Aligos Therapeutics Reports Recent Business Progress and Second Quarter 2021 Financial Results

Raised $83.6 million in gross proceeds from common stock offering
STOPS™ and CAM programs: initial data presented at conferences, dosing in 2nd CHB cohorts ongoing
Clinical trial application filed for 3rd CHB drug candidate ALG-0202572 (antisense oligonucleotide) – dosing in HVs anticipated in Q4 2021

SOUTH SAN FRANCISCO, Calif., Aug. 05, 2021 (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 reported recent business progress and financial results for the second quarter, June 30, 2021.

"Over the past few months, in addition to completing our recent financing, we have made significant strides in advancing our CHB and NASH drug candidates," commented Lawrence Blatt, PhD, MBA, Chairman and CEO of Aligos. "At recent scientific conferences, healthy volunteer data from our STOPS™ program and initial antiviral data in CHB subjects from our CAM program, were presented. For both the STOPS and CAM programs, enrollment in the first CHB cohort is complete and is ongoing in the second cohort. Additionally, we recently filed the first clinical trial application (CTA) for our ASO drug candidate, ALG-020572, which is anticipated to begin dosing in healthy volunteers in Q4 2021. We are also on track to file a CTA in Q3 for ALG-055009, our NASH drug candidate, and start dosing in healthy volunteers in Q4 2021. We look forward to continuing to advance these important development programs."

Recent Business Progress

Aligos Portfolio of Drug Candidates:

Preliminary safety and pharmacokinetic data in healthy volunteers (HVs) from the ongoing Phase 1a/b multi-part dose range finding trial (NCT04485663) of our S-antigen Transport-inhibiting Oligonucleotide Polymers (STOPS™) compound, ALG-010133, were presented at the European Association for the Study of the Liver (EASL) Digital International Liver Congress™ 2021 (ILC 2021) in June. These data showed that single and multiple doses up to 200 mg and 180 mg, respectively, were generally well tolerated.

Enrollment and dosing in our Phase 1b trial evaluating subjects with CHB is ongoing and we continue to initiate more clinical trial centers to support this study. However, recent delays to enrollment of chronic hepatitis B subjects have been encountered due to COVID-19 related logistical challenges and an increasing number of competitive phase 2 clinical trials. Consequently, data from the planned 3 cohorts, evaluating a range of doses, are expected to be available in the first half of 2022.

Given that STOPS molecules work by a novel mechanism and patient antiviral response characteristics are unknown, we believe it is important to generate a dataset from multiple cohorts. This should enable us to refine the PK-PD model to optimize dosing for evaluation in subsequent cohorts and studies. We plan to unblind virological data, including HBsAg, once dosing in the first three cohorts has been completed.

In addition, evaluation of ALG-000184, a small molecule class II capsid assembly modulator (CAM), was initiated in patients with CHB in April. This dose range finding study (NCT04536337) is evaluating 28 days of once daily oral dosing of ALG-000184 or placebo in treatment naïve/currently not treated CHB patients. Initial 14-day data from the first cohort demonstrated that a 100 mg dose was well tolerated and resulted in significant antiviral activity. These 14-day data were presented at the HBV-TAG 2021 meeting in June. Data from additional cohorts are expected to be presented at one or more scientific conferences in the second half of 2021.

The initial CTA for our third CHB drug candidate, ALG-020572, an antisense oligonucleotide (ASO), was recently filed. We expect to begin evaluating ALG-020572 in HVs in the fourth quarter of 2021.

The CTA for our first nonalcoholic steatohepatitis (NASH) drug candidate, ALG-055009, a thyroid hormone receptor beta agonist, remains on track to be filed in the third quarter of 2021 to enable evaluation in HVs to commence in the fourth quarter of 2021.

Aligos has a broad CHB portfolio that targets different clinically validated mechanisms of action in the hepatitis B virus life cycle. The portfolio includes ALG-000184, a class II CAM, ALG-010133, a STOPS molecule, ALG-020572, an ASO, and ALG-020755, a small interfering RNA (siRNA) drug candidate. The properties of these candidates indicate that their use in combination could yield potentially best-in-class treatment regimens that may achieve higher rates of functional cure than current standard of care. For each of these drug candidates, Aligos plans to initially establish proof of concept as monotherapy in Phase 1 dose range finding trials before evaluating them in combination in subsequent trials.

Corporate:

The company announced the pricing of its underwritten public offering of 4,400,000 shares of common stock at a public offering price of $19.00 per share. In addition, the company granted the underwriters a 30-day option to purchase up to an additional 660,000 shares of common stock at the same terms and conditions. All of the shares of common stock were offered by the company.

The gross proceeds from the offering, before deducting underwriting discounts and commissions and other offering expenses payable by Aligos, were $83.6 million, excluding any exercise of the underwriters' option to purchase additional shares. The offering closed on July 6, 2021, subject to customary closing conditions.

Financial Results for the Second Quarter 2021

Net losses for the three months ended June 30, 2021 were $29.8 million or basic and diluted net loss per common share of $(0.79) compared to net losses of $20.8 million or basic and diluted net loss per common share of $(7.40) for the three months ended June 30, 2020.

Research and development (R&D) expenses for the three months ended June 30, 2021, were $24.6 million compared with $17.2 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 of ALG-010133 and ALG-000184 clinical trial activities, as well as increases in salaries and employee-related expenses and preclinical programs. Total R&D stock-based compensation expense incurred for the three months ended June 30, 2021, was $2.0 million compared with $0.2 million for the same period for 2020.

General and administrative (G&A) expenses for the three months ended June 30, 2021, were $6.6 million compared with $4.1 million for the same periods of 2020. The increase in G&A expenses for this comparative period is primarily attributable to higher employee-related costs associated with the growth of the Company's operations and additional professional and consulting services related to being a public company. Total G&A stock-based compensation expense incurred for the three months ended June 30, 2021, was $1.5 million compared with $0.1 million for the same period for 2020.

Cash, cash equivalents and short-term investments totaled $190.7 million as of June 30, 2021 compared with $243.5 million as of December 31, 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's anticipation to begin dosing of ALG-020572 in HVs and CHB subjects in the fourth quarter of 2021; Aligos being on track to file a CTA for ALG-055009 and to start dosing in HBs in the fourth quarter of 2021; Aligos's expectation that generating a complete dataset from multiple cohorts for its ongoing Phase 1a/b multi-part dose range finding trial for ALG-010133 should enable the company to refine a PK-PD model to optimize dosing for evaluation in subsequent cohorts and studies and its plan to unblind virological data upon completion of the dosing in the first three cohorts in such ongoing ALG-010133 trial; Aligos's expectation to present data from additional cohorts of its ALG-000184 dose range finding study in the second half of 2021; Aligos's expectation to begin evaluating ALG-020572 in HVs and CHB subjects in the fourth quarter of 2021; Aligos remaining on track to file its CTA for ALG-055009 in the third quarter of 2021 to enable evaluation in HVs to commence in the fourth quarter of 2021; the use of the candidates in Aligos's CHB portfolio in combination yielding potentially best-in-class treatment regimens that may achieve higher rates of functional cure than current standard of care; and Aligos's plans to initially establish proof of concept as monotherapy in Phase 1 dose range finding trials for each of these CHB drug candidates before evaluating them in combination in subsequent trials. 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 candidates, 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. 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 5, 2021 and as well as other documents Aligos files from time to time 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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue from Collaborations	$ 1,545	$ -	$ 2,455	$ -
Operating Expenses:				
Research and development	24,554	17,176	47,422	34,478
General and administrative	6,556	4,095	12,337	7,514
Total operating expenses	31,110	21,271	59,759	41,992
Loss from operations	(29,565)	(21,271)	(57,304)	(41,992)
Interest and other income (expense), net	(225)	415	(114)	1,108
Loss before income tax expense	(29,790)	(20,856)	(57,418)	(40,884)
Income tax income (expense)	(28)	59	(74)	58

Net loss	$ (29,818)	$ (20,797)	$ (57,492)	$ (40,826)
Basic and diluted net loss per common share	$ (0.79)	$ (7.40)	$ (1.53)	$ (14.96)
Weighted-average number of shares used in computing basic and diluted net loss per common share	37,619,039	2,810,854	37,526,650	2,729,827

Aligos Therapeutics, Inc
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2021	December 31, 2020
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 187,650	$ 220,383
Short-term investments	3,003	23,130
Prepaid expenses and other current assets	5,989	6,504
Total current assets	196,642	250,017
Other assets	15,234	15,285
Total assets	$ 211,876	$ 265,302
Liabilities and Stockholders' Equity		
Current liabilities	$ 30,098	$ 30,274
Other liabilities, noncurrent	12,894	14,989
Total liabilities	42,992	45,263
Total stockholders' equity	168,884	220,039
Total liabilities and stockholders' equity	$ 211,876	$ 265,302

(1) The condensed, consolidated balance sheet at December 31, 2020 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, 2020.

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