# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

Washington, D.C. 20549

#### **CURRENT REPORT**

### Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): August 5, 2021

#### Aligos Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

**Delaware** (State or Other Jurisdiction of Incorporation)

**001-39617** (Commission File Number)

**82-4724808** (I.R.S. Employer Identification Number)

One Corporate Dr., 2nd Floor South San Francisco, CA 94080 (Address of Principal Executive Offices) (Zip Code)

(800) 466-6059

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

-	-				
ı	1	Written communications pursu	ant to Rule 425 under	the Securities Act	(17 CFR 230 425)
L	1	Wiltich Communications parsa	ant to Ruic 425 under	the occurred fact	(1/ CI IX 230.723)

- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	Name of each exchange on which registered		
Common Stock, \$0.0001 par value per share	ALGS	The Nasdaq Stock Market LLC		
		(Nasdaq Global Select Market)		

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

#### Item 2.02. Results of Operations and Financial Condition.

On August 5, 2021, the Registrant issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 2.02 and the attached Exhibit 99.1 are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed to be incorporated by reference in any filing made by the Registrant under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

#### Item 9.01. Financial Statements and Exhibits.

Exhibit 99.1. Press release dated August 5, 2021

### **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aligos Therapeutics, Inc.

By: <u>/s/ Lesley Ann Calhoun</u> Lesley Ann Calhoun Date: August 5, 2021

Executive Vice President, Chief Financial Officer

# 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 2<sup>nd</sup> CHB cohorts ongoing Clinical trial application filed for 3<sup>rd</sup> CHB drug candidate ALG-0202572 (antisense oligonucleotide) – dosing in HVs anticipated in O4 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<sup>TM</sup>) compound, ALG-010133, were presented at the European Association for the Study of the Liver (EASL) Digital International Liver Congress<sup>TM</sup> 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,				
	· · · · · · · · · · · · · · · · · · ·		2020	2021		2020		
	(U	naudited)	(	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	3	7,619,039		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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