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): March 9, 2023

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 March 9, 2023, 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 March 9, 2023

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: March 9, 2023

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

EXHIBIT 99.1

Aligos Therapeutics Reports Recent Business Progress and Fourth Quarter and Full Year 2022 Financial Results

SOUTH SAN FRANCISCO, Calif., March 09, 2023 (GLOBE NEWSWIRE) -- Aligos Therapeutics, Inc. (Nasdaq: ALGS), a clinical stage biopharmaceutical company focused on developing novel therapeutics to address unmet medical needs in liver and viral diseases, today reported recent business progress and financial results for the fourth quarter and full year 2022.

"Last year was very productive for our team," said Lawrence Blatt, PhD, MBA, Chairman & CEO of Aligos. "We made great progress advancing our NASH, COVID-19, and CHB drug candidates. In particular, our drug candidate for NASH, ALG-055009, continued to generate positive data in the clinic that differentiates it from other THR-beta agonists in development. Additionally, important nonclinical advances were made for ALG-097558, our protease inhibitor for COVID-19, which is anticipated to enter the clinic in the first half of this year. Finally, our CAM-E, ALG-000184, continues to generate potentially best-in-class antiviral activity data, including HBsAg reductions that are significantly more substantial than competitor CAM-E drugs, suggesting that it may be an important component in future treatments for CHB. Taken together, we expect these programs to have multiple important data readouts as we continue to advance them throughout 2023. These data have the potential to be important drivers of shareholder value and we look forward to sharing them as they emerge."

Recent Business Progress

Aligos Portfolio of Drug Candidates

NASH Program

- ALG-055009 – Evaluation of single and multiple ascending doses (SAD, MAD) in healthy volunteers and subjects with hyperlipidemia was completed and MAD data were presented in November at The Liver Meeting (AASLD). Data from this Phase 1 study continue to be favorable and are positively differentiated compared to competitor drugs in the same class. We remain on track to submit a Phase 2 clinical trial filing by the end of 2023.

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, with top line safety and PK data available by Q4 2023.

HBV Programs

- ALG-000184 (CAM-E) – Evaluation of a range of doses given over 28 days to both HBeAg positive and HBeAg negative CHB subjects was completed. Additionally, new interim data from cohorts evaluating dosing durations of up to 48 weeks in HBeAg positive subjects were presented by Professor Hou, Nanfang Medical University, China at the Asian Pacific Association for the Study of the Liver meeting (APASL) in February 2023. This presentation demonstrated favorable safety and antiviral activity for up to 12 weeks of dosing, including notable reductions in HBsAg levels. We anticipate sharing additional safety and antiviral activity data for up to 48 weeks of dosing from these and other ongoing cohorts at scientific conferences throughout 2023.

- ALG-125755 (siRNA) – The SAD evaluation of ALG-125755 in healthy volunteers was completed and doses up to 200 mg were found to have a favorable safety and PK profile (Gane et al., APASL 2023). As a result, SAD cohorts in CHB subjects are now being evaluated. We anticipate sharing emerging data from these cohorts at scientific conferences throughout 2023.

Financial Results for the Fourth Quarter and Full Year 2022

Cash, cash equivalents and investments totaled $125.8 million as of December 31, 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 through the end of 2024.

Net losses for the three months ended December 31, 2022, were $21.9 million or basic and diluted net loss per common share of $(0.51), compared to net losses of $37.7 million or basic and diluted net loss per common share of $(0.89) for the three months ended December 31, 2021.

Net losses for the year ended December 31, 2022, were $96.0 million or basic and diluted net loss per common share of $(2.25), compared to net losses of $128.3 million or basic and diluted net loss per common share of $(3.22) for the year ended December 31, 2021.

Research and development (R&D) expenses for the three months ended December 31, 2022, were $19.1 million compared with $28.6 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 to our continued wind down related to the discontinuation of our STOPS and ASO programs, and the manufacturing of drug supply in advance of our clinical and nonclinical activities. Total R&D stock-based

compensation expense incurred for the three months ended December 31, 2022, was $1.9 million compared with $1.9 million for the same period of 2021.

R&D expenses for the year ended December 31, 2022 were $85.1 million, compared with $104.2 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 to our continued wind down related to the discontinuation of our STOPS and ASO programs, and the manufacturing of drug supply in advance of our clinical and nonclinical activities. Total R&D stock-based compensation expense incurred in the year ended December 31, 2022, was $8.0 million, compared with $7.6 million for the same period of 2021.

General and administrative (G&A) expenses for the three months ended December 31, 2022, were $7.1 million compared with $9.7 million for the same period of 2021. The decrease in G&A expenses for this comparative period is primarily attributable to facility costs and outside services costs. Total G&A stock-based compensation expense incurred for the three months ended December 31, 2022, was $1.6 million compared with $1.7 million for the same period of 2021.

General and administrative (G&A) expenses for the year ended December 31, 2022, were $26.4 million compared with $28.5 million for the same period of 2021. The decrease in G&A expenses for this comparative period is primarily attributable to facility costs and outside services costs. Total G&A stock-based compensation expense incurred for the year ended December 31, 2022, was $6.7 million compared with $5.9 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 liver and viral diseases. Aligos' strategy is to harness the deep expertise and decades of drug development experience its team has in liver and viral diseases to discover and develop potentially best in class therapeutics for nonalcoholic steatohepatitis (NASH) and viruses with high unmet medical need such as coronaviruses and chronic hepatitis B (CHB).

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, that Aligos expects that its described NASH, COVID-19 and CHB programs will have multiple important data readouts as it continues to advance them throughout 2023, and that these data have the potential to be important drivers of shareholder value; with respect to Aligos' THR-beta agonists for NASH, ALG-055009, statements that the company remains on track to submit a Phase 2 clinical trial filing by the end of 2023; with respect to Aligos' COVID-19 protease inhibitor, ALG-097558, statements that the company anticipates it will enter the clinic in the first half of 2023, more specifically Q2 2023, with top line safety and PK data available by Q4 2023; with respect to Aligos' CAM-E, ALG-000184, statements that the company anticipates sharing additional safety and antiviral activity data from cohorts evaluating dosing durations of up to 48 weeks in HBeAg positive subjects and other ongoing cohorts at scientific conferences throughout 2023, that its antiviral data, including HBsAg reductions, suggest that it may be an important component in future treatments for CHB; with respect to Aligos' siRNA, ALG-125755, statements that the company anticipates sharing emerging data from the SAD cohorts in CHB subjects at scientific conferences throughout 2023; and statements with respect to Aligos' belief its cash balance provides sufficient cash to fund planned operations through the end 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' 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' ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of Aligos' 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' Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 9, 2023 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,	
	2022	2021	2022	2021
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited) (1)

Revenue from Collaborations	$3,537	$367	$13,907	$4,359
Operating Expenses:				
Research and development	19,100	28,598	85,077	104,153
General and administrative	7,119	9,717	26,410	28,527
Total operating expenses	26,219	38,315	111,487	132,680
Loss from operations	(22,682)	(37,948)	(97,580)	(128,321)
Interest and other income, net	845	176	1,640	132
Loss before income tax expense	(21,837)	(37,772)	(95,940)	(128,189)
Income tax benefit (expense)	(49)	58	(106)	(143)
Net loss	(21,886)	(37,714)	(96,046)	(128,332)
Basic and diluted net loss per common share	$(0.51)	$(0.89)	$(2.25)	$(3.22)
Weighted-average number of shares used in computing basic and diluted net loss per common share	42,836,163	42,341,972	42,695,227	39,855,403

Aligos Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

	December 31, 2022	December 31, 2021
	(Unaudited)	(Unaudited) (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 81,347	$ 186,816
Short-term investments	44,480	3,918
Prepaid expenses and other current assets	7,718	13,690
Total current assets	133,545	204,424
Long-term investments	-	15,110
Other assets	13,148	15,835
Total assets	$ 146,693	$ 235,369
Liabilities and Stockholders' Equity		
Current liabilities	$ 33,129	$ 38,957
Other liabilities, noncurrent	9,664	11,681
Total liabilities	42,793	50,638
Total stockholders' equity	103,900	184,731
Total liabilities and stockholders' equity	$ 146,693	$ 235,369

(1) The condensed, consolidated statement of operations for the year ended December 31, 2021, and balance sheet as of 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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