Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Financial Results for Fiscal Year 2020 and Provides Corporate Update

December 23, 2020

- **All planned clinical trials for ONS-5010 / LYTENAVA™ (bevacizumab-vikg) wetAMD BLA now fully enrolled or completed**

- **Pivotal data expected in mid-2021 from ongoing, fully enrolled Phase 3 registration trial for ONS-5010 (NORSE TWO) with new BLA filing expected in second half of 2021**

MONMOUTH JUNCTION, N.J., Dec. 23, 2020 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, today announced its corporate highlights and financial results for its fiscal year ended September 30, 2020.

Outlook Therapeutics also provided a clinical development and pre-commercialization update on ONS-5010 / LYTENAVA ™ (bevacizumab-vikg), its investigational ophthalmic formulation of bevacizumab-vikg for the treatment of wet age-related macular degeneration (wet AMD) and other retinal indications.

“2020 has been a pivotal year for Outlook Therapeutics. Not only have we continued to make significant progress with our pre-commercialization activities in anticipation of our planned BLA filing for ONS-5010 to treat wet AMD in 2021, but all of our planned clinical trials for this indication also have either been completed or achieved full enrollment,” commented Lawrence A. Kenyon, President, CEO and CFO of Outlook Therapeutics. “In the near-term, we are focused on the successful completion and data readout for the pivotal Phase 3 study in the third calendar quarter of 2021 followed by our planned BLA submission. Beyond that, we are also engaged with regulatory authorities in Europe for anticipated submissions in those markets, plus we are planning to initiate registration clinical trials for ONS-5010 for DME and BRVO later in 2021.”

2020 Corporate Highlights

- Reported topline results demonstrating anticipated safety and efficacy and positive proof-of-concept of ONS-5010 / LYTENAVA™ from the NORSE ONE clinical experience trial, the first of two required registration clinical trials;
- Completed patient enrollment for the NORSE TWO pivotal registration study evaluating ONS-5010 / LYTENAVA ™ , the second of two required registration clinical trials;
- Completed patient enrollment for the NORSE THREE open-label safety study for ONS-5010 / LYTENAVA ™ ahead of schedule;
- Successfully completed technology transfer and scale-up consistent with global cGMP standards to world-class manufacturing partners; and
- Announced the formation of Global Retina Advisory Council to collaborate on outreach to retinal clinicians to support development and commercialization of ONS-5010 / LYTENAVA ™ .

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Development Updates

Outlook Therapeutics reported positive data in August 2020 from its clinical experience trial (NORSE ONE). The study enrolled a total of 61 treatment-naïve and previously treated patients diagnosed with wet AMD at nine sites in Australia. Patients on ONS-5010 were dosed monthly compared to those on LUCENTIS® (ranibizumab), who were dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing. Results from the study demonstrated anticipated safety and efficacy signals consistent with previously published results for ophthalmic bevacizumab. The data from this study will be used to support the planned new U.S. Biologics License Application (BLA) filing with the U.S. Food and Drug Administration (FDA) in 2021.

Outlook Therapeutics completed patient enrollment in its pivotal Phase 3 (NORSE TWO) clinical trial in July 2020, enrolling a total of 227 patients at 39 clinical trial sites in the United States. Patients in the trial are being treated for 12 months. The primary endpoint for the study is the difference in proportion of patients who gain at least 15 letters in the best corrected visual acuity (BCVA) at 11 months for ONS-5010 dosed on a monthly basis, compared to LUCENTIS®, which is being dosed quarterly per the PIER regimen. Outlook Therapeutics expects to report pivotal safety and efficacy data in the third calendar quarter of 2021.

Outlook Therapeutics completed enrollment of 195 subjects with a range of retinal diseases for which an anti-VEGF drug is a therapeutic option, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and branch retinal vein occlusion (BRVO), for its open-label safety study (NORSE THREE) in November 2020. The open-label safety study is being conducted to ensure the adequate number of safety exposures to ONS-5010 are available for the initial regulatory filings. Subjects enrolled in the study are receiving three monthly intravitreal (IVT) doses of ONS-5010/LYTENAVA™. The data from this study will be included in the complete data package to support the planned BLA filing for wet AMD, on schedule for submission to the FDA in the second half of 2021. In addition to the clinical development plan evaluating ONS-5010 for wet AMD, Outlook Therapeutics has received agreements from the FDA on three Special Protocol Assessments (SPAs) for three additional registration clinical trials. These SPAs cover the protocols for a planned registration clinical trial evaluating ONS-5010 to treat branch retinal vein occlusion (BRVO) (NORSE FOUR), and two planned registration clinical trials evaluating ONS-5010 for the treatment of diabetic macular edema (DME) (NORSE FIVE and NORSE SIX).

Commercial launch planning for ONS-5010, including distribution, physician and patient outreach, key opinion leader support and payor community engagement, remains ongoing. With an enhanced safety and cost-effectiveness profile, Outlook Therapeutics expects ONS-5010, if approved, to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated “step edit” in the United States for retina indications. Outlook Therapeutics is in active late-stage discussions for the licensing and/or co-development rights to ONS-5010.

Financial Highlights for the 2020 Fiscal Year Ended September 30, 2020

For the fiscal year ended September 30, 2020, Outlook Therapeutics reported a net loss attributable to common stockholders of $48.9 million, or $0.67 per basic and diluted share, compared to a net loss attributable to common stockholders of $36.0 million, or $1.98 per basic and diluted share, for the prior fiscal year. For the fiscal year ended September 30, 2020, Outlook Therapeutics also reported an adjusted net loss attributable to common stockholders of $33.8 million, or $0.47 per basic and diluted share, as compared to an adjusted net loss attributable to common stockholders of $22.5 million, or $1.24 per basic and diluted share, for fiscal 2019.

Adjusted net loss attributable to common stockholders in the fiscal year ended September 30, 2020 includes $2.8 million of stock-based compensation expense, $0.6 million of depreciation and amortization, $0.2 million of non-cash interest expense, a $1.9 million loss on the extinguishment of debt, $1.8 million decrease in the fair value of redemption feature of senior secured notes, $0.2 million decrease in the fair value of warrant liability, $3.3 million of income tax benefit from sale of state tax net operating losses (NOLs), $0.5 million impairment of property and equipment, $0.7 million loss on lease termination, $0.2 million stock dividend for the Company's Series A-1 convertible preferred stock, $3.1 million of deemed dividend upon modification of warrants, and $10.3 million of deemed dividend upon amendment of Series A-1 convertible preferred stock. Adjusted net loss attributable to common stockholders for 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, $3.4 million of income tax benefit from the sale of state tax NOLs, $11.3 million of impairment loss on property and equipment, $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.

At September 30, 2020, Outlook Therapeutics had cash and cash equivalents of $12.5 million, compared to $24.0 million at June 30, 2020.

About ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) 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. Because no currently approved ophthalmic formulations of bevacizumab are available, clinicians wishing to treat retinal patients with bevacizumab have had to use unapproved repackaged IV bevacizumab provided by compounding pharmacists, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 will reduce the need for use of unapproved repackaged IV bevacizumab from compounding pharmacists for retinal disease.

ONS-5010 is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (or mAb) that inhibits VEGF and associated angiogenic activity. VEGF is a protein that promotes the growth of new abnormal blood vessels. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. 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 ONS-5010/LYTENAVA™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg for use in treating a range of retinal diseases in the United States, United Kingdom, Europe, Japan, China and other markets. Outlook Therapeutics expects to file ONS-5010 with the U.S. FDA as a new BLA under the PHSA 351(a) regulatory pathway, initially 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 its core business, such as income tax benefits from the sale of state NOLs, impairment losses on property and equipment, losses on lease terminations, or gains 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, deemed dividends upon warrant or convertible note modifications, stock-based compensation expense, depreciation and amortization expense, interest expense, and fair value measurements for equity and debt securities. Management uses 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 "expect," "plan," "anticipate," "may," "might," "will," "should," "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 completion of, and pivotal safety and efficacy data from, NORSE 2, and the timing of BLA submission, plans for regulatory approvals in other markets, statements about Outlook Therapeutics' other planned clinical trials for ONS-5010, plans for the Global Retina Advisory Council, ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, including benefits therefrom to patients, payors and physicians, , as well as statements about a potential strategic partnership for ONS-5010. Although Outlook Therapeutics believes that it has a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting Outlook Therapeutics 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, risks in obtaining necessary regulatory approvals, risks of negotiating and finalizing binding definitive agreements with third parties, as well as those risks detailed in Outlook Therapeutics' filings with the Securities and Exchange Commission, which include the uncertainty of future impacts related to the ongoing

COVID-19 pandemic. 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. Outlook Therapeutics 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 Outlook Therapeutics' financial performance during the quarter, please see the Outlook Therapeutics filings with the Securities and Exchange Commission.

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

	Year Ended September 30,	
	2020	**2019**
Collaboration revenues	$ -	$ 8,146
Operating expenses:		
Research and development	26,342	23,805
General and administrative	9,971	9,370
Impairment of property and equipment	528	11,270
	36,841	- 44,445
Loss from operations	(36,841)	(36,299)
Interest expense, net	1,756	3,467
Loss on extinguishment of debt	1,896	607
Change in fair value of redemption feature	(1,797)	-
Change in fair value of warrant liability	(185)	(2,438)
Loss before income taxes	(38,511)	(37,935)
Income tax benefit	(3,272)	(3,411)
Net loss	(35,239)	(34,524)
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	(61)
Series A-1 convertible preferred stock dividends and related settlement	(166)	(625)
Deemed dividend upon modification of warrants	(3,140)	(830)
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	(10,328)	-
Net loss attributable to common stockholders	$ (48,873)	$ (36,040)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.67)	$ (1.98)
Weighted average shares outstanding, basic and diluted	72,556	18,192

Consolidated Balance Sheet Data
(Amounts in thousands)

	September 30,	
	2020	2019
Cash	$ 12,536	$ 8,016
Total assets	$ 19,733	$ 17,135
Current liabilities	$ 15,889	$ 20,290
Series A-1 convertible preferred stock	$ -	$ 5,359
Total stockholders' equity (deficit)	$ 2,826	$ (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)

	Year Ended September 30,	
	2020	2019
Net loss attributable to common stockholders, as reported (GAAP)	$ (48,873)	$ (36,040)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	2,807	1,313
Depreciation and amortization	554	3,362
Non-cash interest expense	236	1,314
Loss on extinguishment of debt	1,896	607
Change in fair value of redemption feature	(1,797)	-
Change in fair value of warrant liability	(185)	(2,438)
Income tax benefit from sale of New Jersey net operating losses	(3,272)	(3,414)
Impairment of property and equipment	528	11,270
Loss on lease termination	680	-
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	61
Series A-1 convertible preferred stock dividends and related settlement	166	625
Deemed dividend upon modification of warrants	3,140	830
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	10,328	-
Adjusted net loss attributable to common stockholders (non-GAAP)	$ (33,792)	$ (22,510)
Net loss attributable to common stockholders per share of common stock - basic and diluted, as reported (GAAP)	$ (0.67)	$ (1.98)
Adjustments for reconciled items:		
Stock-based compensation, non-cash	0.04	0.07
Depreciation and amortization	0.01	0.18
Non-cash interest expense	-	0.07
Loss on extinguishment of debt	0.03	0.03
Change in fair value of redemption feature	(0.02)	-
Change in fair value of warrant liability	-	(0.13)
Income tax benefit from sale of New Jersey net operating losses	(0.05)	(0.19)
Impairment of property and equipment	-	0.63
Loss on lease termination	0.01	-
Beneficial conversion feature upon issuance of Series A-1 convertible preferred stock	-	-
Series A-1 convertible preferred stock dividends and related settlement	-	0.03
Deemed dividend upon modification of warrants	0.04	0.05
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	0.14	-
Adjusted net loss attributable to common stockholders per share of common stock - basic and diluted (non-GAAP)	$ (0.47)	$ (1.24)

Source: Outlook Therapeutics, Inc.