Outlook Therapeutics, Inc. Logo

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

February 14, 2019

CRANBURY, N.J., Feb. 14, 2019 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (NASDAQ:OTLK) (the “Company”) today reported financial results and business highlights for its first fiscal quarter ended December 31, 2018.

Recent Highlights:

- Reached 75% enrollment completion in ONS-5010-001, a Phase 3 clinical trial in wet AMD
- Ongoing preparations for planned March 2019 IND submission to the FDA on target
- Received final $8.0 milllion of a $20.0 million private placement of common stock from BioLexis

“We moved into fiscal year 2019 with building momentum as we execute against our new strategy to pursue a high value opportunity with ONS-5010 in the multi-billion dollar anti-VEGF ophthalmic market,” said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer. “To date, we have enrolled 75% of the patients in our ONS-5010-001 clinical trial, which is the first of two Phase 3 clinical trials of ONS-5010 in wet AMD. Over the next few months, we expect to make additional progress in our wet AMD clinical program. Our second wet AMD Phase 3 study, ONS-5010-002, is expected to begin enrolling patients this quarter in Australia and New Zealand. In addition, we plan to submit an IND to the FDA within the coming weeks, which will allow us to begin enrolling patients in the U.S. for ONS-5010-002.”

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 approximately 75% complete. The second of the two Phase 3 studies (ONS-5010-002) has been initiated in Australia and is expected to begin enrolling patients in March 2019. The Company plans to submit an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) in the first quarter of calendar 2019, which is expected to allow the Company to begin enrolling patients in the U.S. portion of ONS-5010-002 shortly thereafter. In anticipation of the IND, the Company held a successful end of Phase 2 meeting with the U.S. FDA in 2018. The ONS-5010-002 study is expected to enroll a total of at least 180 patients in the United States, Australia, and New Zealand.

If the ONS-5010 clinical program is successful, it will support the Company’s plans 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.

Financial Highlights for the Fiscal Quarter Ended December 31, 2018
For the fiscal quarter ended December 31, 2018, the Company reported a net loss attributable to common stockholders of $9.9 million, or $0.13 per diluted share, compared to $17.7 million, or $0.71 per diluted share, for the first quarter of fiscal 2018.

For the fiscal quarter ended December 31, 2018, the Company reported an adjusted net loss attributable to common stockholders of $6.9 million, or $0.09 per diluted share, as compared to an adjusted net loss of $4.0 million, or $0.16 per diluted share, in the first quarter of fiscal 2018. Adjusted net loss attributable to common stockholders in the first quarter of fiscal 2019 includes $0.9 million of non-cash stock-based compensation, $0.8 million of depreciation and amortization, $0.5 million of non-cash interest expense, $2.3 million of loss on disposal of property and equipment, and a $0.2 million stock dividend for the Company’s Series A-1 convertible preferred stock, which was partially offset by $1.6 million of income from a decrease in the fair value of warrant liability. For the fiscal 2018 first quarter, adjusted net loss attributable to common stockholders included $1.9 million of non-cash stock-based compensation expense, $0.7 million of depreciation and amortization, $0.6 million of non-cash interest expense, $1.3 million of loss on extinguishment of debt, $15.4 million for recognition of the beneficial conversion feature for convertible preferred stock, and a $0.5 million stock dividend for the Company’s Series A convertible preferred stock, which was partially offset by $0.1 million of income from a decrease in the fair value of warrant liability and a $3.2 million of tax benefit recognized from the sale of state of New Jersey net operating losses.

At December 31, 2018, the Company had cash of $0.2 million, compared to $1.7 million at September 30, 2018.

On November 5, 2018, Outlook Therapeutics announced that it has received an equity financing commitment for $20.0 million from BioLexis and restructured and extended the maturity of its senior secured notes that were previously scheduled to mature on December 22, 2018. The Company completed the sale of the first two tranches of common stock to BioLexis in this private placement for aggregate cash proceeds of $12.0 million in November and December 2018. The final $8.0 million was received in two equal tranches on each of January 2, 2019 and February 1, 2019. These proceeds along with the pending receipt of approximately $3.4 million from the sale of New Jersey net operating losses and research and development credits are expected to fund the Company’s operations into June 2019.

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. Previously, this product candidate met the primary and secondary endpoints in a 3-arm single-dose pharmacokinetic (PK) Phase 1 clinical trial. All of the PK endpoints met the bioequivalency criteria of the geometric mean ratios within 90% confidence interval of 80-125% when compared to both U.S.- and EU-sourced Avastin® reference products.

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). ONS-5010 is currently in its first Phase 3 clinical trial, which is being conducted in Australia and is designed to serve as the first of two adequate and well controlled studies for 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 from extinguishment of debt, sales of state net operating losses, losses on the disposal of property and equipment, as well as the settlement of a clinical development contract in connection with the decision to postpone clinical trials of two biosimilar programs, 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, including submission of an IND with the FDA. 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
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 December 31,	
	2018	**2017**
Collaboration revenues	$ 1,068	$ 772
Operating expenses:		
Research and development	8,421	403
General and administrative	2,904	3,549
	11,325	3,952

Loss from operations	(10,257)	(3,180)
Interest expense, net	1,121	718
Loss on extinguishement of debt	-	1,252
Change in fair value of warrant liability	(1,636)	(79)
Loss before income taxes	(9,742)	(5,071)
Income tax (benefit) expense	-	(3,151)
Net loss	(9,742)	(1,920)
Recognition of beneficial conversion feature upon issuance of Series A and A-1 preferred stock	-	(15,355)
Series A and A-1 convertible preferred stock dividends and related settlement	(150)	(451)
Net loss attributable to common stockholders	$ (9,892)	$ (17,726)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.13)	$ (0.71)
Weighted average shares outstanding, basic and diluted	78,748	25,003

Consolidated Balance Sheet Data

(Amounts in thousands)

	December 31, 2018	September 30, 2018
Cash	$ 228	$ 1,717
Total assets	$ 18,710	$ 22,283
Current liabilities	$ 27,536	$ 32,042
Series A-1 convertible preferred stock	$ 4,885	$ 4,734
Total stockholders' deficit	$ (26,354)	$ (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 December 31,	
	2018	2017
Net loss attributable to common stockholders, as reported (GAAP)	$ (9,892)	$ (17,726)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	872	1,890
Depreciation and amortization	823	677
Non-cash interest expense	450	580
Loss on extinguishment of debt	-	1,252
Change in fair value of warrant liability	(1,636)	(79)
Loss on disposal of fixed assets	2,349	-
Income tax benefit from sale of New Jersey NOLs	-	(3,151)
Recognition of Series A and A-1 beneficial conversion feature	-	15,355
Series A and A-1 convertible preferred stock dividends	150	451
Settlement of clinical development contract	-	(3,229)

Adjusted net loss attributable to common stockholders (non-GAAP)	$ (6,884)	$ (3,980)
Net loss attributable to common stockholders per share of common stock, basic and diluted, as reported (GAAP)	$ (0.13)	$ (0.71)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	0.01	0.08
Depreciation and amortization	0.01	0.03
Non-cash interest expense	0.01	0.02
Loss on extinguishment of debt	-	0.05
Change in fair value of warrant liability	(0.02)	-
Loss on disposal of fixed assets	0.03	-
Income tax benefit from sale of New Jersey NOLs	-	(0.13)
Recognition of Series A and A-1 beneficial conversion feature	-	0.61
Series A and A-1 convertible preferred stock dividends	-	0.02
Settlement of clinical development contract	-	(0.13)
Adjusted net loss attributable to common stockholders per share of common stock, basic and diluted (non-GAAP)	$ (0.09)	$ (0.16)

Source: Outlook Therapeutics, Inc.