Aligos Therapeutics Reports Recent Business Progress and Third Quarter 2023 Financial Results

SOUTH SAN FRANCISCO, Calif., Nov. 02, 2023 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), 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 third quarter 2023.

“Over this quarter, we raised approximately $92 million in a private placement financing allowing the advancement of our NASH THR-ß and CHB CAM-E programs. Additionally, we successfully received clearance for Aligos’ first US IND (for ALG-055009) and secured an $8.5 million contract with the NIAID to advance our coronavirus protease inhibitor into Phase 2 clinical trials. We are proud to have achieved these critical milestones,” noted Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics. “With these achievements in hand, our team is well positioned to execute on our priorities, which include conducting a Ph2a MRI-PDFF study in NASH with ALG-055009, conducting Phase 2 enabling activities for our promising CAM-E, ALG-000184, in CHB, and advancing our potentially best-in-class coronavirus protease inhibitor, ALG-097558. Over the next quarter our research team will continue to identify promising novel small molecule drug candidates as backup molecules for our lead clinical programs as well as discover new small molecules targeting novel molecular pathways in viral and liver diseases.”

Recent Business Progress

Aligos Portfolio of Drug Candidates

NASH (THR-ß; ALG-055009)

- The US IND was cleared by the FDA, which now enables execution of a planned Phase 1 statin drug-drug interaction study in Q4 2023, prior to filing the Phase 2a protocol to the IND in Q4 2023
- In the meantime, Phase 2a startup activities were initiated and are now underway
- A preliminary Phase 2a study design was formulated in close collaboration with the study’s Principal Investigator, Dr. Stephen Harrison. The final study design is subject to feedback from the FDA which is expected in early Q1 2024
- The final Phase 1 FIH study data were accepted as a poster presentation (Poster #2900-A) at the AASLD Liver Meeting in November 2023

CHB (CAM-E, ALG-000184)

- Dosing and enrollment in ongoing Study ALG-000184-201 continues. The total dosing duration now exceeds 48 weeks in some subjects in this Phase 1a/1b study
- Data from long term dosing cohorts in Study ALG-000184-201, including a late breaking poster (Poster #5028-C) summarizing the effects of ALG-000184 on various viral markers, will be presented at the AASLD Liver Meeting in November 2023
- With the recent completion of the PIPE, we plan to initiate Ph2 enabling activities, including manufacturing of drug supply, in the near future

Coronavirus (PI, ALG-097558)

- Dosing continues in the ongoing first in human study, ALG-097558-701. Dosing is ongoing in the single ascending dose portion of the study and is due to start soon in the multiple ascending dose portion. We continue to project having topline data from this important safety and pharmacokinetics study in H1 2024
- The NIAID awarded Aligos an $8.5M contract to conduct Phase 2 enabling activities, which includes multiple nonclinical and clinical studies. These studies will be initiated in H1 2024 and topline data are expected in H2 2025. The ALG-097558 program has been awarded over $11M across two NIH grants and contracts and we plan to seek additional external funding from both public and private sources to further advance this important program

Financial Results for the Third Quarter 2023

Cash, cash equivalents and investments totaled $70.4 million as of September 30, 2023, compared with $125.8 million as of December 31, 2022. Additionally, we raised in private placement financing approximately $92 million in gross proceeds, before deducting placement agent’s fees and other expenses, in October 2023. Including the expected net proceeds from the private placement, we believe our cash balance provides sufficient cash to fund planned operations through the end of 2025.

Net losses for the three months ended September 30, 2023 were $18.0 million or basic and diluted net loss per common share of $(0.41), compared to net losses of $18.6 million or basic and diluted net loss per common share of $(0.44) for the three months ended September 30, 2022.

Research and development (R&D) expenses for the three months ended September 30, 2023 were $15.9 million, compared with $17.8 million for the same period of 2022. The decrease was primarily due to employee-related costs and other costs including facility expenses, partially offset by an increase in third party expenses due to the milestone payments made as a result of dosing the first patient in a clinical trial. Total R&D stock-based compensation expense incurred for the three months ended September 30, 2023 was $1.6 million, compared with $1.9 million for the same period of 2022.

General and administrative (G&A) expenses for the three months ended September 30, 2023 were $6.4 million, compared with $5.3 million for the same period of 2022. The increase in G&A expenses for this comparative period is primarily attributable to an increase in legal and related costs. Total G&A stock-based compensation expense incurred for the three months ended September 30, 2023 was $1.6 million, compared with $1.5 million for the same period of 2022.

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 nonalcoholic steatohepatitis (NASH) and viruses with high unmet medical need such as coronaviruses and chronic hepatitis B (CHB).

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 that the team is well positioned to execute on the company's priorities which include conducting a Ph2a MRI-PDFF study in NASH with ALG-055009, conducting Phase 2 enabling activities for the CAM-E, ALG-000184, in CHB, and advancing its coronavirus protease inhibitor, ALG-097558, and that over the next quarter, the research team will continue to identify promising novel small molecule drug candidates as backup molecules for the lead clinical programs as well as discover new small molecules targeting novel molecular pathways in viral and liver diseases; with respect to the NASH ALG-055009 program, that the company plans to execute on a Phase 1 statin drug-drug interaction study in Q4 2023 prior to filing the Phase 2a protocol to the IND in Q4 2023, with final study design subject to feedback from the FDA, expected in early Q1 2024; with respect to the CHB ALG-000184 program, that the dosing and enrollment in ongoing Study ALG-000184-201 continues and the plan is to initiate Ph2 enabling activities, including manufacturing of drug supply, in the near future; with respect to the company's COVID-19 ALG-097558 program, that dosing continues in the single ascending dose portion of the ALG-097558-701 study and is due to start soon in the multiple ascending dose portion, that the company continues to project having topline data from this safety and pharmacokinetics study in H1 2024, that the plan is to initiate Phase 2 enabling activities, which include multiple nonclinical and clinical studies, in H1 2024, that the expectation is to have topline data in H2 2025 and that the plan is to seek additional external funding from both public and private sources to further advance the program; and that the company continues to believe 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, 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 2, 2023 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue from Collaborations	$ 2,154	$ 4,106	$ 7,329	$ 10,370
Revenue from Customers	1,085	-	5,519	-
Operating Expenses:				
Research and development	15,867	17,791	50,783	65,977
General and administrative	6,443	5,263	24,195	19,291
Total operating expenses	22,310	23,054	74,978	85,268
Loss from operations	(19,071)	(18,948)	(62,130)	(74,898)
Interest and other income, net	1,059	284	3,168	795
Loss before income tax expense	(18,012)	(18,664)	(58,962)	(74,103)
Income tax benefit (expense)	(29)	43	(825)	(57)
Net loss	(18,041)	(18,621)	(59,787)	(74,160)
Basic and diluted net loss per common share	$ (0.41)	$ (0.44)	$ (1.38)	$ (1.74)

Weighted-average number of shares used in computing basic and diluted net loss per common share	43,496,975	42,761,928	43,209,656	42,647,732

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

	September 30, 2023	December 31, 2022
	(Unaudited)	(audited) (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 70,429	$ 81,347
Short-term investments	-	44,480
Prepaid expenses and other current assets	4,214	7,718
Total current assets	74,643	133,545
Other assets	11,209	13,148
Total assets	$ 85,852	$ 146,693
Liabilities and Stockholders' Equity		
Current liabilities	$ 22,468	$ 33,129
Other liabilities, noncurrent	8,563	9,664
Total liabilities	31,031	42,793
Total stockholders' equity	54,821	103,900
Total liabilities and stockholders' equity	$ 85,852	$ 146,693

(1) The balance sheet as of December 31, 2022 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, 2022.

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