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

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): November 4, 2021

ALIGOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39617**	**82-4724808**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

One Corporate Dr., 2nd Floor
South San Francisco, California 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:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ 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:

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

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

Emerging growth company ☒

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 November 4, 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 November 4, 2021

Exhibit 104. Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: November 4, 2021

By: /s/ Lesley Ann Calhoun
Lesley Ann Calhoun
Executive Vice President, Chief Financial Officer

EXHIBIT 99.1

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

Dosing of ALG-020572 (ASO) in healthy volunteers underway

Enrollment in first 2 STOPS cohorts (120, 200 mg) complete; enrollment in 3rd cohort (400 mg) underway

Clinical trial application (CTA) filed for 1st NASH drug candidate, ALG-055009, a THR-beta agonist

SOUTH SAN FRANCISCO, Calif., Nov. 04, 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 third quarter ended, September 30, 2021.

“The last quarter has been busy and productive for Aligos,” said Lawrence Blatt, PhD, MBA, Chairman and CEO of Aligos. “We now have three of our four drug candidates targeting chronic hepatitis B, each of which has a distinct additive or synergistic mechanism of action, dosing in the clinic. Additionally, enrollment of CHB patients has improved, and our planned safety and viral kinetic data readout for the first three cohorts of STOPS™ remains on track for the first half of 2022. In parallel to this effort, the Aligos team was able to successfully file the CTA for our first drug candidate for the treatment of NASH, ALG-055009. The progress made by our team over the last quarter positions us well to be able to deliver key data for multiple programs in 2022.”

Recent Business Progress
Aligos’ portfolio of drug candidates has continued to advance during the quarter with the following accomplishments achieved:

- S-Antigen Transport-Inhibiting Oligonucleotide Polymers (STOPS; ALG-010133)
  - Our Phase 1b dose range finding trial (NCT04485663) evaluating subjects with CHB is ongoing. Enrollment in the second cohort, evaluating the 200 mg dose level, was completed and enrollment in the third cohort, evaluating a 400 mg dose level, is now underway. We remain on track to unblind and share topline safety and viral kinetic data, including Hepatitis B S-antigen (HBsAg) data, from the first three cohorts in the first half of 2022.
- Capsid Assembly Modulator (CAM; ALG-000184)
  - Our Phase 1b dose range finding trial (NCT04536337) evaluating CHB subjects is ongoing. Enrollment of hepatitis B E-antigen (HBeAg) negative subjects into 50 and 100 mg dose cohorts is now complete. Enrollment of a 10 mg dose cohort is underway to determine the minimum efficacious dose. A cohort of HBeAg-positive CHB patients receiving a 100 mg dose for 28 days has also been fully enrolled in China.
  - A poster describing the safety, PK, and antiviral activity of the 50 and 100 mg doses of ALG-000184 given for 28 days in HBeAg-negative CHB subjects will be presented at The Liver Meeting® (American Association for the Study of Liver Disease) later this month.
- Antisense Oligonucleotide (ASO; ALG-020572)
  - Our Phase 1a/b multi-part study (NCT05001022) evaluating ALG-020572 in healthy volunteers and CHB subjects has recently commenced. Enrollment of healthy volunteers in the single ascending dose (SAD) portion of the study was initiated in October 2021.
- Nonalcoholic Steatohepatitis (NASH; ALG-055009, a thyroid hormone receptor beta (THR-B) agonist)
  - The CTA for ALG-055009 was filed in France to enable a SAD and multiple ascending dose (MAD) study in healthy volunteers and hyperlipidemic subjects, respectively.
  - Study startup activities remain on track with dosing in healthy volunteers expected to begin 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 a STOPS molecule, ALG-000184, a class II CAM, ALG-010133, ALG-020572, an ASO, and ALG-020755, an 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.

Financial Results for the Third Quarter 2021
Net losses for the three months ended September 30, 2021 were $33.1 million or basic and diluted net loss per common share of $(0.78) compared to net losses of $33.3 million or basic and diluted net loss per common share of $(11.00) for the three months ended September 30, 2020.

Research and development (R&D) expenses for the three months ended September 30, 2021, were $28.1 million compared with $17.3 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-010133, ALG-000184 and ALG-020572 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 September 30, 2021, was $1.9 million compared with $0.3 million for the same period for 2020.

General and administrative (G&A) expenses for the three months ended September 30, 2021, were $6.5 million compared with $4.2 million for the same period 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, legal and consulting services related to being a public company. Total G&A stock-based compensation expense incurred for the three months ended September 30, 2021, was $1.7 million compared with $0.7 million for the same period for 2020.

Cash, cash equivalents and investments totaled $242.7 million as of September 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 with respect to its ALG-010133 Phase 1b dose range finding trial to be able to share safety and viral kinetic data, including Hepatitis B S-antigen (HBsAg) data, from the first three cohorts in the first half of 2022; Aligos's being able to deliver key data for multiple programs in 2022; Aligos's expectation with respect to ALG-055009 to begin dosing in healthy volunteers 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 its 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 November 4, 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue from Collaborations	$ 1,537	$ -	$ 3,992	$ -
Operating Expenses:				
Research and development	28,132	17,332	75,555	51,809
General and administrative	6,473	4,225	18,810	11,739
Total operating expenses	34,605	21,557	94,365	63,548
Loss from operations	(33,068)	(21,557)	(90,373)	(63,548)
Interest and other income (expense), net	70	(11,740)	(44)	(10,633)
Loss before income tax expense	(32,998)	(33,297)	(90,417)	(74,181)
Income tax income (expense)	(126)	-	(201)	58

Net loss	$ (33,124)	$ (33,297)	$ (90,618)	$ (74,123)
Basic and diluted net loss per common share	$ (0.78)	$ (11.00)	$ (2.31)	$ (26.20)
Weighted-average number of shares used in computing basic and diluted net loss per common share	42,399,984	3,027,825	39,151,095	2,829,160

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

	September 30, 2021	December 31, 2020
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 239,734	$ 220,383
Short-term investments	2,451	23,130
Prepaid expenses and other current assets	6,485	6,504
Total current assets	248,670	250,017
Long-term investments	492	--
Other assets	13,906	15,285
Total assets	$ 263,068	$ 265,302
Liabilities and Stockholders' Equity		
Current liabilities	$ 34,780	$ 30,274
Other liabilities, noncurrent	11,277	14,989
Total liabilities	46,057	45,263
Total stockholders' equity	217,011	220,039
Total liabilities and stockholders' equity	$ 263,068	$ 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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