

Outlook Therapeutics Provides Business Update and Reports Financial Results for Third Quarter of Fiscal 2019

August 14, 2019

CRANBURY, N.J., Aug. 14, 2019 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (NASDAQ: OTLK) (the "Company") today reported business highlights and financial results for its third quarter ended June 30, 2019.

Recent Highlights:

- NORSE 2 (formerly "ONS-5010-002") Phase 3 clinical trial begins dosing patients
- NORSE 1 (formerly "ONS-5010-001") Phase 3 clinical trial nears completion of enrollment
- FUJIFILM Diosynth Biotechnologies selected as ONS-5010 global manufacturing partner

"We continue to make steady progress advancing our ONS-5010 clinical program. With the dosing of patients now occurring in the NORSE 2 Phase 3 clinical trial, the ONS-5010 program remains on schedule with our regulatory approval plan, including submitting a Biologics License Application submission to the FDA in 2020," said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer. "I am confident that our engagement of FUJIFILM Diosynth Biotechnologies as the global producer of ONS-5010 puts us in a stronger position for commercialization as we look past the clinical development program and towards seeking regulatory approvals."

Recent ONS-5010 Highlights

The Company recently began dosing patients in the NORSE 2 trial, the second of the two ongoing adequate and well controlled Phase 3 clinical trials evaluating ONS-5010 against ranibizumab (Lucentis®) for wet age related macular degeneration (wet AMD). The trial is expected to enroll a total of 220 patients 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.

Enrollment in NORSE 1, the first Phase 3 clinical trial for ONS-5010 in wet AMD patients, is expected to complete enrollment in Australia in August 2019. A total of 59 of the 60 patients have been enrolled in this trial and the Company expects to announce primary data in the third quarter of calendar 2020.

In June 2019, the Company signed a master services agreement with FUJIFILM Diosynth Biotechnologies (FDB) for the global production of ONS-5010. Under the terms of this agreement, FDB will provide global manufacturing of ONS-5010 in support of the Company's commercialization strategy for the drug.

If the ONS-5010 clinical program is successful, it will support the Company's plan to submit the drug for regulatory approval in multiple markets in 2020. If approved, ONS-5010 has potential to mitigate risks associated with off-label use of Avastin or other drugs. Off label use of Avastin is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States.

Financial Highlights for the Fiscal Third Quarter Ended June 30, 2019

For the fiscal third quarter ended June 30, 2019, the Company reported a net loss attributable to common stockholders of \$4.6 million, or \$0.20 per basic and diluted share, compared to a net loss attributable to common stockholders of \$9.1 million, or \$2.10 per basic and diluted share, for the third quarter of fiscal 2018.

For the fiscal third quarter ended June 30, 2019, the Company reported an adjusted net loss attributable to common stockholders of \$5.5 million, or \$0.24 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of \$7.1 million, or \$1.64 per basic and diluted share, in the third quarter of fiscal 2018. Adjusted net loss attributable to common stockholders in the third quarter of fiscal 2019 includes \$0.8 million of depreciation and amortization, \$0.4 million of non-cash interest expense, \$0.4 million of loss on extinguishment of debt, a \$1.9 million decrease in the fair value of warrant liability, \$0.8 million of income tax benefit from the sale of state tax NOLs, \$0.1 million of loss on disposal of property and equipment, and \$0.2 million stock dividend for the Company's Series A-1 convertible preferred stock. For the third quarter of fiscal 2018, adjusted net loss attributable to common stockholders included \$0.2 million of stock-based compensation expense, \$0.8 million of depreciation and amortization, \$0.2 million of non-cash interest expense, a \$0.1 million increase in the fair value of warrant liability, and a \$0.7 million stock dividend for the Company's Series A convertible preferred stock.

At June 30, 2019, the Company had cash of \$14.0 million, compared to \$1.7 million at September 30, 2018. In April 2019, the Company completed a public offering of common stock and warrants for net proceeds of approximately \$26.2 million, after payment of fees, expenses and underwriting discounts and commissions.

About ONS-5010

ONS-5010 is an ophthalmic formulation of bevacizumab to be administered as an intravitreal injection for the treatment of wet AMD and other retina diseases. Bevacizumab is a full length humanized anti-VEGF (Vascular Endothelial Growth Factor) antibody that inhibits VEGF and associated angiogenic activity. The Company's proprietary ophthalmic bevacizumab product candidate is an anti-VEGF recombinant humanized monoclonal antibody (or mAb) formulated as a single use vial for IVT injection. By inhibiting the VEGF receptor from binding, bevacizumab prevents the growth and maintenance of tumor blood vessels.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a clinical-stage biopharmaceutical company focused on developing its lead clinical program, ONS-5010, an ophthalmic bevacizumab product candidate for the treatment of wet age related macular degeneration (wet AMD) and other retina diseases. ONS-5010 is currently in Phase 3 clinical trials for patients suffering from 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 the Company's core business, such as losses on the disposal of property and equipment or extinguishment of debt, and sales of state of New Jersey net operating losses, 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 plans for seeking regulatory approval for ONS-5010, the effects of the engagement of FUJIFILM Diosynth, statements regarding enrollment in the Company's ongoing clinical trials, including timing of completion of enrollment and timing of data announcements and the outcome of such clinical trials, as well as statements regarding the ability of ONS-5010 to mitigate risks associated with off-label use of Avastin. 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 and financing such clinical trials, 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](#).

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

	Three months ended June 30,		Nine Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenues	\$ 584	\$ 772	\$ 2,293	\$ 2,316
Operating expenses:				
Research and development	4,393	5,796	19,312	11,355
General and administrative	1,835	2,196	6,588	8,192
	<u>6,228</u>	<u>7,992</u>	<u>25,900</u>	<u>19,547</u>
Loss from operations	(5,644)	(7,220)	(23,607)	(17,231)
Interest expense, net	1,082	1,147	3,257	2,786
Loss on extinguishment of debt	424	-	607	1,252

Change in fair value of warrant liability	(1,931)	65	(2,266)	(226)
Loss before income taxes	(5,219)	(8,432)	(25,205)	(21,043)
Income tax benefit	(778)	-	(778)	(3,151)
Net loss	(4,441)	(8,432)	(24,427)	(17,892)
Recognition of beneficial conversion feature upon issuance of Series A and A-1 convertible preferred stock	-	-	(61)	(15,737)
Series A and A-1 convertible preferred stock dividends and related settlement	(158)	(653)	(463)	(1,740)
Deemed dividend upon modification of warrants	-	-	(830)	-
Net loss attributable to common stockholders	\$ (4,599)	\$ (9,085)	\$ (25,781)	\$ (35,369)
Per share information:				
Net loss per share of common stock, basic and diluted	\$ (0.20)	\$ (2.10)	\$ (1.74)	\$ (9.96)
Weighted average shares outstanding, basic and diluted	23,007	4,318	14,787	3,553

Consolidated Balance Sheet Data
(Amounts in thousands)

	June 30, 2019	September 30, 2018
Cash	\$ 14,027	\$ 1,717
Total assets	33,214	22,283
Current liabilities	23,218	32,042
Series A-1 convertible preferred stock	5,197	4,734
Total stockholders' deficit	(6,556)	(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 share data)

	Three months ended June 30,		Nine Months Ended June 30,	
	2019	2018	2019	2018
Net loss attributable to common stockholders, as reported (GAAP)	\$ (4,599)	\$ (9,085)	\$ (25,781)	\$ (35,369)
Adjustments for reconciled items:				
Stock-based compensation, non-cash	(31)	234	1,109	1,824
Depreciation and amortization	833	822	2,473	2,230
Non-cash interest expense	419	231	1,314	1,201
Loss on extinguishment of debt	423	-	607	1,252
Change in fair value of warrant liability	(1,931)	65	(2,266)	(226)
Income tax benefit from sale of New Jersey NOLs	(778)	-	(778)	(3,151)
Loss on disposal of property and equipment	51	-	2,962	-

Recognition of Series A and A-1 beneficial conversion feature	-	-	61	15,737
Series A and A-1 convertible preferred stock dividends	158	653	463	1,740
Deemed dividend upon modification of warrants	-	-	830	-
Settlement of clinical development contract	-	-	-	(3,229)
Adjusted net loss attributable to common stockholders (non-GAAP)	<u>\$ (5,455)</u>	<u>\$ (7,080)</u>	<u>\$ (19,006)</u>	<u>\$ (17,991)</u>
Net loss per share of common stock - basic and diluted, as reported (GAAP)				
Adjustments for reconciled items:	\$ (0.20)	\$ (2.10)	\$ (1.74)	\$ (9.96)
Stock-based compensation, non-cash	-	0.05	0.07	0.51
Depreciation and amortization	0.04	0.19	0.16	0.63
Non-cash interest expense	0.01	0.05	0.09	0.34
Loss on extinguishment of debt	0.02	-	0.04	0.35
Change in fair value of warrant liability	(0.08)	0.02	(0.15)	(0.06)
Income tax benefit from sale of New Jersey NOLs	(0.04)	-	(0.05)	(0.88)
Loss on disposal of property and equipment	-	-	0.20	-
Recognition of Series A and A-1 beneficial conversion feature	-	-	-	4.43
Series A and A-1 convertible preferred stock dividends	0.01	0.15	0.03	0.49
Deemed dividend upon modification of warrants	-	-	0.06	-
Settlement of clinical development contract	-	-	-	(0.91)
Adjusted net loss per share of common stock - basic and diluted (non-GAAP)	<u>\$ (0.24)</u>	<u>\$ (1.64)</u>	<u>\$ (1.29)</u>	<u>\$ (5.06)</u>



Source: Outlook Therapeutics, Inc.