

**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): May 4, 2022

ALIGOS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-39617

(Commission File Number)

82-4724808

(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 May 4, 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 May 4, 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: May 4, 2022

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

Aligos Therapeutics Reports Recent Business Progress and First Quarter 2022 Financial Results

SOUTH SAN FRANCISCO, Calif., May 04, 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 first quarter March 31, 2022.

"From the very beginning, we designed Aligos to be a company with a diverse portfolio of drug candidates across a broad range of indications," said Lawrence Blatt, PhD, MBA, Chairman & CEO of Aligos. "This approach has allowed us to continue to advance promising new drug candidates from our portfolio even in the face of the recent discontinuation of our STOPS™ and antisense oligonucleotide (ASO) HBV programs in Q1. Our teams remain focused on advancing our pipeline and we look forward to achieving important milestones this year, including top line data for ALG-000184, our Class II CAM for HBV, and ALG-055009, our THR-β agonist for NASH. In addition, we are on track to file a clinical trial application in second half of 2022 to conduct a first in human study evaluating ALG-125755, our HBV siRNA. Finally, we are excited to see ALG-097558, a broad-spectrum coronavirus inhibitor that was identified in our collaboration with KU Leuven, advance towards the clinic."

Recent Business Progress

Aligos Portfolio of Drug Candidates:

HBV Programs

- ALG-000184 (Class II CAM) – dosing in the 10-300 mg range for 28 days in chronic hepatitis B (CHB) patients continued in Q1 and is set to complete in Q3 2022. Cohorts evaluating doses of 10-300 mg given over 12 weeks are also set to begin in Q3. We plan to share top line results for 28 day and 12-week cohorts in Q2 and Q4 2022, respectively.
- ALG-125755 (siRNA) – first in human enabling nonclinical studies continued in Q1 and are set to complete in Q3 2022 when we plan to file a clinical trial application (CTA) to enable dosing in healthy volunteers beginning in Q4 2022.
- Our STOPS and ASO programs were terminated in Q1 due to insufficient antiviral activity and poor tolerability, respectively, being observed in Phase 1 studies.

NASH Programs

- ALG-055009 (THR- β) – dosing in healthy volunteers (HVs) and subjects with hyperlipidemia continued in Q1 and is set to complete in Q2. Preliminary data after single and multiple oral doses will be shared as a poster presentation (Abstract #3109) at the upcoming EASL ILC meeting 22-26 June 2022. Topline results from this Phase 1 proof of concept study remain on track for release in Q3 2022.
- Significant progress has been made in the nonalcoholic steatohepatitis (NASH) oligonucleotide research collaboration with Merck with respect to the two undisclosed targets, utilizing Aligos' know-how and our proprietary oligonucleotide chemistry platform. Both collaboration programs are currently advancing further into lead optimization.

COVID Protease Inhibitor (PI) Program

ALG-097558 – we recently announced that we selected this broad-spectrum coronavirus protease inhibitor to move forward into development. ALG-097558 has shown superior potency compared to nirmatrelvir (PF-07321332) against SARS-CoV-2 and multiple resistant variants in all cell-based and biochemical assays tested to date. ALG-097558 is 7 to 20-fold more active than nirmatrelvir, depending on the variant. ALG-097558 exerts potent broad-spectrum activity against alpha and beta coronaviruses, and its highly conserved target site indicates a high probability that it will retain potent activity against potential future SARS-CoV-2 variants that may emerge. Projected efficacious doses of ALG-097558 can be achieved in humans without ritonavir boosting. Aligos expects to file a Phase 1 clinical trial application in second half of 2022.

Financial Results for the First Quarter 2022

Cash, cash equivalents and marketable securities totaled \$183.2 million as of March 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 into the first half of 2024.

Net losses for the three months ended March 31, 2022, were \$35.6 million or basic and diluted net loss per common share of \$0.84 compared to net losses of \$27.7 million or basic and diluted net loss per common share of \$0.74 for the three months ended March 31, 2021.

Research and development (R&D) expenses for the three months ended March 31, 2022, were \$31.7 million compared with \$22.9 million for the same period of 2021. The increase in R&D expenses for this comparative period is primarily attributable to an increase in third-party expenses primarily due to our continued increase in expenditures related to research, development and manufacturing activities associated with our CAM clinical trial activities as well as costs related to our NASH program, and our discontinued STOPS and ASO programs, leading to write off charges for non-cancelable purchase obligations. Total R&D stock-

based compensation expense incurred for the three months ended March 31, 2022, was \$2.0 million compared with \$1.7 million for the same period for 2021.

General and administrative (G&A) expenses for the three months ended March 31, 2022, were \$6.5 million compared with \$5.8 million for the same period of 2021. The increase in G&A expenses for this comparative period is primarily attributable to an increase in ordinary routine employee-related costs partially offset by a decrease in in third-party expenses primarily due to decreased legal and accounting service costs. Total G&A stock-based compensation expense incurred for the three months ended March 31, 2022, was \$1.8 million compared with \$1.0 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 statements regarding our continuing to advance new drug candidates from our portfolio in the face of the discontinuation of our STOPS™ and ASO HBV programs; our advancing our pipeline and looking forward to achieving important milestones this year, including top line data for ALG-000184 and ALG-055009; our being on track to file a clinical trial application in second half of 2022 to conduct a first in human study evaluating ALG-125755; our seeing ALG-097558 advance towards the clinic; with respect to ALG-000184, dosing for 28 days set to be complete in Q3 2022 while dosing for over 12 weeks set to begin in Q3, and our plan to share top line results for 28 day and 12-week cohorts in Q2 and Q4 2022, respectively; with respect to ALG-125755, first in human enabling nonclinical studies set to complete in Q3 2022 and our plan to file a CTA to enable dosing in healthy volunteers beginning in Q4 2022; with respect to ALG-055009, dosing in HVs and subjects with hyperlipidemia set to complete in Q2, sharing of preliminary data after single and multiple oral doses as a poster presentation (Abstract #3109) at the upcoming EASL ILC meeting 22-26 June 2022 and our being on track to release topline results from this Phase 1 proof of concept study in Q3 2022; with respect to the NASH oligonucleotide research collaboration with Merck, the further advancement of the collaboration programs into lead optimization; with respect to ALG-097558, the high probability that it will retain potent activity against potential future SARS-CoV-2 variants that may emerge, the ability to achieve projected efficacious doses of ALG-097558 in humans without ritonavir boosting and our expectation to file a Phase 1 clinical trial application in second half of 2022; and our belief 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 developing 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 May 4, 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 March 31,	
	2022	2021
	(Unaudited)	(Unaudited)
Revenue from Collaborations	\$ 2,571	\$ 910
Operating Expenses:		

Research and development	31,676	22,869
General and administrative	6,452	5,781
Total operating expenses	<u>38,128</u>	<u>28,650</u>
Loss from operations	(35,557)	(27,740)
Interest and other income (expense), net	<u>(5)</u>	<u>111</u>
Loss before income tax expense	(35,562)	(27,629)
Income tax expense	<u>(53)</u>	<u>(45)</u>
Net loss	<u>\$ (35,615)</u>	<u>\$ (27,674)</u>
Basic and diluted net loss per common share	<u>\$ (0.84)</u>	<u>\$ (0.74)</u>
Weighted-average number of shares used in computing basic and diluted net loss per common share	<u>42,511,559</u>	<u>37,434,261</u>

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

	<u>March 31, 2022</u>	<u>December 31, 2021</u>
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 104,562	\$ 186,816
Short-term marketable securities	78,660	3,918
Prepaid expenses and other current assets	11,854	13,690
Total current assets	<u>195,076</u>	<u>204,424</u>
Long-term investments	-	15,110
Other assets	15,394	15,835
Total assets	<u>\$ 210,470</u>	<u>\$ 235,369</u>
Liabilities and Stockholders' Equity		
Current liabilities	\$ 41,356	\$ 38,957
Other liabilities, noncurrent	16,228	11,681
Total liabilities	<u>57,584</u>	<u>50,638</u>
Total stockholders' equity	152,886	184,731
Total liabilities and stockholders' equity	<u>\$ 210,470</u>	<u>\$ 235,369</u>

(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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