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 2, 2022

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 2, 2022, 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 2, 2022

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 2, 2022

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 2022 Financial Results

SOUTH SAN FRANCISCO, Calif., Nov. 02, 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 reported recent business progress and financial results for the third quarter, September 30, 2022.

“We continue to make important progress in advancing our portfolio of drug candidates targeting chronic hepatitis B (CHB), COVID-19, and NASH,” said Lawrence Blatt, PhD, MBA, Chairman and CEO of the Board at Aligos. “For our capsid assembly modulator (CAM), ALG-000184, we have observed a favorable safety and antiviral activity profile after 28 days of dosing and, as a result, have recently initiated longer term dosing cohorts. These cohorts will evaluate up to 48 weeks of treatment with ALG-000184 and will further define the potential role of this drug candidate in achieving chronic suppression and functional cure in CHB. We also recently began clinical evaluation in healthy volunteers of ALG-125755, our siRNA targeting HBsAg production. We anticipate evaluating this drug in CHB subjects in Q1 2023.”

“For our NASH thyroid hormone receptor beta agonist program, we will be sharing new safety and pharmacodynamic data after multiple doses of ALG-055009 in subjects with hyperlipidemia at The Liver Meeting (AASLD). The emerging safety and anti-lipid activity data appear favorable and support advancing this drug into phase 2 development.”

“As with our development programs, our discovery projects are also making important progress,” said Leonid Beigelman, PhD, President of Aligos. “ALG-097558, our potent, pan-coronavirus protease inhibitor that doesn’t require boosting with ritonavir is currently undergoing Phase 1 enabling non-clinical studies and we plan to initiate clinical evaluation of this important drug candidate in Q2 2023.”

Recent Business Progress

Aligos Portfolio of Drug Candidates

HBV Programs

- ALG-000184 (CAM) – Evaluation of a range of doses given over 28 days to both HBeAg positive and HBeAg negative CHB subjects is largely complete. New data from cohorts evaluating 100 and 300 mg in HBeAg positive CHB subjects will be presented at The Liver Meeting (AASLD) in November. Based on the favorable safety and antiviral activity profile from these cohorts, the Study Review Committee (SRC) recommended the evaluation of 100 mg and 300 mg in HBeAg positive CHB subjects for up to 48 weeks. We anticipate sharing antiviral activity data from these new cohorts throughout 2023.

- ALG-125755 (siRNA) – Single ascending doses (SAD) of ALG-125755 are currently being evaluated in healthy volunteers in New Zealand. If the safety profile is favorable, we anticipate initiating cohorts evaluating SAD in CHB subjects in Q1 2023 and sharing data at scientific conferences throughout 2023.

NASH Program

- ALG-055009 – Evaluation of single and multiple ascending doses (SAD, MAD) in healthy volunteers and subjects with hyperlipidemia is complete and MAD data will be presented in November at The Liver Meeting (AASLD). Data from this Phase 1 study continue to be favorable.

COVID-19

- ALG-097558 – First in human enabling nonclinical studies are ongoing. We anticipate initiating the clinical evaluation of single and multiple ascending doses of this drug candidate in healthy volunteers in Q2 2023.

Financial Results for the Third Quarter 2022

Cash, cash equivalents, and investments totaled $142.3 million as of September 30, 2022, compared with $205.8 million as of December 31, 2021. We continue to believe our cash balance provides sufficient cash to fund planned operations into the first half of 2024.

Net losses for the three months ended September 30, 2022, were $18.6 million or basic and diluted net loss per common share of $(0.44), compared to net losses of $33.1 million or basic and diluted net loss per common share of $(0.78) for the three months ended September 30, 2021.

Research and development (R&D) expenses for the three months ended September 30, 2022, were $17.8 million compared with $28.1 million for the same period of 2021. The decrease in R&D expenses for this comparative period is primarily attributable to a decrease in third-party expenses due primarily to our continued winddown related to the discontinuation of our STOPS and ASO programs, and the manufacturing of drug supply in advance of our clinical trial activity for our CAM and siRNA programs. Total R&D stock-based compensation expense incurred for the three months ended September 30, 2022, was $1.9 million compared with $1.9 million for the same period of 2021.

General and administrative (G&A) expenses for the three months ended September 30, 2022, were $5.3 million compared with $6.5 million for the same period of 2021. The decrease in G&A expenses for this comparative period is primarily attributable to facility costs and updated expense allocations. Total G&A stock-based compensation expense incurred for the three months ended September 30, 2022, was $1.5 million compared with $1.7 million for the same period of 2021.

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, with respect to our CAM, ALG-000184, statements regarding the evaluation of 100 mg and 300 mg in HBeAg positive CHB subjects for up to 48 weeks, our anticipation of sharing antiviral activity data from these cohorts throughout 2023 and that such cohorts will further define the potential role of this drug candidate in achieving chronic suppression and functional cure in CHB; with respect to our siRNA, ALG-125755, statements regarding our evaluating this drug in CHB subjects in Q1 2023 and sharing data at scientific conferences throughout 2023; with respect to our NASH thyroid hormone receptor beta agonist program, ALG-055009, statements that the emerging safety and anti-lipid activity data appear favorable and support advancing this drug into phase 2 development; with respect to our pan-coronavirus protease inhibitor, ALG-097558, statements around our plan to initiate clinical evaluation thereof in Q2 2023; and the statement regarding our belief that our cash balance provides sufficient cash to fund planned operations into the first half 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'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 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's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 2, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue from Collaborations	$ 4,106	$ 1,537	$ 10,370	$ 3,992
Operating Expenses:				
Research and development	17,791	28,132	65,977	75,555
General and administrative	5,263	6,473	19,291	18,810
Total operating expenses	23,054	34,605	85,268	94,365
Loss from operations	(18,948)	(33,068)	(74,898)	(90,373)
Interest and other income (expense), net	284	70	795	(44)
Loss before income tax expense	(18,664)	(32,998)	(74,103)	(90,417)

Income tax benefit (expense)	43	(126)	(57)	(201)
Net loss	(18,621)	(33,124)	(74,160)	(90,618)
Basic and diluted net loss per common share	$ (0.44)	$ (0.78)	$ (1.74)	$ (2.31)
Weighted-average number of shares used in computing basic and diluted net loss per common share	42,761,928	42,399,984	42,647,732	39,151,095

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

	September 30, 2022	December 31, 2021
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 86,440	$ 186,816
Short-term investments	55,864	3,918
Prepaid expenses and other current assets	7,789	13,690
Total current assets	150,093	204,424
Long-term investments	-	15,110
Other assets	13,976	15,835
Total assets	$ 164,069	$ 235,369
Liabilities and Stockholders' Equity		
Current liabilities	$ 30,541	$ 38,957
Other liabilities, noncurrent	11,515	11,681
Total liabilities	42,056	50,638
Total stockholders' equity	122,013	184,731
Total liabilities and stockholders' equity	$ 164,069	$ 235,369

(1) The condensed, consolidated balance sheet at December 31, 2021 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, 2021.

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