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 29, 2021

Adagio Therapeutics, Inc.
(Exact name of registrant as specified in its Charter)

Delaware	**001-40703**	**85-1403134**
(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)**

(781) 819-0080
(Registrant's Telephone Number, Including Area Code)

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 Instructions 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, $0.0001 par value	**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 7.01 Regulation FD Disclosure.

On November 29, 2021, Adagio Therapeutics, Inc. (the "Company") issued a press release entitled "Adagio Therapeutics Reports That None of the Mutations Present in SARS-CoV-2 Variant, Omicron, Are Associated with Escape from ADG20 Neutralization In Vitro." The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01, including the attached Exhibit 99.1, is being furnished and shall not be deemed "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 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 shall be 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 November 29, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Adagio Therapeutics, Inc.

Dated: November 29, 2021

By: /s/ Jane Pritchett Henderson
Jane Pritchett Henderson
Chief Financial Officer

Exhibit 99.1

Adagio Therapeutics Reports That None of the Mutations Present in SARS-CoV-2 Variant, Omicron, Are Associated with Escape from ADG20 Neutralization In Vitro

Additional in vitro studies to determine neutralization activity of ADG20 against Omicron are ongoing

ADG20 EUA submissions planned for prevention and treatment of COVID-19 in mid-2022

Inventory build continues in anticipation of EUA in second half of 2022, with 4 million doses available for distribution over the next two years

Waltham, MA – Nov. 29, 2021 – Adagio Therapeutics, Inc., (Nasdaq: ADGI) a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential, today provided information related to the potential of its lead SARS-CoV-2 antibody, ADG20, to address the Omicron SARS-CoV-2 variant, and other known variants of concern. ADG20 is an investigational monoclonal antibody (mAb) product candidate designed to provide broad and potent neutralizing activity against SARS-CoV-2, including variants of concern, for the prevention and treatment of COVID-19 with potential duration of protection for up to one year in a single injection.

“The continued global scale of the COVID-19 pandemic has led to increased levels of immune pressure on the virus, which is driving the emergence of variants containing mutations associated with escape from common classes of neutralizing antibodies induced by natural infection or vaccination. Unlike most antibodies currently available under EUA, ADG20 has been shown to target an epitope that is highly conserved among clade I sarbecoviruses and that is not readily targeted by the endogenous neutralizing antibody response,” said Laura Walker, Ph.D., co-founder and chief scientific officer of Adagio. “Due to the highly conserved and immunorecessive nature of the epitope recognized by ADG20, we expect that ADG20 will retain activity against Omicron, as we have observed in *in vitro* models with all other variants of concern identified previously. Further, none of the mutations present in the spike protein of the Omicron variant have been associated with escape from ADG20 neutralization. ADG20 was engineered for potent and broadly neutralizing activity in anticipation of both the rapid antigenic evolution of SARS-CoV-2 and the emergence of future SARS-like viruses with pandemic potential.”

“ADG20 was uniquely designed to combine breadth, potency and duration of protection against SARS-CoV-2 for up to one year in a single injection. We did this anticipating that SARS-CoV-2 would continue to evolve and potentially render some early therapies and vaccines obsolete,” said Tillman Gerngross, Ph.D., co-founder and chief executive officer of Adagio. “Our global clinical trials are advancing with potential EUA submissions in mid-2022 for both prevention and treatment of COVID-19. We continue to engage with the FDA and other regulatory bodies and governmental agencies to discuss potential acceleration of development plans and the need for a portfolio of therapeutic solutions to combat the COVID-19 pandemic.”

Given the significant potential health crisis resulting from the emergence of Omicron, Adagio is undertaking a number of activities to support ADG20’s utility in addressing this newly emerged variant of concern, including:

- Conducting *in vitro* studies to evaluate the expected binding and neutralizing activity of ADG20 against Omicron. Initial data from these studies is anticipated by the end of the year; and

- Recruiting patients in Adagio's Phase 2/3 COVID-19 treatment trial, known as STAMP, across several clinical sites in South Africa (along with ongoing clinical trial efforts globally) in an effort to generate clinical data for ADG20 against infections due to the Omicron variant.

Based on the data being generated, Adagio plans to engage with health authorities and government agencies to accelerate development and supply of ADG20 to combat SARS-CoV-2 and its variants of concern.

ADG20 and Variants of Concern

The neutralizing antibody response induced by SARS-CoV-2 infection and vaccination is dominated by three classes of receptor binding domain (RBD)-directed antibodies (Class 1, Class 2 and Class 3), which often share common escape mutations. The newly emerged Omicron (B.1.1.529) variant identified in South Africa contains mutations associated with resistance to a large proportion of these commonly elicited antibodies, which may be due to immune pressure on these antigenic sites. Data for most antibodies available under EUA or in late-stage clinical development show they target one of these three dominant antigenic regions within the RBD.

In vitro studies have shown that ADG20 binds to a highly conserved epitope within the RBD that is not targeted by any of the common classes of neutralizing antibodies induced by SARS-CoV-2 infection and vaccination. Thus, unlike many other clinical-stage antibodies, which were isolated from COVID-19 patients and recognize epitopes that are also targeted by endogenous neutralizing antibodies, there is limited immune pressure on the ADG20 binding site. The ADG20 epitope has remained conserved in 99.99% of the nearly 4 million full length SARS-CoV-2 viral sequences deposited in the GISAID database as of October 15, 2021 and, as shown in *in vitro* studies, ADG20 retains activity against prior variants of concern including Alpha, Beta, Delta, and Gamma. For the Omicron variant, none of the mutations present in the spike protein are associated with escape from ADG20 neutralization. Based on published epitope mapping and structural studies, Adagio anticipates that ADG20 will retain neutralizing activity against the Omicron variant whereas other mAb products may lose substantial activity against this variant.

Previously disclosed *in vitro* data demonstrated retained neutralizing activity of ADG20 against a diverse panel of circulating SARS-CoV-2 variants, including the recently emerged Lambda, Mu and Delta plus variants. Notably, findings from these *in vitro* studies showed that ADG20 demonstrated potent neutralizing activity against all SARS-CoV-2 variants of concern tested, including those with reduced susceptibility to mAb products currently available under EUA or in late-stage development.

About ADG20

ADG20, an investigational monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses, is advancing through global clinical trials for the prevention and treatment of COVID-19, the disease caused by SARS-CoV-2. ADG20 was designed and engineered to possess high potency and broad neutralization activity against SARS-CoV-2 and additional clade 1 sarbecoviruses by targeting a highly conserved epitope in the receptor binding domain. ADG20 was further engineered to provide an extended half-life for durable protection. ADG20 has demonstrated potent neutralizing activity against the original SARS-CoV-2 virus, SARS-CoV-2 variants of concern Alpha, Beta, Delta, and Gamma, other SARS-CoV-2 variants to date, and additional SARS-like viruses in preclinical studies. ADG20 is administered in clinical trials by a single intramuscular injection. To date, ADG20 has been well-tolerated in a Phase 1 trial with no safety signals identified through a minimum of three months follow-up across all cohorts. ADG20 has not been approved for use in any country, and safety and efficacy have not yet been established.

About Adagio Therapeutics

Adagio (Nasdaq: ADGI) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential, including COVID-19 and influenza. The company's portfolio of antibodies has been optimized using Adimab's industry-leading antibody engineering capabilities and is designed to provide patients and clinicians with the potential for a powerful combination of potency, breadth, durable protection (via half-life extension), manufacturability and affordability. Adagio's portfolio of SARS-CoV-2 antibodies includes multiple non-competing, broadly neutralizing antibodies with distinct binding epitopes, led by ADG20. Adagio has secured manufacturing capacity for the production of ADG20 with third-party contract manufacturers to support the completion of clinical trials and initial commercial launch, ensuring the potential for broad accessibility to people around the world. For more information, please visit www.adagiotx.com.

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," "expects," "intends," "projects," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, the timing, progress and results of our preclinical studies and clinical trials of ADG20, including the timing of our planned EUA submissions, initiation, modification and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs; the expected neutralizing activity of ADG20 against the Omicron variant; our ability to obtain and maintain regulatory approvals for, our product candidates; our ability to identify patients, including in specific populations, with the diseases treated by our product candidates and to enroll these patients in our clinical trials; our expectations regarding the scope of any approved indication for ADG20; and the risk/benefit profile of our product candidates to patients; our manufacturing capabilities and strategy, including plans for doses available in the near future; and our ability to successfully commercialize our product candidates. 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, clinical trials and financial position, unexpected safety or efficacy data observed during preclinical studies or clinical trials, 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. 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 Adagio's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 and in Adagio's future reports to be filed with the SEC, including Adagio's Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. 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.

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