Aligos Therapeutics Reports Recent Business Progress and Third Quarter 2024 Financial Results

Nov 6, 2024

SOUTH SAN FRANCISCO, Calif., Nov. 06, 2024 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS, “Aligos”), a clinical stage biopharmaceutical company focused on improving patient outcomes through best-in-class therapies for liver and viral diseases, today reported recent business progress and financial results for the third quarter 2024.

“This quarter we reached a key milestone when we announced the positive topline HERALD data in MASH subjects,” stated Lawrence Blatt, Ph.D., MBA, Chairman, President, and Chief Executive Officer of Aligos Therapeutics. “With placebo-adjusted median relative reductions in liver fat of up to 46.2%, we continue to believe ALG-055009 has best-in-class potential. We are completing Phase 2b enabling studies and evaluating a variety of options to fund continued development, including potential partnering where discussions are underway. In addition, we are progressing ALG-000184 for CHB towards a Phase 2 study next year. Lastly, we expect to begin externally funded clinical studies for ALG-097558 later this year in COVID subjects. 2024 has been an exciting year for the company, and we believe we are laying the groundwork for important future successes in 2025 and beyond.”

Recent Business Progress

Aligos Portfolio of Drug Candidates

ALG-000184: Potential first-/best-in-class small molecule CAM-E for CHB

- Dosing continues in this ongoing Phase 1a/1b study, with subjects expected to dose for up to 96 weeks. Additional interim data readouts are planned to be presented this year at the American Association for the Study of Liver Disease’s (AASLD) The Liver Meeting (TLM) 2024
- Received positive feedback from the FDA and the National Medical Products Administration in China to move forward with sustained HBV DNA suppression as the primary efficacy endpoint for future studies designed to support the potential registration of ALG-000184 for the treatment of hepatitis B infection
- Announced a clinical collaboration with Xiamen Amoytop Biotech Co., Ltd.
    - Amoytop agreed to sponsor and perform a Phase 1b exploratory clinical study evaluating the efficacy and safety of ALG-000184 in combination with PEGBING® (mipeginterferon alfa-2b) in chronic hepatitis B (CHB) patients in China
- Phase 2 enabling activities are underway, including drug supply manufacturing

ALG-055009: Potential best-in-class small molecule THR-β agonist for MASH

- Topline HERALD data were presented in September 2024, demonstrating that ALG-055009 dose groups met the primary endpoint with statistically significant reductions in liver fat at Week 12 as measured by MRI-PDFF
    - Doses of 0.5 mg to 0.9 mg ALG-055009 demonstrated statistically significant reductions in liver fat at Week 12, with placebo-adjusted median relative reductions up to 46.2% as measured by MRI-PDFF. Up to 70% of subjects achieved ≥30% relative reduction in liver fat compared to baseline
    - ALG-055009 demonstrated a favorable tolerability profile with no clinical hyper/hypothyroidism. Incidence of gastrointestinal-related treatment emergent adverse events were similar in ALG-055009 dose groups compared to placebo. Specifically, a non-dose-related, lower incidence of diarrhea was observed in ALG-055009 dose groups compared to placebo
    - Treatment with ALG-055009 resulted in significant reductions in atherogenic lipids, including LDL-C, lipoprotein (a) (LpA), and apolipoprotein B (ApoB). In addition, dose dependent increases in sex hormone binding globulin (SHBG), a marker of THR-β target engagement in the liver, were observed
- Additional data readouts are planned to be presented this year at AASLD’s The Liver Meeting (TLM) 2024

ALG-097558: Potential best-in-class small molecule pan-coronavirus protease inhibitor

- Three additional clinical studies are expected to begin in 2024
    - AGILE University of Liverpool, a UK-government supported platform trial (with MRC and Wellcome Trust funding), has agreed to sponsor and perform a study in high-risk COVID patients evaluating ALG-097558 as monotherapy or in combination with remdesivir
    - The NIAID has agreed to sponsor clinical studies evaluating pharmacokinetic (PK) differences in special populations (renal/hepatic impairment subjects)
- Phase 2 enabling activities, including nonclinical and clinical studies, are underway with financial support from the NIH

Financial Results for the Third Quarter 2024

Cash, cash equivalents and investments totaled $74.9 million as of September 30, 2024, compared with $135.7 million as of December 31, 2023. We continue to believe our cash balance provides sufficient cash to fund planned operations through the end of 2025.

Net loss for the three months ended September 30, 2024 were $19.3 million or basic and diluted net loss per common share of $(3.07), compared to net losses of $18.0 million or basic and diluted net loss per common share of $(10.37) for the three months ended September 30, 2023.

Research and development (R&D) expenses for the three months ended September 30, 2024 were $16.8 million, compared with $15.9 million for the same period of 2023. The increase was primarily due to an increase in third party expenses for the clinical trials. Total R&D stock-based compensation expense incurred for the three months ended September 30, 2024 was $1.2 million, compared with $1.6 million for the same period of 2023.

General and administrative (G&A) expenses for the three months ended September 30, 2024 were $4.6 million, compared with $6.4 million for the same period of 2023. The decrease in G&A expenses for this comparative period is primarily due to a decrease in third party expenses including legal expenses. Total G&A stock-based compensation expense incurred for the three months ended September 30, 2024 was $0.9 million, compared with $1.6 million for the same period of 2023.

Interest and other income, net, for the three months ended September 30, 2024 was income of $1.0 million compared with income of $1.1 million for the same period of 2023.

About Aligos

Aligos Therapeutics, Inc. (NASDAQ: ALGS) is a clinical stage biopharmaceutical company founded with the mission to improve patient outcomes by developing best-in-class therapies for the treatment of liver and viral diseases. Aligos applies its science driven approach and deep R&D expertise to advance its purpose-built pipeline of therapeutics for metabolic dysfunction-associated steatohepatitis (MASH) and viruses with high unmet medical need such as hepatitis B and coronaviruses.

For more information, please visit www.aligos.com or follow us on LinkedIn or X.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this press release that are not historical facts may be considered “forward-looking statements,” including without limitation, statements with respect to Aligos being positioned for success; the potential of the company’s three clinical programs, Phase 2 enabling activities, and financial support from the NIH for ALG-097558; the collaboration with Xiamen Amoytop; studies to support potential registration, and Phase 2 enabling activities for ALG-000184; the planned readouts for ALG-055009 at this year’s AASLD; the continuation of dosing in the ongoing Phase 1a/1b study for ALG-000184 with subjects planning to dose for up to 96 weeks; the planned presentation of additional interim data readouts at this year’s AASLD; and the company’s continued belief its cash balance provides sufficient cash to fund planned operations through the end of 2025. Forward-looking statements are typically, but not always, identified by the use of words such as “may,” “will,” “would,” “believe,” “intend,” “plan,” “anticipate,” “estimate,” “expect,” and other similar terminology indicating future results. Such forward looking statements are subject to substantial risks and uncertainties that could cause our development programs, future results, performance, or achievements to differ materially from those anticipated in the forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties inherent in the drug development process, including Aligos’ clinical-stage of development, the process of designing and conducting clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, Aligos’ ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of Aligos’ capital resources to fund operations, reliance on third parties for manufacturing and development efforts, changes in the competitive landscape and the impact of global events and other macroeconomic conditions on the Aligos’ business. For a further description of the risks and uncertainties that could cause actual results to differ from those anticipated in these forward-looking statements, as well as risks relating to the business of Aligos in general, see Aligos’ Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 6, 2024 and its future periodic reports to be filed or submitted with the Securities and Exchange Commission. Except as required by law, Aligos undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

Aligos Therapeutics, Inc
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023

Revenue from Collaborations	19	2,154	311	7,329
Revenue from Customers	1,250	1,085	3,005	5,519
Operating Expenses:				
Research and development	16,774	15,867	54,238	50,783
General and administrative	4,626	6,443	17,669	24,195
Total operating expenses	21,400	22,310	71,907	74,978
Loss from operations	(20,131)	(19,071)	(68,591)	(62,130)
Interest and other income, net	963	1,059	19,834	3,168
Loss before income tax expense	(19,168)	(18,012)	(48,757)	(58,962)
Income tax expense	(91)	(29)	(304)	(825)
Net loss	(19,259)	(18,041)	(49,061)	(59,787)
Basic and diluted net loss per common share	(3.07)	(10.37)	(7.84)	(34.59)
Weighted-average shares common stock, basic and diluted	6,272,291	1,739,847	6,258,706	1,728,282

Aligos Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2024	December 31, 2023
	(Unaudited)	(audited) (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 35,331	$ 135,704
Short-term investments	39,591	-
Prepaid expenses and other current assets	4,900	5,380
Total current assets	79,822	141,084
Other assets	8,604	10,443
Total assets	$ 88,426	$ 151,527
Liabilities and Stockholders' Equity		
Current liabilities	$ 20,956	$ 23,906
Other liabilities, noncurrent	17,374	35,541
Total liabilities	38,330	59,447
Total stockholders' equity	50,096	92,080
Total liabilities and stockholders' equity	$ 88,426	$ 151,527

(1) The balance sheet as of December 31, 2023 has been derived from the audited consolidated financial statements at that date included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

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