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): January 12, 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)**

(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 January 13, 2022, Adagio Therapeutics, Inc. (the "Company") intends to make a presentation at the J.P. Morgan Healthcare Conference, a copy of which can be found on the Company's website at https://investors.adagiotx.com/news-events/events-presentations and is incorporated herein by reference.

The information in this Item 7.01 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 8.01 Other Events.

On January 12, 2022, the Company issued a press release entitled "Adagio Therapeutics Summarizes ADG20 Neutralizing Activity Against SARS-CoV-2 Variants and Outlines Initiatives to Address Omicron." The full text of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated January 12, 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, 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: January 13, 2022

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

Exhibit 99.1

Adagio Therapeutics Summarizes ADG20 Neutralizing Activity Against SARS-CoV-2 Variants and Outlines Initiatives to Address Omicron

Recent Publications by Several Independent Laboratories Show ADG20 Has Neutralizing Activity with Potency Comparable to Other Antibodies that Retain Activity Against Omicron

Multiple Efforts Underway to Address Omicron and Potential Future SARS-CoV-2 Variants

Waltham, MA – January 12, 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 with pandemic potential, today summarized recent findings reported in three separate publications that show ADG20, its lead monoclonal antibody (mAb), has neutralization activity against the Omicron (B.1.1.529) variant of SARS-CoV-2, and outlined initiatives to address current and future SARS-CoV-2 variants of concern. Adagio is evaluating ADG20 in its global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19. Adagio is engaging with the U.S. Food and Drug Administration (FDA) regarding potential protocol updates to its global Phase 2/3 clinical trials, including an increased dose of ADG20 for the potential prevention and treatment of COVID-19 resulting from the Omicron variant.

ADG20 Neutralizing Activity Against Omicron

Recently published *in vitro* studies examined the neutralization potencies of large panels of mAbs against the Omicron variant in both authentic and pseudovirus assays. Findings across all three studies show that among mAbs in late-stage clinical development or with Emergency Use Authorization (EUA), ADG20 is one of only a few mAbs that demonstrated neutralizing activity against Omicron. Across two distinct authentic neutralization assays against Omicron, the data show that ADG20 had an IC_{50}, a measurement of neutralization potency, of approximately 0.4 to 1.1 µg/mL, which is comparable with the two other active mAbs, sotrovimab and AZD7742.

“What is critical to assessing potential clinical effectiveness of SARS-CoV-2 mAbs is the neutralization potency by the mAb against a *specific* variant. While findings may show that ADG20 has reduced potency against Omicron when compared to its high potency against all other variants of concern, including Delta, the data support that ADG20 is among the few mAbs to demonstrate neutralizing activity against the Omicron variant and warrants its continued development,” said Laura Walker, Ph.D., chief scientific officer and co-founder of Adagio.

These data add to previously reported *in vitro* data from a variety of preclinical studies that showed that ADG20 retains activity against other variants of concern including Alpha, Beta, Delta and Gamma, and that ADG20 retains neutralizing activity against a diverse panel of circulating SARS-CoV-2 variants, including the Lambda, Mu and Delta plus variants.

Clinical Trial Update to Address Omicron

Adagio is continuing evaluation of ADG20 in its EVADE and STAMP clinical trials. Adagio is engaging with the FDA on dosing strategy, including an increased dose of ADG20 and other protocol updates in light of the spread of the Omicron variant. Adagio is pausing the enrollment of new patients in the 300 mg dose arm in both clinical trials as the company updates its protocols. Follow-up and monitoring of patients previously administered ADG20 are continuing per the original protocols.

Additional Efforts to Address Omicron and Future Variants

In addition to its clinical trial updates, Adagio is pursuing multiple strategies to address both Omicron and potential future variants that may emerge. Leveraging its exclusive partnership with Adimab LLC, a global leader in antibody engineering, Adagio is exploring the potential to engineer ADG20 to further improve binding to the Omicron variant to enhance its neutralization potency against Omicron while retaining its broad neutralization against other SARS-CoV-2 variants of concern. In parallel, Adagio is assessing several hundred mAbs from its proprietary library of previously isolated SARS-CoV-2 antibodies for their neutralization potency against Omicron. Such an additional neutralizing mAb could be developed as a stand-alone product or as part of a combination approach. These efforts are underway, and the company anticipates preliminary findings from its research in the first quarter of 2022.

“SARS-CoV-2 is a quickly evolving virus, and at Adagio, we are committed to adapting just as quickly. It is abundantly clear that no single product will fully address the evolving nature of the COVID-19 pandemic, and that multiple preventative and therapeutic solutions are needed. Based on both in-house data and third-party findings, we are confident that ADG20 can be an important tool in the fight against this virus,” added Tillman Gerngross, Ph.D., co-founder and chief executive officer of Adagio.

About ADG20

ADG20, an investigational monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses, is being evaluated in global clinical trials for the prevention and treatment of COVID-19, the disease caused by SARS-CoV-2. ADG20 was designed 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. *In vitro* data from a variety of preclinical studies have shown that ADG20 retains neutralizing activity against all known SARS-CoV-2 variants of concern. In a Phase 1 trial, ADG20 was well-tolerated 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, if authorized or approved for use. 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 initiation, modification and completion of studies or trials and related preparatory work, including our plans to evaluate dosing regimens and other protocol updates in our clinical trials, the period during which the results of our clinical trials and other studies and research activities will become available, and our research and development programs; our ability to obtain and maintain regulatory approvals for our product candidates; our pursuit of other strategies to address the Omicron variant, including modification of

clinical trial protocols; 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, clinical trials and financial position, unexpected safety or efficacy data observed during preclinical studies or clinical trials, the predictability of clinical success of ADG20 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. 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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