

**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): December 14, 2021

Adagio Therapeutics, Inc.

(Exact name of registrant as specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40703
(Commission
File Number)

85-1403134
(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 December 14, 2021, Adagio Therapeutics, Inc. (the “Company”) issued a press release entitled “Adagio Therapeutics Reports Reduction in In Vitro Neutralizing Activity of ADG20 Against Omicron SARS-CoV-2 Variant.” 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 December 14, 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: December 14, 2021

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



Adagio Therapeutics Reports Reduction in *In Vitro* Neutralizing Activity of ADG20 Against Omicron SARS-CoV-2 Variant

Previously Reported In Vitro Data Demonstrating that Individual Omicron Mutations Were Not Associated with ADG20 Escape Do Not Translate to Omicron Authentic and Pseudovirus Assays

Waltham, MA – Dec. 14, 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 an update following external *in vitro* analyses to evaluate neutralizing activity of ADG20 against the Omicron SARS-CoV-2 variant. The *in vitro* data generated through both authentic and pseudovirus testing of the Omicron variant show a greater than 300-fold reduction in neutralizing activity of ADG20 against Omicron. Additional analyses are ongoing, and the company plans to engage with regulatory and government agencies to assess the role ADG20 can play for the prevention and treatment of COVID-19, particularly as the industry’s understanding of the epidemiology and impact of Omicron and potential new variants develops.

“Due to the highly conserved and immunorecessive nature of the epitope recognized by ADG20, we anticipated that ADG20 would retain neutralizing activity against Omicron, consistent with activity observed in *in vitro* models with all other known variants of concern,” said Tillman Gerngross, Ph.D., chief executive officer of Adagio. “While the individual mutations present in the Omicron receptor binding domain were not associated with escape from ADG20 in the context of an original strain of the virus, new data show that the combination of mutations present in the Omicron spike protein led to a reduction in ADG20 neutralization that was not suggested by prior data. The continued prevalence of the Delta variant in the U.S. and other countries, evolution of SARS-CoV-2 variants and potential future coronaviruses means a multitude of therapies and approaches are needed. With an expert team committed to advancing antibody solutions that combat this unprecedented pandemic and a strong balance sheet, we’re conducting additional analyses to assess the optimal path forward with ADG20 as both a prophylactic and treatment option for COVID-19.”

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 with a single injection. In previously disclosed *in vitro* studies, ADG20 retained activity against prior variants of concern including Alpha, Beta, Delta and Gamma. In addition, *in vitro* data demonstrated retained neutralizing activity of ADG20 against a diverse panel of circulating SARS-CoV-2 variants, including the Lambda, Mu and Delta plus variants. The safety and efficacy of ADG20 have not been established, and ADG20 is not authorized or approved for use in any country.

Adagio is currently evaluating ADG20 in global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19. Based on the *in vitro* findings related to Omicron, Adagio plans to pause patient recruitment in its Phase 2/3 COVID-19 treatment trial at clinical sites in South Africa, where Omicron has emerged as the dominant variant. Adagio is evaluating next steps for its ADG20 program.

In vitro analyses were also conducted on ADG10, a second mAb in development, which showed minimal neutralizing activity against the Omicron variant in both authentic and pseudovirus neutralization assays.



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 future program updates and the 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 additional and ongoing analyses to evaluate the activity of ADG20 against the Omicron variant and the potential of ADG20 to play a role as both a prophylactic and a treatment option for COVID-19; the risk/benefit profile of our product candidates to patients; and the adequacy of our cash, cash equivalents and marketable securities. 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 September 30, 2021 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.

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