of income tax benefit from the sale of state tax NOLs, \$0.1 million of beneficial conversion recognition for the Company's Series A-1 convertible preferred stock, \$0.6 million stock dividend for the Company's Series A-1 convertible preferred stock, and \$0.8 million of deemed dividend upon modification of warrants. For fiscal year 2018, adjusted net loss attributable to common stockholders includes \$2.0 million of stock-based compensation expense, \$3.1 million of depreciation and amortization, \$1.3 million of non-cash interest expense, a \$1.3 million loss on extinguishment of debt, a \$1.0 million decrease in the fair value of warrant liability, \$3.2 million of income tax benefit from the sale of state tax NOLs, \$16.0 million of beneficial conversion recognition for the Company's Series A and A-1 convertible preferred stock, a \$1.9 million stock dividend for the Company's Series A and Series A-1 convertible preferred stock, and \$3.2 million from the settlement of a clinical development contract.

At September 30, 2019, the Company had cash of \$8.0 million, compared to \$1.7 million at September 30, 2018.

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 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, and sales of state of New Jersey NOLs, as well as significant non-cash items that impact financial results but not cash flows, such as stock dividends on the Series A and 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, as well as recognition of a beneficial conversion feature on the Series A and Series A-1 Convertible Preferred Stock, and the effects of settlement of a clinical development contract. 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 Company’s expected announcement of topline data for NORSE 1 and NORSE 2, plans for timing of commercial launch of ONS-5010, including the outcome of clinical trials for ONS-5010 and FDA approval, its ability to build clinical data for ONS-5010 and plans for seeking regulatory approval for ONS-5010, the ability of ONS-5010 to provide benefits to patients, payors and physicians, and the benefits of having an FDA approved bevacizumab. 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](http://www.sec.gov).

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

	Year Ended September 30,	
	2019	2018
Collaboration revenues	\$ 8,146	\$ 3,088
Operating expenses:		
Research and development	23,805	18,504
General and administrative	9,370	14,228
Impairment of property and equipment	11,270	-
	<u>44,445</u>	<u>32,732</u>
Loss from operations	(36,299)	(29,644)
Interest expense, net	3,467	3,891
Loss on extinguishment of debt	607	1,253
Change in fair value of warrant liability	(2,438)	(1,048)
Loss before income taxes	<u>(37,935)</u>	<u>(33,740)</u>
Income tax (benefit) expense	(3,411)	(3,648)
Net loss	<u>(34,524)</u>	<u>(30,092)</u>
Recognition of beneficial conversion feature upon sale of Series A and A-1 preferred stock	(61)	(16,023)
Series A and A-1 convertible preferred stock dividends and related settlement	(625)	(1,904)
Deemed dividend upon modification of warrants	(830)	-
Net loss attributable to common stockholders	<u>\$ (36,040)</u>	<u>\$ (48,019)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	<u>\$ (1.98)</u>	<u>\$ (9.74)</u>
Weighted average shares outstanding, basic and diluted	<u>18,192</u>	<u>4,932</u>

Consolidated Balance Sheet Data
(Amounts in thousands)

	September 30,	
	2019	2018
Cash	\$ 8,016	\$ 1,717
Total assets	\$ 17,135	\$ 22,283
Current liabilities	\$ 20,290	\$ 32,042
Series A and A-1 convertible preferred stock	\$ 5,359	\$ 4,734
Total stockholders' deficit	\$ (16,129)	\$ (25,545)

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

	Year Ended September 30,	
	2019	2018
Net loss attributable to common stockholders, as reported (GAAP)	\$ (36,040)	\$ (48,019)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	1,313	1,986
Depreciation and amortization	3,362	3,054
Non-cash interest expense	1,314	1,316
Loss on extinguishment of debt	607	1,253
Change in fair value of warrant liability	(2,438)	(1,048)
Impairment of property and equipment	11,270	-
Income tax benefit from sale of New Jersey NOLs	(3,414)	(3,151)
Recognition of Series A and A-1 beneficial conversion feature	61	16,023
Series A and A-1 convertible preferred dividends	625	1,904
Deemed dividend upon modification of warrants	830	-
Settlement of clinical development contract	-	(3,229)
Adjusted net loss attributable to common stockholders (non-GAAP)	\$ (22,510)	\$ (29,911)
Net loss attributable to common stockholders per share of common stock - diluted, as reported (GAAP)	\$ (1.98)	\$ (9.74)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	0.07	0.40
Depreciation and amortization	0.18	0.62
Non-cash interest expense	0.07	0.27
Loss on extinguishment of debt	0.03	0.25
Change in fair value of warrant liability	(0.13)	(0.21)
Impairment of property and equipment	0.63	-
Income tax benefit from sale of New Jersey NOLs	(0.19)	(0.64)
Recognition of Series A and A-1 beneficial conversion feature	-	3.25
Series A and A-1 convertible preferred dividends	0.03	0.39
Deemed dividend upon modification of warrants	0.05	-
Settlement of clinical development contract	-	(1)
Adjusted net loss attributable to common stockholders per share of common stock - diluted (non-GAAP)	\$ (1.24)	\$ (6.06)



Source: Outlook Therapeutics, Inc.