Aligos Therapeutics Reports Recent Business Progress and Second Quarter 2025 Financial Results

Aug 6, 2025

SOUTH SAN FRANCISCO, Calif., Aug. 06, 2025 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS, “Aligos”), a clinical stage biotechnology 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 second quarter 2025.

“Initiation of the Phase 2 B-SUPREME study of ALG-000184 is well underway with regulatory approvals across a number of countries, including the US, China, Canada, Taiwan, UK, New Zealand, and Moldova,” stated Lawrence Blatt, Ph.D., M.B.A., Chairman, President, and Chief Executive Officer of Aligos Therapeutics. “Site activations are in progress, subjects are being screened, and we expect dosing to commence in the coming weeks. This pertinent study is the next step in our journey to potentially deliver better therapies for patients living with HBV infection and create value for our stakeholders. The Phase 1 data showcasing 96 weeks of treatment presented at the EASL meeting suggests that ALG-000184 has the potential to replace standard of care treatment for chronic suppression of HBV infection and may become the backbone of treatments aimed at a functional cure. We remain excited about the potential of ALG-000184 and the entirety of our pipeline, including ALG-055009 which remains in discussions with potential partners.”

Recent Business Progress

Pipeline Updates

ALG-000184: Potential first-/best-in-class small molecule CAM-E for chronic hepatitis B virus (HBV) infection

- The Phase 2 B-SUPREME study (NCT04746183) of ALG-000184 in subjects with chronic HBV infection recently began obtaining regulatory approvals, activating global sites, and screening subjects. Dosing is expected to commence in the coming weeks.
    - The study is designed as a randomized, double-blind, active-controlled multicenter study evaluating the safety and efficacy of ALG-000184 monotherapy compared with tenofovir disoproxil fumarate in approximately 200 untreated $HBeAg^+$ and $HBeAg^-$ adult subjects with chronic HBV infection for 48 weeks. The primary endpoint in the $HBeAg^+$ part will be HBV DNA <LLOQ (10 IU/mL, target detected [TD] or target not detected [TND]) and the primary endpoint in the $HBeAg^-$ part will be HBV DNA <LLOQ (10 IU/mL, target not detected [TND]). The study is also evaluating the safety, pharmacokinetics, and other secondary and exploratory biomarkers, including reductions in HBV antigens and other markers of HBV infection. The company expects to announce interim data in 2026, and topline data in 2027.
- 96-week dosing recently completed in the Phase 1 study and data readouts, including post-treatment data, are planned for scientific conferences this year. Interim data from up to 96 weeks following an oral daily dose of 300 mg ALG-000184 in both $HBeAg^+$ and $HBeAg^-$ subjects with chronic HBV infection were presented at the European Association for the Study of the Liver (EASL) Congress 2025.
    - ALG-000184 administered for up to 96 weeks was well tolerated by study participants, exhibited a favorable PK profile, and suggested potentially best-in-class antiviral activity.
    - In $HBeAg^+$ subjects with a very high mean HBV DNA level of 8.0 $\log_{10}$ IU/mL at baseline, all experienced profound and persistent HBV DNA reductions after receiving an oral daily dose of 300 mg ALG-000184 monotherapy. At Week 48, 6 of 10 subjects (60%) achieved HBV DNA < LLOQ (10 IU/mL, target detected or target not detected). With treatment extension, this rate increased to 9 of 9 subjects (100%) at Week 96. Additionally, HBV DNA level continuously declined to < LLOQ (10 IU/mL, target not detected) in 5 of 9 subjects at Week 96.
    - In $HBeAg^-$ subjects, all 11 (100%) had rapid decline in HBV DNA levels and achieved sustained HBV DNA suppression (HBV DNA < LLOQ (10 IU/mL, target detected or target not detected)) by Week 24. The HBV DNA suppression level was maintained in the ALG-000184 monotherapy cohort for up to 96 weeks, with further decline in HBV DNA to < LLOQ (10 IU/mL, target not detected), observed in all subjects (8/8) at Week 96.
    - Multi-$\log_{10}$ reductions in HBsAg, HBeAg, and HBcrAg were observed in $HBeAg^+$ subjects, and HBcrAg decline was observed in $HBeAg^-$ subjects.
    - In both patient populations in this study, ALG-000184 was well tolerated with no viral breakthrough observed and no known CAM resistant mutations identified with monotherapy treatment.

ALG-055009: Potential best-in-class small molecule THR-β agonist for metabolic dysfunction-associated steatohepatitis (MASH)

- The Phase 2a HERALD data were presented at EASL 2025, 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.
    - Additionally, new data demonstrated substantial, dose-dependent reductions in liver fat were observed across all key subgroups with 12 weeks of once daily ALG-055009 treatment. Statistically significant improvements in atherogenic lipids were achieved with 12 weeks of ALG-055009 treatment. Reductions in lipids/lipoproteins were observed even in the context of stable GLP-1 agonist or statin use. This data suggests a potential added benefit of ALG-055009 for patients at risk for cardiovascular disease in addition to the previously reported liver fat lowering properties in a MASLD/MASH population.
    - As shared previously, ALG-055009 demonstrated a favorable tolerability profile with no evidence of clinical hyper/hypothyroidism. Incidence of gastrointestinal-related treatment emergent adverse events were similar in ALG-055009 dose groups compared to placebo. Specifically, similar rates of diarrhea were observed in ALG-055009 dose groups compared to placebo, with no dose-response. Significant reductions in atherogenic lipids, including LDL-C, lipoprotein (a), and apolipoprotein B, were also observed (Loomba et al, AASLD 2024).
- The company is continuing to evaluate a variety of options to fund continued development, including potential out-licensing.

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

- The AGILE platform study (NCT04746183) assessing ALG-097558 monotherapy or in combination with remdesivir in high-risk subjects with COVID-19 began in 2024.
- The NIAID is sponsoring a drug-drug interaction and relative bioavailability study of ALG-097558 in healthy volunteers that began dosing in the second quarter of 2025.
- The company expects any future development of ALG-097558 to be funded by external sources.

Financial Results for the Second Quarter 2025

Cash, cash equivalents and investments totaled $122.9 million as of June 30, 2025, compared with $56.9 million as of December 31, 2024. Our cash, cash equivalents and investments are expected to provide sufficient funding of planned operations into the second half of 2026.

Net loss for the three months ended June 30, 2025 was $15.9 million or basic and diluted net loss per common share of $(1.53), compared to net income of $5.1 million or basic and diluted net income per common share of $0.81 for the three months ended June 30, 2024.

Research and development (R&D) expenses for the three months ended June 30, 2025 were $14.0 million, compared with $21.1 million for the same period of 2024. The decrease was primarily due to a decrease in third-party expenses due to reduced clinical study costs as a result of the completion of the MASH Phase 2a clinical trial, partially offset by increased spend in the chronic HBV infection program. Total R&D stock-based compensation expense incurred for the three months ended June 30, 2025 was $0.6 million, compared with $1.2 million for the same period of 2024.

General and administrative (G&A) expenses for the three months ended June 30, 2025 were $5.6 million, compared with $6.4 million for the same period of 2024. 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, 2025 was $0.5 million, compared with $0.9 million for the same period of 2024.

Interest and other income, net, was income of $1.2 million each for the three months ended June 30, 2025 and June 30, 2024.

Change in fair value of 2023 common warrants for the three months ended June 30, 2025 was income of $1.7 million compared with income of $30.4 million for the same period of 2024.

About Aligos

Aligos Therapeutics, Inc. (NASDAQ: ALGS) is a clinical stage biotechnology 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 high unmet medical needs such as chronic hepatitis B virus (HBV) infection, metabolic dysfunction-associated steatohepatitis (MASH), 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 the expected enrollment of Phase 2 participants for ALG-000184; the potential impact of ALG-000184 on patient populations, stakeholder value, and treatment therapies; the planned data releases, data readouts at

scientific conferences, and primary endpoints for ALG-000184; the potential additional benefits and out-licensing of ALG-055009; the expectations regarding funding for ALG-097558; and the company's expectation that its cash, cash equivalents and investments provide sufficient funding of planned operations into the second half of 2026. 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 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, 2025 and Aligos' Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 2025 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.

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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,	
	2025	**2024**	**2025**	**2024**
Revenue from collaborations	$ -	$ -	$ -	$ 292
Revenue from customers	965	1,061	1,276	1,755
Operating expenses:				
Research and development	13,976	21,099	28,478	37,464
General and administrative	5,556	6,376	10,608	13,043
Total operating expenses	19,532	27,475	39,086	50,507
Loss from operations	(18,567)	(26,414)	(37,810)	(48,460)
Interest and other income, net	1,207	1,227	2,087	2,765
Change in fair value of 2023 common warrants	1,682	30,437	63,176	16,106
(Loss) income before income tax	(15,678)	5,250	27,453	(29,589)
Income tax provision	(185)	(189)	(228)	(213)
Net (Loss) income	$ (15,863)	$ 5,061	$ 27,225	$ (29,802)
Net (loss) income per share, basic	$ (1.53)	$ 0.81	$ 2.90	$ (4.77)
Net (loss) income per share, diluted	$ (1.53)	$ 0.81	$ 2.90	$ (4.77)
Weighted-average shares of common stock, basic	10,351,120	6,257,713	9,385,167	6,251,913
Weighted-average shares of common stock, diluted	10,351,120	6,265,853	9,401,645	6,251,913

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

	June 30, 2025	December 31, 2024
	(Unaudited)	(audited) (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 18,661	$ 36,997
Short-term investments	104,284	19,942
Prepaid expenses and other current assets	4,999	5,202
Total current assets	127,944	62,141
Other assets	6,762	7,953
Total assets	$ 134,706	$ 70,094
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities	$ 20,265	$ 21,737
Other liabilities, noncurrent	12,575	77,330
Total liabilities	32,840	99,067
Total stockholders' equity (deficit)	101,866	(28,973)
Total liabilities and stockholders' equity (deficit)	$ 134,706	$ 70,094

(1) The condensed consolidated balance sheet as of December 31, 2024 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, 2024.