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

May 7, 2024

SOUTH SAN FRANCISCO, Calif., May 07, 2024 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS, “Aligos”), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in liver and viral diseases, today reported recent business progress and financial results for the first quarter 2024.

“We have executed on a number of key deliverables to position Aligos for success,” stated Lawrence Blatt, Ph.D., MBA, Chairman, President & CEO of Aligos Therapeutics. “Importantly, we began dosing in the Phase 2a HERALD study of our THR-drug candidate, ALG-055009, and we expect topline data in Q4 2024. In addition, we recently presented data from our three clinical programs at scientific conferences, showcasing our robust pipeline of potentially best-in-class small molecule drug candidates. In particular, we demonstrated positive safety, tolerability, and antiviral activity data after dosing for up to 64 weeks with our hepatitis B virus capsid assembly modulator, ALG-000184, and positive safety and PK data for our ritonavir-free, pan-coronavirus protease inhibitor, ALG-097558. We remain excited by the potential of these programs and look forward to continuing to deliver for our shareholders.”

Recent Business Progress

Aligos Portfolio of Drug Candidates

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

- Data presented at the Asian Pacific Association for the Study of the Liver (APASL) conference highlighted ALG-055009 Phase 1 data that showed multiple-ascending doses (MAD) over 14 days in hyperlipidemic subjects produced favorable, dose-dependent pharmacodynamic effects on atherogenic lipids and sex hormone binding globulin (SHBG), an indicator of target engagement in the liver
- The Phase 2a HERALD study was initiated in Q1 2024 with the first subject dosed in April 2024
- Topline HERALD data are anticipated in Q4 2024

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

- Interim data from Parts 3 and 4 of Study ALG-000184-201 were presented at the APASL conference and showed consistent, potent antiviral activity across multiple cohorts of untreated chronic hepatitis B (CHB) patients receiving once daily doses of ALG-000184 as monotherapy or in combination with entecavir (ETV) x ≤ 64 weeks
- Dosing continues in this ongoing Phase 1a/1b study, with subjects planning to dose for up to 96 weeks. Additional interim data readouts are planned to be presented this year at the following conferences: European Association for the Study of the Liver (EASL) and American Association for the Study of Liver Diseases (AASLD)
- Phase 2 enabling activities, including regulatory interactions and drug supply manufacturing, are underway

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

- Topline data presented at the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Annual Meeting demonstrated single (up to 2000 mg) and multiple (up to 800 mg Q12 for 7 days) doses of ALG-097558 were well tolerated in healthy volunteers with a pharmacokinetic (PK) profile supporting twice daily, ritonavir-free dosing without a food effect
- Received an additional $1.3M grant from the National Institutes of Health (NIH)
- Phase 2 enabling activities, including nonclinical and clinical studies, are underway with financial support from the NIH

Financial Results for the First Quarter 2024

Cash, cash equivalents and investments totaled $112.7 million as of March 31, 2024, compared with $135.7 million as of December 31, 2023. Additionally, in October 2023, we raised $92.1 million in gross proceeds in private placement financing, before deducting placement agent’s fees and other expenses. Including the proceeds from the private placement financing, we continue to believe our cash balance provides sufficient cash to fund planned operations through the end of 2025.

Net losses for the three months ended March 31, 2024 were $34.9 million or basic and diluted net loss per common share of $(0.22), compared to net losses of $23.0 million or basic and diluted net loss per common share of $(0.53) for the three months ended March 31, 2023.

Research and development (R&D) expenses for the three months ended March 31, 2024 were $16.4 million, compared with $18.1 million for the same period of 2023. The decrease was primarily due to a decrease in employee related costs, partially offset by an increase in third party expenses. Total R&D stock-based compensation expense incurred for the three months ended March 31, 2024 was $1.4 million, compared with $2.2 million for the same period of 2023.

General and administrative (G&A) expenses for the three months ended March 31, 2024 were $6.7 million, compared with $8.5 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 March 31, 2024 was $1.2 million, compared with $1.5 million for the same period of 2023.

Interest and other income (expense), net, for the three months ended March 31, 2024 was an expense of $12.8 million compared with income of $1.0 million for the same period of 2023. The change in interest and other income (expense), net, is primarily due to an increase in the fair value of the Common Warrants liability, which resulted in a non-cash charge, associated with the Securities Purchase Agreement entered into in October 2023 following the private investment in public equity (PIPE) offering.

About Aligos

Aligos Therapeutics, Inc. is a clinical stage biopharmaceutical company that was founded in 2018 with the mission to become a world leader in the treatment of liver and viral diseases. Aligos' strategy is to harness the deep expertise and decades of drug development experience its team has in liver and viral diseases to discover and develop potentially best-in-class therapeutics for metabolic dysfunction-associated steatohepatitis (MASH) and viruses with high unmet medical need such as hepatitis B and coronaviruses.

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 and the company looking forward to continuing to deliver for its shareholders; the expectation of topline Phase 2a HERALD data for ALG-055009 in Q4 2024; the continuation of dosing in the ongoing Phase 1a/1b study for ALG-000184 with subjects planning to dose for up to 96 weeks and the planned presentation of additional interim data readouts at this year's EASL and 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 May 7, 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)

	Three Months Ended March 31,	
	2024	2023
	(Unaudited)	(Unaudited)
Revenue from Collaborations	$ 292	$ 2,583
Revenue from Customers	694	140
Operating Expenses:		
Research and development	16,366	18,135
General and administrative	6,666	8,506
Total operating expenses	23,032	26,641

Loss from operations	(22,046)	(23,918)
Interest and other income (expense), net	(12,793)	1,002
Loss before income tax expense	(34,839)	(22,916)
Income tax expense	(24)	(39)
Net loss	(34,863)	(22,955)
Basic and diluted net loss per common share	$ (0.22)	$ (0.53)
Weighted-average number of shares used in computing basic and diluted net loss per common share	156,154,156	42,910,065

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

	March 31, 2024 (Unaudited)	December 31, 2023 (audited) (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 24,151	$ 135,704
Short-term investments	88,588	-
Prepaid expenses and other current assets	5,325	5,380
Total current assets	118,064	141,084
Other assets	9,838	10,443
Total assets	$ 127,902	$ 151,527
Liabilities and Stockholders' Equity		
Current liabilities	$ 18,880	$ 23,906
Other liabilities, noncurrent	49,226	35,541
Total liabilities	68,106	59,447
Total stockholders' equity	59,796	92,080
Total liabilities and stockholders' equity	$ 127,902	$ 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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