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

SOUTH SAN FRANCISCO, Calif., May 04, 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 first quarter 2023.

"Our team is off to a great start in 2023, having already achieved multiple important milestones," said Lawrence Blatt, PhD, MBA, Chairman & CEO of Aligos. "For our key NASH program, we recently collected and presented data demonstrating the excellent PK properties for our Phase 2 gelcap formulation, which has enabled the initiation of Ph2 drug supply manufacturing activities. We remain on track to file an IND for Ph2 in Q4 of this year. For our COVID-19 protease inhibitor, ALG-097558, we recently submitted the CTA to enable initiation of a first in human safety and PK study with dosing anticipated to start mid-year. For our chronic hepatitis B portfolio, our capsid assembly modulator continues to show best-in-class HBsAg lowering activity with data recently presented at the Global Hepatitis Summit meeting showing subjects dosed with 300 mg ALG-000184 for up to 28 weeks achieving HBsAg reductions of up to 1.65 $\log_{10}$ IU/mL. Finally, our CHB siRNA drug, ALG-125755, recently completed enrollment in the 3rd cohort of Part 2, which is evaluating single ascending doses in CHB patients. We plan to continue to share emerging data from both of these CHB clinical programs next month at EASL 2023 and at future scientific meetings."

Recent Business Progress

Aligos Portfolio of Drug Candidates

NASH Program

- In Part 3 of Study ALG-055009-301, the bioavailability of the Phase 2 gel cap formulation was found to compare favorably relative to the liquid formulation used in the SAD (Part 1) and MAD (Part 2) portions of the study. Exposures for the gel cap formulation were similar to the liquid formulation with low variability and no evidence of a meaningful food effect.
- After conducting a comprehensive data review, the proposed doses for Ph2 were identified and include a planned top dose (gel cap) approximately equivalent to 0.75 mg (liquid formulation). Because this planned top dose was not specifically studied in earlier MAD cohorts, Aligos plans to conduct in Q2 2023 a MAD cohort evaluating the safety, PK and PD of 0.75 mg ALG-055009 (liquid formulation) x 14 days.
- Phase 2 enabling activities, including 13 week GLP toxicology studies and gel cap manufacturing, were initiated in Q1 and both activities remain on track for a Q4 2023 Ph2 IND filing.

COVID-19

- The CTA for the FIH Study ALG-097558-701 was successfully submitted in the UK in April. Additional Ph1 startup activities are ongoing to support initiation of ALG-097558 dosing, which is anticipated to start mid-year.

HBV Programs

- Additional HBsAg lowering data from ongoing cohorts in Study ALG-000184-201 were presented at the Global Hepatitis Summit in April. These data showed that subjects dosed with 300 mg ALG-000184 + entecavir for up to 28 weeks are achieving HBsAg reductions of up to 1.65 $\log_{10}$ IU/mL and a majority (4 of 5 subjects) that have been dosed for ~24 weeks demonstrated at least a 1.00 $\log_{10}$ IU/mL reduction in HBsAg levels.

Financial Results for the First Quarter 2023

Cash, cash equivalents and investments totaled $103.5 million as of March 31, 2023, compared with $125.8 million as of December 31, 2022. We continue to believe our cash balance provides sufficient cash to fund planned operations through the end of 2024.

Net losses for the three months ended March 31, 2023, were $23.0 million or basic and diluted net loss per common share of $(0.53), compared to net losses of $35.6 million or basic and diluted net loss per common share of $(0.84) for the three months ended March 31, 2022.

Research and development (R&D) expenses for the three months ended March 31, 2023, were $18.1 million compared with $31.7 million for the same period of 2022. The decrease in R&D expenses for this comparative period is primarily attributable to a decrease in third-party expenses due to our continued wind down related to the discontinuation of our STOPS and ASO programs, and the manufacturing of drug supply in advance of our clinical and nonclinical activities. Total R&D stock-based compensation expense incurred for the three months ended March 31, 2023, was $2.2 million compared with $2.0 million for the same period of 2022.

General and administrative (G&A) expenses for the three months ended March 31, 2023, were $8.5 million compared with $6.5 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 offset by a decrease in facility expenses. Total G&A stock-based compensation expense incurred for the three months ended March 31, 2023, was $1.5 million compared with $1.8 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, with respect to the key NASH program, the company remaining on track to file an IND for Ph2 in Q4 of 2023 and planning to conduct in Q2 2023 a MAD cohort evaluating the safety, PK and PD of 0.75 mg ALG-055009 (liquid formulation) x 14 days; statements, with respect to the company's COVID-19 protease inhibitor, ALG-097558, the company's anticipation that it will begin dosing in humans mid-year of 2023; statements regarding the company's plan to continue to share emerging data from its ALG-000184 and ALG-125755 CHB clinical programs at EASL 2023 and at future scientific meetings; and statements with respect to the company's continued belief that its cash balance provides sufficient cash to fund planned operations through the end of 2024. 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 effects on our business of the worldwide COVID-19 pandemic and the ongoing conflict between Russia and Ukraine. 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 4, 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 March 31,	
	2023	**2022**
	(Unaudited)	(Unaudited)
Revenue from Collaborations	$ 2,583	$ 2,571
Revenue from Customers	140	-
Operating Expenses:		
Research and development	18,135	31,676
General and administrative	8,506	6,452
Total operating expenses	26,641	38,128
Loss from operations	(23,918)	(35,557)
Interest and other income (expense), net	1,002	(5)
Loss before income tax expense	(22,916)	(35,562)
Income tax expense	(39)	(53)
Net loss	(22,955)	(35,615)
Basic and diluted net loss per common share	$ (0.53)	$ (0.84)
Weighted-average number of shares used in computing basic and diluted net loss per common share	42,910,065	42,511,559

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

	March 31, 2023	**December 31, 2022**
	(Unaudited)	(audited) (1)
Assets		
Current assets:		

Cash and cash equivalents	$ 78,671	$ 81,347
Short-term investments	24,845	44,480
Prepaid expenses and other current assets	5,913	7,718
Total current assets	109,429	133,545
Other assets	12,309	13,148
Total assets	$ 121,738	$ 146,693
Liabilities and Stockholders' Equity		
Current liabilities	$ 28,079	$ 33,129
Other liabilities, noncurrent	8,909	9,664
Total liabilities	36,988	42,793
Total stockholders' equity	84,750	103,900
Total liabilities and stockholders' equity	$ 121,738	$ 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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