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

Aug 6, 2024

SOUTH SAN FRANCISCO, Calif., Aug. 06, 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 second quarter 2024.

“This quarter we continued to execute on our key clinical programs,” stated Lawrence Blatt, Ph.D., MBA, Chairman, President, and Chief Executive Officer of Aligos Therapeutics. “We completed enrollment ahead of schedule for the Phase 2a HERALD study of our THR-β agonist drug candidate, ALG-055009, and we expect topline data in early Q4 2024. In addition, we presented data from ALG-000184 at the EASL Congress 2024, including new data from the HBeAg-negative cohort, that demonstrated no viral breakthrough and unprecedented reductions in viral markers of CHB. We also received positive regulatory feedback from the FDA supporting subsequent studies of chronic suppressive therapy with sustained HBV DNA suppression as the primary approvable endpoint. We look forward to continuing to develop our drug candidates for patients in need of better outcomes.”

Recent Business Progress

Aligos Portfolio of Drug Candidates

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

- The Phase 2a HERALD study completed enrollment in May 2024
- Topline HERALD data are anticipated in early 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 European Association for the Study of the Liver (EASL) Congress 2024 and showed consistent, potent antiviral activity across multiple cohorts of untreated chronic hepatitis B (CHB) patients
    - Data from ≤ 72 weeks following an oral daily dose of 300 mg ALG-000184 monotherapy demonstrated sustained HBV DNA suppression (<LLOQ <10 IU/mL) in 9/10 (90%) HBeAg-positive CHB subjects with no viral breakthrough. New data also showed that as HBeAg declined to near negativity, anti-HBe antibody (HBeAb) levels exhibited a positive trend
    - Reported for the first time were the antiviral and safety data in HBeAg-negative CHB subjects who received a daily oral dose of 300 mg ALG-000184 monotherapy for ≤60 weeks. In all 11 (100%) subjects, complete suppression of HBV DNA (<LLOQ 10 IU/mL) and RNA (<LLOQ 10 copies/mL) were noted with no viral breakthrough
- 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 American Association for the Study of Liver Diseases (AASLD) conference
- Received positive feedback from the FDA regarding future studies with sustained HBV DNA suppression as the primary efficacy endpoint, leading to the potential registration of ALG-000184 for the treatment of hepatitis B infection
- Phase 2 enabling activities, including 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
- Phase 2 enabling activities, including nonclinical and clinical studies, are underway with financial support from the NIH

Financial Results for the Second Quarter 2024

Cash, cash equivalents and investments totaled $94.5 million as of June 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 income for the three months ended June 30, 2024 was $5.1 million or basic and diluted net income per common share of $0.03, compared to net losses of $18.8 million or basic and diluted net loss per common share of $(0.43) for the three months ended June 30, 2023. Net income for the three months ended June 30, 2024 was primarily due to a decrease in the fair value of

the Company's warrant liability, which resulted in non-cash income of $30.5 million, or $0.19 per share, associated with the warrants issued in October 2023 as part of the private investment in public equity (PIPE) offering.

Research and development (R&D) expenses for the three months ended June 30, 2024 were $21.1 million, compared with $16.8 million for the same period of 2023. The increase was primarily due to an increase in third party expenses for clinical trials. Total R&D stock-based compensation expense incurred for the three months ended June 30, 2024 was $1.2 million, compared with $1.6 million for the same period in 2023.

General and administrative (G&A) expenses for the three months ended June 30, 2024 were $6.4 million, compared with $9.2 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 June 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 June 30, 2024 was income of $31.7 million compared with income of $1.1 million for the same period of 2023. The change in interest and other income, net, is primarily due to a decrease of $30.5 million in the fair value of the company's warrant liability, which resulted in non-cash income.

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.

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; the FDA supporting subsequent studies of chronic suppressive therapy with sustained HBV DNA suppression as the primary approvable endpoint; the expectation of topline Phase 2a HERALD data for ALG-055009 in early 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 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 August 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue from Collaborations	-	2,592	292	5,175
Revenue from Customers	1,061	4,294	1,755	4,434
Operating Expenses:				

Research and development	21,099	16,781	37,464	34,916
General and administrative	6,376	9,246	13,043	17,752
Total operating expenses	27,475	26,027	50,507	52,668
Loss from operations	(26,414)	(19,141)	(48,460)	(43,059)
Interest and other income, net	31,664	1,107	18,871	2,109
Income (loss) before income tax expense	5,250	(18,034)	(29,589)	(40,950)
Income tax expense	(189)	(757)	(213)	(796)
Net income (loss)	5,061	(18,791)	(29,802)	(41,746)
Basic and diluted net income (loss) per common share	0.03	(0.43)	(0.19)	(0.97)
Weighted-average shares common stock, basic	156,444,408	43,215,478	156,299,282	43,063,615
Weighted-average shares common stock, diluted	156,647,917	43,215,478	156,299,282	43,063,615

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

	June 30, 2024 (Unaudited)	December 31, 2023 (audited) (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 45,078	$ 135,704
Short-term investments	49,458	-
Prepaid expenses and other current assets	5,034	5,380
Total current assets	99,570	141,084
Other assets	9,241	10,443
Total assets	$ 108,811	$ 151,527
Liabilities and Stockholders' Equity		
Current liabilities	$ 23,564	$ 23,906
Other liabilities, noncurrent	18,018	35,541
Total liabilities	41,582	59,447
Total stockholders' equity	67,229	92,080
Total liabilities and stockholders' equity	$ 108,811	$ 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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