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): August 3, 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 August 3, 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 August 3, 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: August 3, 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 Second Quarter 2023 Financial Results

SOUTH SAN FRANCISCO, Calif., Aug. 03, 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 second quarter 2023.

“We continue to make important progress in advancing our portfolio of drug candidates,” said Lawrence Blatt, Ph.D., MBA, Chairman & CEO of Aligos Therapeutics. “Phase 2a enabling activities for our lead program in NASH, ALG-055009, are going well and we remain on track to file this important Phase 2a protocol to the US IND in Q4 2023. Additionally, our COVID-19 protease inhibitor, ALG-097558, is now dosing in the clinic in a first in human study and our best-in-class capsid assembly modulator, ALG-000184, continues to generate impressive DNA, RNA, and HBsAg lowering activity as dosing continues in CHB subjects. We look forward to sharing emerging data from these exciting programs at future scientific conferences.”

Recent Business Progress

Aligos Portfolio of Drug Candidates

NASH Program (ALG-055009)

- Dosing in the Phase 1 first-in-human study is now complete and the database is locked. Data at all dose levels continue to support a favorable risk-benefit profile for ALG-055009
- Phase 2a enabling activities (e.g., drug manufacturing, non-clinical studies) are ongoing and on track for a Q4 2023 filing of the Phase 2a protocol
- Key design elements/milestones of the Phase 2a study have been formulated and include:
  - Randomized, double-blind, placebo-controlled trial evaluating dosing for 12 weeks
  - Evaluation of multiple dose levels of ALG-055009 vs. placebo (gelcap formulation)
  - Primary endpoint based on change from baseline at 12 weeks in MRI-PDFF
  - Additional non-invasive biomarkers commonly evaluated in NASH trials will also be assessed
  - All sites will be in the US
  - Anticipated top line data: Q4 2024
- Stephen Harrison, MD has signed on to be the Phase 2a study’s Principal Investigator

COVID-19 (ALG-097558)

- The first-in-human study (ALG-097558-701) clinical trial application was approved in the UK
- Dosing in Part 1, which is evaluating single ascending oral doses in healthy volunteers, of this multi-part study is ongoing
- Dosing is expected to continue throughout 2023 and early 2024 with topline data anticipated in H1 2024

HBV Programs

Capsid-Assembly Modulator (ALG-000184)

- Ongoing cohort data continue to show that 300 mg ALG-000184 + entecavir (ETV) is well tolerated and results in unprecedented HBsAg lowering activity for an oral CHB drug. Specifically, Hou et al., showed at EASL 2023 that a majority of HBeAg positive CHB subjects dosed with 300 mg ALG-000184 + ETV demonstrated declines of ≥0.4 and ≥1.0 $\log_{10}$ IU/mL at 12 and 24 weeks, respectively. The largest HBsAg reduction observed among subjects receiving this regimen was a 2 $\log_{10}$ IU/mL decline in a subject dosed for 36 weeks
- Dosing with ALG-000184 + entecavir for up to 96 weeks in HBeAg positive and HBeAg negative CHB subjects is planned
- Emerging data will continue to be presented at upcoming scientific conferences

ALG-125755

- Dosing in Parts 1 and 2, which evaluated single ascending subcutaneous doses of ALG-125755 in healthy volunteers and virologically suppressed HBeAg negative CHB subjects, respectively, is now complete
- Single doses of up to 320 mg ALG-125755:
  - Were found to be well tolerated with predicted PK
  - Lowered HBsAg levels across the dose range evaluated, but comparative efficacy data vs. competitor siRNAs are inconclusive
  - Further clinical evaluation of ALG-125755 is not prioritized with current funding. Further advancement will require partnership of the program.

Corporate

- On July 31, 2023, Aligos Therapeutics, Inc. (the “Company”) and Janssen Biopharma, LLC (“Janssen”) filed a stipulation staying the case in their ongoing legal proceedings. The Company and Janssen have reached an agreement in principle to resolve their disputes and expect to finalize a settlement agreement promptly.

Financial Results for the Second Quarter 2023

Cash, cash equivalents and investments totaled $90.8 million as of June 30, 2023, compared with $125.8 million as of December 31, 2022. 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 June 30, 2023, were $18.8 million or basic and diluted net loss per common share of $(0.43), compared to net losses of $19.9 million or basic and diluted net loss per common share of $(0.47) for the three months ended June 30, 2022.

Research and development (R&D) expenses for the three months ended June 30, 2023, were $16.8 million compared with $16.5 million for the same period of 2022. The increase was primarily due to other costs including facility expenses due to the right-of-use asset impairment, largely offset by a decrease in third party expenses from the reduced manufacturing of drug supply in advance of our NASH program in 2022, and employee-related costs. Total R&D stock-based compensation expense incurred for the three months ended June 30, 2023, was $1.6 million compared with $2.2 million for the same period of 2022.

General and administrative (G&A) expenses for the three months ended June 30, 2023, were $9.2 million compared with $7.6 million for the same period of 2022. The increase in G&A expenses for this comparative period is primarily attributable to an increase in legal and related costs offset by a decrease in facility expenses. Total G&A stock-based compensation expense incurred for the three months ended June 30, 2023, was $1.6 million compared with $1.8 million for the same period of 2022.

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, with respect to the NASH ALG-055009 program, the data from the Phase 1 first-in-human study continuing to support a favorable risk-benefit profile, the ongoing Phase 2a enabling activities and the company remaining on track for a Phase 2a protocol filing in Q4 2023 and the anticipation of topline data in Q4 2024; with respect to the company’s COVID-19 ALG-097558 program, the ongoing dosing in Part 1 of the first-in-human multi-part study and the expectation that dosing will continue throughout 2023 and early 2024 with topline data anticipated in H1 2024; with respect to the capsid assembly modulator ALG-000184 program, the planned dosing with ALG-000184 + entecavir for up to 96 weeks in HBeAg positive and HBeAg negative CHB subjects and the program continuing to generate impressive DNA, RNA, and HBsAg lowering activity as dosing continues in CHB subjects; with respect to the siRNA ALG-125755 program, the requirement to partner for further advancement of the program; the company looking forward to sharing emerging data from these programs at upcoming/future scientific conferences; the company’s expectation that a settlement of the ongoing legal proceeding with Janssen will be reached promptly; and the company’s continued belief that 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’ Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 3, 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenue from Collaborations	$ 2,592	$ 3,693	$ 5,175	6,264
Revenue from Customers	4,294	-	4,434	-
Operating Expenses:				
Research and development	16,781	16,510	34,916	48,186
General and administrative	9,246	7,576	17,752	14,028
Total operating expenses	26,027	24,086	52,668	62,214
Loss from operations	(19,141)	(20,393)	(43,059)	(55,950)
Interest and other income, net	1,107	516	2,109	510
Loss before income tax expense	(18,034)	(19,877)	(40,950)	(55,440)
Income tax expense	(757)	(47)	(796)	(99)
Net loss	$ (18,791)	$ (19,924)	$ (41,746)	(55,539)
Basic and diluted net loss per common share	(0.43)	(0.47)	(0.97)	(1.30)
Weighted-average number of shares used in computing basic and diluted net loss per common share	43,215,478	42,665,598	43,063,615	42,590,479

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

	June 30, 2023	December 31, 2022
	(Unaudited)	(audited) (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 90,828	$ 81,347
Short-term investments	10	44,480
Prepaid expenses and other current assets	3,405	7,718
Total current assets	94,243	133,545
Other assets	11,887	13,148
Total assets	$ 106,130	$ 146,693
Liabilities and Stockholders' Equity		
Current liabilities	$ 27,225	$ 33,129
Other liabilities, noncurrent	9,270	9,664
Total liabilities	36,495	42,793
Total stockholders' equity	69,635	103,900
Total liabilities and stockholders' equity	$ 106,130	$ 146,693

(1) The balance sheet as of December 31, 2022, 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, 2022.

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