Aligos Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Recent Business Highlights

Mar 10, 2022

CAM (ALG-000184) continues to demonstrate best in class potential in Phase 1b
ASO (ALG-020572) completed dosing in Phase 1a (HVs); Phase 1b study (CHB) initiated – 1st cohort fully enrolled
siRNA (ALG-125755) progressing on track through Phase 1 enabling nonclinical studies
THR-β (ALG-055009) currently dosing in healthy volunteers and subjects with hyperlipidemia
Multiple COVID-19 3CL protease inhibitor drug candidates without need for ritonavir boosting identified – all more potent than nirmatrelvir
Merck expanded the NASH research collaboration utilizing Aligos' proprietary oligonucleotide technology

Cash, cash equivalents and investments of $205.8 million as of December 31, 2021
A sufficient cash balance to fund planned operations into the first half 2024

SOUTH SAN FRANCISCO, Calif., March 10, 2022 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in viral and liver diseases, today announced its financial results for the fourth quarter and full year 2021 and provided an overview of recent business highlights.

"Last year was very productive for our team," said Lawrence Blatt, PhD, MBA, Chairman & CEO of Aligos. "We made great strides in advancing our CHB, NASH and COVID portfolios, which has resulted in 3 drug candidates currently being evaluated in their target patient populations and our 4th drug candidate (CHB siRNA) on track to begin dosing in the clinic in the second half of this year. As a result, we expect multiple important data readouts to occur throughout 2022, including safety and proof of concept data for our CAM, ASO and THR-β drug candidates. These data have the potential to be important drivers of shareholder value and we look forward to sharing them as they emerge."

"In 2021, we received important validation of our expertise in developing oligonucleotide drug candidates when Merck entered into a second NASH research collaboration with Aligos," added Leo Beigelman, PhD, President of Aligos. "We view oligonucleotide approaches as powerful tools for silencing mRNA transcripts in a highly specific and durable manner. These approaches are well adapted to silencing transcripts important in driving the pathogenesis seen in CHB and NASH."

Recent Business Highlights

Aligos Portfolio of Drug Candidates:

Capsid Assembly Modulator (CAM)(ALG-000184)
After demonstrating an acceptable safety and PK profile and similar, robust DNA and RNA suppressive effects in HBeAg-negative subjects at the 50 and 100 mg dose levels and in HBeAg-positive subjects at the 100 mg dose level in 2021, further dose exploration has been initiated for our CAM (ALG-000184). Currently, the 10 mg dose level is being evaluated in HBeAg-negative subjects to better define the dose-response characteristics of ALG-000184. Additionally, based on the marked, best-in-class reductions seen in HBV DNA and RNA levels, we are currently exploring the potential of 300 mg ALG-000184 to reduce HBsAg levels (via the "secondary mechanism of action" of CAMs) in HBeAg-positive subjects. We plan to conduct longer term studies (12 weeks) later this year and share these data at a scientific conference in H2 2022.

Antisense Oligonucleotide (ASO)(ALG-02572)
Recently, our Phase 1a evaluation of single ascending doses (SAD) of subcutaneously administered ALG-020572 in healthy volunteers (HVs) was completed and we initiated the Phase 1b portion of the study (in subjects with chronic hepatitis B (CHB)). Enrollment in the first CHB cohort is now complete. Over this year, we plan to evaluate multiple CHB cohorts at varying dose levels to define the dose-response characteristics and risk-benefit profile of ALG-020572. Safety and antiviral activity data are planned to be shared at a scientific conference in H2 2022.

Small Interfering RNA (siRNA)(ALG-125755)
Phase 1 enabling nonclinical studies for our siRNA (ALG-125755) were initiated in 2021 and remain on track for completion in H1 2022. If positive, we expect these data to enable dosing in a planned Phase 1a/1b study starting in HVs in H2 2022. Dosing in CHB subjects is anticipated to begin in H1 2023. HV data are planned to be shared at a scientific conference in H2 2022.

Thyroid Hormone Receptor – Beta (THR-B)(ALG-055009)
Phase 1 enabling nonclinical studies for our THR-β drug candidate (ALG-055009) were completed in 2021, which enabled initiation of a SAD study in HVs in Q4 2021. Administration of single doses in HVs and multiple doses in subjects with

hyperlipidemia is ongoing. Topline data, including safety, PK, and pharmacodynamic (lipid) data, are expected in Q3 2022. We also plan to share these data at a scientific conference in H2 2022.

SARS-CoV-2 3CL Protease Inhibitor (COVID-PI)
Multiple COVID-PIs which are more potent in vitro than nirmatrelvir and do not require ritonavir boosting have been identified. These drug candidates are in late lead optimization and we expect to nominate a clinical candidate in the near future. Phase 1 enabling nonclinical studies of this compound are planned to initiate in Q3 2022.

Merck Collaboration
Significant progress has been made in the nonalcoholic steatohepatitis (NASH) oligonucleotide research collaboration with Merck with respect to an initial undisclosed target, utilizing Aligos' know-how and our proprietary oligonucleotide chemistry platform. In addition to advancing this program further into lead optimization, the achievements of this collaboration also resulted in Merck committing to an oligonucleotide research collaboration for a second undisclosed NASH target.

PD-L1 Small Molecule Inhibitors
We are also developing orally delivered, liver-targeted small molecule PD-L1 inhibitors in order to modulate host immune responses to hepatitis B virus (HBV). This approach has demonstrated favorable effects on HBsAg lowering in patients with CHB. A lead compound, ALG-093453, has been shown to induce T cell activation in an in vitro Jurkat T cell-NFAT assay with similar activity to the PD-1 monoclonal antibody (mAb), nivolumab. In addition, ALG-093453 induces HBV-antigen specific IFN-γ secretion from T cells from patients infected with HBV to a similar extent to nivolumab and the PD-L1 mAb, durvalumab.

Corporate:

NASH Related License & Collaboration Agreement
Aligos Expands Collaboration with Merck to Develop Oligonucleotide Therapies for NASH (Q1'22)

- Under the original agreement, Merck and Aligos committed to applying Aligos' oligonucleotide platform technology to discover, research, optimize and develop oligonucleotides directed against a certain undisclosed NASH target. That agreement has now been expanded to include the granting of a license to Merck of an early-stage program with respect to a second undisclosed NASH target on which Aligos has previously been working independently and separately from Merck. In addition, under this expanded arrangement, Merck has the ability to add to the collaboration a third target of interest with respect to the cardiometabolic/fibrosis space.

Financial Results for the Fourth Quarter and Full Year 2021

Cash, cash equivalents and investments totaled $205.8 million on December 31, 2021, compared with $243.5 million on December 31, 2020. With the discontinuation of the development of our STOPS™ drug candidate, ALG-010133, that was being explored to address CHB, together with the proceeds resulting from our partnering activities and other cost saving measures, we believe our December 31, 2021 cash balance provides sufficient cash to fund planned operations into the first half of 2024.

Net losses for the three months ended December 31, 2021 were $37.7 million or basic and diluted net loss per common share of $(0.89) compared to $34.4 million or basic and diluted net loss per common share of $(1.09) for the three months ended December 31, 2020. For the year ended December 31, 2021, Net losses were $128.3 million or basic and diluted net loss per common share of $(3.22) compared to $108.5 million or basic and diluted net loss per common share of $(10.87) for the year ended December 31, 2020.

Research and development (R&D) expenses for the three months ended December 31, 2021 were $28.6 million, compared with $28.1 million for the same period of 2020. The increase in R&D expenses for this comparative period is primarily related to increases in salaries and employee-related expenses. Total R&D stock-based compensation expense incurred for the three months ended December 31, 2021, was $1.9 million compared with $0.7 million for the same period for 2020. R&D expenses for the year ended December 31, 2021 were $104.2 million, compared with $79.9 million for the same period of 2020. The increase in R&D expenses for this comparative period is primarily attributable to increased expenses related to the Company's continued development and manufacturing of ALG-000184, ALG-020572 clinical trial activities and remaining clinical and manufacturing expenses related to the discontinuation of ALG-010133 clinical program, as well as increases in salaries and employee-related expenses and preclinical programs. Total R&D stock-based compensation expense incurred in the year ended December 31, 2021, was $7.6 million, compared with $1.0 million for the same period of 2020.

General and administrative expenses for the three months ended December 31, 2021 were $9.7 million, compared to $6.2 million for the same periods of 2020 and for the year ended December 31, 2021 were $28.5 million, compared to $17.9 million for the same period of 2020. The increase in G&A expenses for both comparable periods is primarily attributable to higher employee-related costs associated with the growth of the Company's operations and additional professional, legal and consulting services related to being a public company. Total G&A stock-based compensation expense incurred for the three months ended December 31, 2021 was $1.7 million compared with $0.6 million for the same period for 2020 and for the year ended December 31, 2021 was $5.9 million, compared with $1.9 million for the same period of 2020.

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 viral infections and liver diseases. Aligos is focused on the discovery and development of targeted antiviral therapies for chronic hepatitis B (CHB) and coronaviruses as well as leveraging its expertise in liver diseases to create targeted therapeutics for nonalcoholic steatohepatitis (NASH). Aligos' strategy is to harness the deep expertise and decades of drug development experience its team has in liver disease, particularly viral hepatitis, to rapidly advance its pipeline of potentially best-in-class molecules.

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 regarding Aligos' 4th drug candidate (CHB siRNA) on track to begin dosing in the clinic in the second half of 2022; the expectation that multiple important data readouts will occur throughout 2022, including safety and proof of concept data for Aligos' CAM, ASO and THR-β drug candidates and the potential for these data to be important drivers of shareholder value; with respect to CAM (ALG-000184), Aligos' plan to conduct longer term studies (12 weeks) later in 2022 and share these data at a scientific conference in H2 2022; with respect to ASO (ALG-02572), Aligos' plan to evaluate multiple CHB cohorts at varying dose levels to define the dose-response characteristics and risk-benefit profile and to share safety and antiviral activity data at a scientific conference in H2 2022; with respect to siRNA (ALG-125755), Aligos being on track for completion of the Phase 1 enabling nonclinical studies in H1 2022, dosing in a planned Phase 1a/1b study to start in HVs in H2 2022, dosing in CHB subjects to begin in H1 2023 and HV data to be shared at a scientific conference in H2 2022; with respect to THR-B (ALG-055009), topline data, including safety, PK, and pharmacodynamic (lipid) data, being available in Q3 2022 and the plan to share these data at a scientific conference in H2 2022; and with respect to the company's COVID-PI program, the expectation to nominate a clinical candidate in the near future and Phase 1 enabling nonclinical studies of this compound being planned to initiate in Q3 2022. 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's 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's ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of Aligos's 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 developing 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's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 10, 2022 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
	(Unaudited)	(Unaudited)		
Revenue from collaborations	$ 367	$ -	$ 4,359	$ -
Operating expenses:				
Research and development	28,598	28,081	104,153	79,890
General and administrative	9,717	6,205	28,527	17,944
Total operating expenses	38,315	34,286	132,680	97,834
Loss from operations	(37,948)	(34,286)	(128,321)	(97,834)
Interest and other income (expense), net	176	85	132	(10,548)
Loss before income tax benefit (expense)	(37,772)	(34,201)	(128,189)	(108,382)
Income tax benefit (expense)	58	(219)	(143)	(161)

Net loss	$ (37,714)	$ (34,420)	$ (128,332)	$ (108,543)
Basic and diluted net loss per common share	$ (0.89)	$ (1.09)	$ (3.22)	$ (10.87)
Weighted-average number of shares used in computing basic and Diluted net loss per common share	42,341,972	31,465,208	39,855,403	9,988,191

Aligos Therapeutics, Inc

Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 186,816	$ 220,383
Short-term investments	3,918	23,130
Other current assets	13,690	6,504
Total current assets	204,424	250,017
Long-term investments	15,110	-
Other assets	15,835	15,285
Total assets	$ 235,369	$ 265,302
Liabilities and Stockholders' Equity		
Current liabilities	$ 38,957	$ 30,274
Other liabilities, noncurrent	11,681	14,989
Total liabilities	50,638	45,263
Total stockholders' equity	184,731	220,039
Total liabilities and stockholders' equity	$ 235,369	$ 265,302

Media Contact
Amy Jobe, Ph.D.
LifeSci Communications
+1 315 879 8192
ajobe@lifescicomms.com

Investor Contact
Corey Davis, Ph.D.
LifeSci Advisors
+1 212 915 2577
cdavis@lifesciadvisors.com