



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

May 15, 2019

CRANBURY, N.J., May 15, 2019 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (NASDAQ:OTLK) (the "Company") today reported business highlights and financial results for its second fiscal quarter ended March 31, 2019.

Recent Highlights:

- FDA acceptance and activation of the IND application for ONS-5010
- Initiated the ONS-5010-002 Phase 3 clinical trial
- Completed a \$28.4 million public offering of common stock and warrants
- Appointed Dr. Jennifer Kissner as SVP of Clinical Development

"We are pleased with the progress being made in both of our Phase 3 clinical trials for ONS-5010 thus far in 2019, which includes the FDA's acceptance of our IND for ONS-5010 and the initiation of our second Phase 3 trial. The two studies remain on track with our plan to submit ONS-5010 for regulatory approval in multiple markets in 2020," said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer. "The financing we secured in the equity offering announced in April has provided us with the capital needed to complete enrollment in our two Phase 3 clinical trials. This was an important step in our strategy and to maintain the positive momentum behind our clinical development program for ONS-5010."

Recent ONS-5010 Highlights

ONS-5010 is an innovative monoclonal antibody (mAb) therapeutic product candidate currently enrolling patients in a Phase 3 clinical trial in Australia (ONS-5010-001), which is designed to serve as the first of two adequate and well controlled studies evaluating ONS-5010 against ranibizumab (Lucentis) for wet age related macular degeneration (wet AMD). Enrollment in ONS-5010-001 is nearly complete with 51 of the planned 60 patients enrolled to date.

ONS-5010-002, the second of the two adequate and well controlled Phase 3 clinical trials evaluating ONS-5010 against ranibizumab (Lucentis®) for wet AMD has been initiated in the United States, Australia and New Zealand and is expected to begin dosing patients in June 2019. In April, the U.S. Food and Drug Administration (FDA) accepted and activated the Company's investigational new drug (IND) application for ONS-5010. Patients enrolled in the ONS-5010-002 study 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.

If the ONS-5010 clinical program is successful, it will support the Company's plan to submit 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.

As the Company has shifted its focus to ONS-5010 over the past year, the requirements asked of the senior leadership team have changed. This has resulted in several new hires and changes at the senior level of the Company. Most recently, the Company appointed Jennifer M. Kissner, Ph.D. as the Senior Vice President of Clinical Development. Dr. Kissner has extensive experience in therapeutic product development from the benchtop through clinical development and regulatory filing, including small molecules, biologics, gene therapy and devices, across multiple therapeutic areas, specifically working in the retina space for 12 years. The Company expects her clinical development expertise, specializing in wet AMD and other retina diseases, to play an important role in the advancement of the ONS-5010 program.

"We continue to attract exceptionally talented people from the wet AMD and retinal disease industry to Outlook Therapeutics. The industry knowledge and experience of those like Dr. Kissner will allow us to efficiently execute on our strategy to advance our streamlined ONS-5010 program through clinical development and, pending the outcome of our trials and regulatory approval, properly implement an effective commercialization strategy," continued Mr. Kenyon.

Financial Highlights for the Fiscal Quarter Ended March 31, 2019

For the fiscal quarter ended March 31, 2019, the Company reported a net loss attributable to common stockholders of \$11.3 million, or \$0.98 per basic and diluted share, compared to a net loss of \$8.6 million, or \$2.66 per basic and diluted share, for the second quarter of fiscal 2018.

For the fiscal quarter ended March 31, 2019, the Company reported an adjusted net loss attributable to common stockholders of \$6.7 million, or \$0.58 per basic and diluted share, as compared to an adjusted net loss of \$6.9 million, or \$2.15 per basic and diluted share, in the second quarter of fiscal 2018. Adjusted net loss attributable to common stockholders in the second quarter of fiscal 2019 includes \$0.3 million of non-cash stock-based compensation, \$0.8 million of depreciation and amortization, \$0.4 million of non-cash interest expense, \$0.2 million of loss on extinguishment of debt, a \$1.3 million increase in the fair value of warrant liability, \$0.6 million of loss on disposal of property and equipment, \$0.1 million for recognition of the beneficial conversion feature of the Company's Series A-1 convertible preferred stock, \$0.2 million stock dividend for the Company's Series A-1 convertible preferred stock, and \$0.8 million for a deemed dividend upon the modification of outstanding warrants. For the fiscal 2018 second quarter, adjusted net loss attributable to common stockholders included \$0.7 million of depreciation and amortization, \$0.4 million of non-cash interest expense, \$0.4 million for recognition of the beneficial conversion feature for convertible preferred stock, and a \$0.6 million stock dividend for the Company's Series A convertible preferred stock, which was partially offset by \$0.2 million of income from a decrease in the fair value of warrant liability and \$0.3 million of income from non-cash stock-based compensation.

At March 31, 2019, the Company had cash of \$0.2 million, compared to \$1.7 million at September 30, 2018. In April, 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. The Company will use the net proceeds from the offering to fund the Phase 3 clinical trials of ONS-5010 for wet AMD, DME and BRVO; and the remainder for general corporate purposes, funding its working capital needs, and scheduled repayments of \$5.0 million outstanding principal and accrued interest on its 5% senior secured notes as required by the terms of a November 2018 amendment.

About ONS-5010

ONS-5010 is a proprietary 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, a proprietary 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, as well as significant non-cash items that impact financial results but not cash flows, such as the recognition of the beneficial conversion feature due to the issuance of Series A and A-1 Convertible Preferred Stock to BioLexis and related stock dividends, 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 Company's planned clinical trials for ONS-5010, enrollment in such trials, the outcome of such clinical trials and plans for seeking regulatory approval for ONS-5010, the ability of ONS-5010 to mitigate risks associated with off-label use of Avastin, as well as the ability of senior management to obtain approval for and commercialize ONS-5010. 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).

CONTACTS:

Outlook Therapeutics:

Lawrence A. Kenyon
LawrenceKenyon@outlooktherapeutics.com

Media & Investors:

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 March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Collaboration revenues	\$ 641	\$ 772	\$ 1,709	\$ 1,544
Operating expenses:				
Research and development	6,497	5,156	14,919	5,559
General and administrative	1,849	2,447	4,753	5,996
	<u>8,346</u>	<u>7,603</u>	<u>19,672</u>	<u>11,555</u>
Loss from operations	(7,705)	(6,831)	(17,963)	(10,011)
Interest expense, net	1,054	921	2,175	1,639
Loss on extinguishment of debt	184	-	184	1,252
Change in fair value of warrant liability	1,302	(212)	(335)	(291)
Loss before income taxes	(10,245)	(7,540)	(19,987)	(12,611)
Income tax benefit	-	-	-	(3,151)
Net loss	(10,245)	(7,540)	(19,987)	(9,460)
Recognition of beneficial conversion feature upon issuance of Series A and A-1 convertible preferred stock	(61)	(382)	(61)	(15,737)
Series A and A-1 convertible preferred stock dividends and related settlement	(154)	(636)	(305)	(1,087)
Deemed dividend upon modification of warrants	(830)	-	(830)	-
Net loss attributable to common stockholders	<u>\$ (11,290)</u>	<u>\$ (8,558)</u>	<u>\$ (21,183)</u>	<u>\$ (26,284)</u>
Per share information:				
Net loss per share of common stock, basic and diluted	<u>\$ (0.98)</u>	<u>\$ (2.66)</u>	<u>\$ (1.98)</u>	<u>\$ (8.29)</u>
Weighted average shares outstanding, basic and diluted	<u>11,524</u>	<u>3,217</u>	<u>10,677</u>	<u>3,171</u>

Consolidated Balance Sheet Data

(Amounts in thousands)

	March 31,		September 30,	
	2019		2018	
Cash	\$	155	\$	1,717
Total assets		17,172		22,283
Current liabilities		26,992		32,042
Series A-1 convertible preferred stock		5,039		4,734
Total stockholders' deficit	\$	(28,086)	\$	(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 March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Net loss attributable to common stockholders, as reported (GAAP)	\$ (11,290)	\$ (8,558)	\$ (21,183)	\$ (26,284)
Adjustments for reconciled items:				
Stock-based compensation, non-cash	268	(300)	1,140	1,590

Depreciation and amortization	817	731	1,640	1,408
Non-cash interest expense	445	391	895	970
Loss on extinguishment of debt	184	-	184	1,252
Change in fair value of warrant liability	1,302	(212)	(335)	(291)
Income tax benefit from sale of New Jersey NOLs	-	-	-	(3,151)
Loss on disposal of property and equipment	562	-	2,911	
Recognition of Series A and A-1 beneficial conversion feature	61	382	61	15,737
Series A and A-1 convertible preferred stock dividends	154	637	305	1,087
Deemed dividend upon modification of warrants	830	-	830	-
Settlement of clinical development contract	-	-	-	(3,229)
Adjusted net loss attributable to common stockholders (non-GAAP)	\$ (6,667)	\$ (6,929)	\$ (13,552)	\$ (10,911)
Net loss attributable to common stockholders per share of common stock - basic and diluted, as reported (GAAP) Adjustments for reconciled items:	\$ (0.98)	\$ (2.66)	\$ (1.98)	\$ (8.29)
Stock-based compensation, non-cash	0.02	(0.09)	0.11	0.50
Depreciation and amortization	0.07	0.23	0.15	0.44
Non-cash interest expense	0.04	0.12	0.08	0.31
Loss on extinguishment of debt	0.02	-	0.02	0.39
Change in fair value of warrant liability	0.11	(0.07)	(0.03)	(0.09)
Income tax benefit from sale of New Jersey NOLs	-	-	-	(0.99)
Loss on disposal of property and equipment	0.05	-	0.27	-
Recognition of Series A and A-1 beneficial conversion feature	0.01	0.12	0.01	4.96
Series A and A-1 convertible preferred stock dividends	0.01	0.20	0.03	0.34
Deemed dividend upon modification of warrants	0.07	-	0.08	-
Settlement of clinical development contract	-	-	-	(1.02)
Adjusted net loss attributable to common stockholders per share of common stock - basic and diluted (non-GAAP)	\$ (0.58)	\$ (2.15)	\$ (1.26)	\$ (3.45)



Source: Outlook Therapeutics, Inc.