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 13, 2022

ADAGIO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40703**	**83-1403134**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1601 Trapelo Road, Suite 178 **Waltham, Massachusetts** **(Address of principal executive offices)**	**02451** **(Zip Code)**

(Registrant's telephone number, including area code): (781) 819-0080

Not Applicable
(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 (see General Instruction A.2. below):

☐ 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, par value $0.0001 per share	**ADGI**	**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 13, 2022, Adagio Therapeutics, Inc. (the "Company") provided a corporate update and announced its financial results for the quarter ended March 31, 2022, in the press release attached hereto as Exhibit 99.1, which is incorporated herein by reference.

The information in this Item 2.02, including the attached Exhibit 99.1, is being furnished and shall not be deemed "filed" for the purposes of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company, under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated May 13, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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.

ADAGIO THERAPEUTICS, INC.

Date: May 13, 2022

By: /s/ Jill Andersen
Name: Jill Andersen
Title: Chief Legal Officer and Corporate Secretary

Exhibit 99.1

Adagio Therapeutics Reports First Quarter 2022 Financial Results

$532.2 Million in Total Cash at Quarter End; Strong Balance Sheet Expected to Support Operations into Second Half of 2024

Additional Data from Adintrevimab Phase 2/3 STAMP Treatment Trial to be Presented at ASM Annual Meeting

Waltham, MA – May 13, 2022 – Adagio Therapeutics, Inc. (Nasdaq: ADGI), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases, today reported financial results for the quarter ended March 31, 2022.

"We continue to be encouraged by adintrevimab's potential as a prophylactic and treatment option for certain variants of SARS-CoV-2, which is supported by the positive data that met all primary endpoints from our global EVADE and STAMP trials. We continue to engage with the FDA and are closely monitoring the evolution of the virus and the *in vitro* activity of adintrevimab against predominant variants in the U.S. to determine the optimal timing for an EUA request," said David Hering, interim chief executive officer and chief operating officer of Adagio. "Our efforts to improve antibody activity to the Omicron variant are ongoing, including modifications to adintrevimab and exploring higher doses in our Phase 1 trial. Additionally, we are advancing efforts to develop next generation monoclonal antibodies and move appropriate candidate(s) into preclinical testing. With capital to fuel our operations into the second half of 2024, we are confident in the road ahead for both Adagio and adintrevimab as we aim to bring differentiated antibody solutions forward for infectious disease."

Publication in *Science Immunology*

Research conducted by Adagio's chief scientific officer, among others, was recently published online in *Science Immunology*. The publication, entitled "Recall of pre-existing cross-reactive B cell memory following Omicron BA.1 breakthrough infection," is the first to describe the antibody response induced by Omicron breakthrough infection in molecular detail.

Upcoming Oral Data Presentation

Adagio plans to present additional data from its global Phase 2/3 STAMP COVID-19 treatment trial of adintrevimab at the American Society for Microbiology annual meeting taking place June 9-13, 2022, in Washington D.C. Details of the oral presentation are as follows:

- **Title:** Preliminary Results from the Phase 2/3 Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Adintrevimab in the Treatment of Ambulatory Participants with Mild or Moderate COVID-19 (STAMP)
- **Date & Time:** Saturday, June 11, 2022, between 9:15-10:05 a.m. ET

First Quarter 2022 Financial Results

- **Cash Position:** Cash and cash equivalents were $532.2 million as of March 31, 2022.
- **Cash Runway:** Based on current operating plans, Adagio expects its existing total cash and cash equivalents will enable the company to fund its operating expenses into the second half of 2024.
- **Research & Development (R&D) Expenses:** R&D expenses were $92.0 million for the first quarter of 2022, compared to $34.0 million for the comparable period of 2021. These increases are attributable to manufacturing validation and supply activities and ongoing clinical trial expenses.

- **Selling, General & Administrative (SG&A) Expenses:** SG&A expenses were $8.7 million for the first quarter of 2022, compared to $3.7 million for the comparable period of 2021. These increases are attributable to higher expenses due to public company costs and personnel.
- **Net Loss and Net Loss per Share:** Net loss was $100.7 million for the first quarter of 2022, compared to $38.7 million for the comparable period in 2021. Basic and diluted net loss per share was $0.93 for the first quarter of 2022.

About Adintrevimab

Adintrevimab (ADG20), Adagio's lead product candidate, is designed to be a potent, broadly neutralizing antibody for both the prevention and treatment of COVID-19, including disease caused by most variants. Adintrevimab is being assessed in two separate Phase 2/3 clinical trials: the EVADE trial for the prevention of COVID-19 in both the post-exposure and pre-exposure settings, and the STAMP trial for the treatment of COVID-19. Preliminary data from these trials demonstrated that in the pre-Omicron population, adintrevimab met the primary endpoints across all three indications, demonstrating statistically significant and clinically meaningful efficacy. Across each of the trials, intramuscular (IM) administration of adintrevimab at the 300mg dose had a similar safety profile to that of placebo. Adintrevimab is also being evaluated in a Phase 1 study to evaluate safety and pharmacokinetics at higher doses and, as of an interim data cut, no study drug related adverse events, serious adverse events, injection-site reactions or hypersensitivity reactions were reported across all dose levels evaluated. Adintrevimab is an investigational monoclonal antibody that is not approved for use in any country. The safety and efficacy of adintrevimab have not been established.

About Adagio Therapeutics

Adagio (Nasdaq: ADGI) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of differentiated products for the prevention and treatment of infectious diseases. The company is developing its lead product candidate, adintrevimab, for the prevention and treatment of COVID-19, the disease caused by the virus SARS-CoV-2 and its variants. Beyond COVID-19, Adagio is leveraging robust antibody discovery and development capabilities that have enabled expedited advancement of adintrevimab into clinical trials to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza.
Adintrevimab is an investigational monoclonal antibody that is not approved for use in any country. The safety and efficacy of adintrevimab have not been established. For more information, please visit www.adagiotx.com.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "could", "expects," "intends," "potential", "projects," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, our plans and strategies related to our emergency use authorization (EUA) submission for adintrevimab; our plans to advance adintrevimab as a potential prophylaxis and treatment option for COVID-19, including disease caused by most variants; our plans for continued communications with the U.S. Food and Drug Administration; our ongoing research and development plans, including our efforts to evaluate higher doses of adintrevimab to improve efficacy against, and to modify adintrevimab to improve binding to, the Omicron variant and its lineages, including BA.1 and BA.2; our plans to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza; the accuracy of the company's estimates regarding expenses, capital requirements and needs for additional financing; the sufficiency of the company's existing capital resources to fund its future operating expenses and capital expenditure requirements; and other statements that are not historical fact. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking

statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: the impacts of the COVID-19 pandemic on our business and those of our collaborators, our clinical trials and our financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of adintrevimab based on neutralizing activity in pre-clinical studies; variability of results in models used to predict activity against SARS-CoV-2 variants of concern; clinical trial site activation or enrollment rates that are lower than expected; changes in expected or existing competition; changes in the regulatory environment; and the uncertainties and timing of the regulatory approval process, including the outcome of our discussions with regulatory authorities concerning our Phase 2/3 clinical trials, whether adintrevimab is able to demonstrate activity against predominant SARS-CoV-2 variant(s) in the U.S., whether we are able to successfully submit an emergency use authorization in the future, and the outcome of any such emergency use application submission; whether research and development efforts will improve efficacy of adintrevimab against predominant variants or identify additional monoclonal antibodies for the prevention and treatment of COVID-19 and other infectious diseases; and whether we have adequate funding to meet future operating expenses and capital expenditure requirements into the second half of 2024. Other factors that may cause our actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (the “SEC”), and in our other filings with the SEC, and in Adagio’s future reports to be filed with the SEC. Such risks may be amplified by the impacts of the COVID-19 pandemic. Forward-looking statements contained in this press release are made as of this date, and Adagio undertakes no duty to update such information except as required under applicable law.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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ADAGIO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share and per share amounts)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$532,220	$ 542,224
Marketable securities	—	49,194
Prepaid expenses and other current assets	22,081	25,293
Total current assets	554,301	616,711
Property and equipment, net	87	83
Operating lease right-of-use asset	1,648	—
Other non-current assets	237	3,297
Total assets	$ 556,273	$ 620,091
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 18,682	$ 5,783
Accrued expenses	76,537	56,277
Operating lease liability, current	315	—
Total current liabilities	95,534	62,060
Early-exercise liability	3	6
Operating lease liability, non-current	1,344	—
Other non-current liability	—	6
Total liabilities	96,881	62,072
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at March 31, 2022 and December 31 2021	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 109,675,173 shares issued and outstanding at March 31, 2022; 1,000,000,000 shares authorized, 111,251,660 shares issued and 110,782,909 shares outstanding at December 31, 2021	11	11
Treasury stock, at cost; 0 shares and 468,751 shares at March 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	852,156	850,125
Accumulated other comprehensive loss	—	(8)
Accumulated deficit	(392,775)	(292,109)
Total stockholders' equity (deficit)	459,392	558,019
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 556,273	$ 620,091

ADAGIO THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)
(In thousands, except share and per share amounts)

	Three Months Ended March 31, 2022	Three Months Ended March 31, 2021
Operating expenses:		
Research and development(1)	$ 92,035	$ 34,032
Acquired in-process research and development(2)	—	1,000
Selling, general and administrative	8,704	3,677
Total operating expenses	100,739	38,709
Loss from operations	(100,739)	(38,709)
Other income (expense):		
Other income (expense), net	73	9
Total other income (expense), net	73	9
Net loss	(100,666)	(38,700)
Other comprehensive income (loss)		
Unrealized gain on available-for-sale securities, net of tax	8	—
Comprehensive loss	$ (100,658)	$ (38,700)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.93)	$ —
Weighted-average common shares outstanding, basic and diluted	107,869,570	—

(1) Includes related-party amounts of $2,000 and $188 for the three months ended March 31, 2022 and 2021, respectively.
(2) Includes related-party amounts of $0 and $1,000 for the three months ended March 31, 2022 and 2021, respectively.