# 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): October 19, 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.)

303 Wyman Street, Suite 300 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  $\boxtimes$ 

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 8.01 Other Events.

On October 19, 2021, Adagio Therapeutics, Inc. (the "Company") issued a press release entitled "Adagio Therapeutics Announces New In Vitro Data Highlighting Broad and Potent Neutralization of ADG20 Against All Known SARS-CoV-2 Variants." 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 October 19, 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.

By: /s/ Jane Pritchett Henderson

Jane Pritchett Henderson Chief Financial Officer

Dated: October 19, 2021



## Adagio Therapeutics Announces New *In Vitro* Data Highlighting Broad and Potent Neutralization of ADG20 Against All Known SARS-CoV-2 Variants

### Data to be presented at the 2021 ISIRV-WHO Virtual Conference

**Waltham, MA – Oct. 19, 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 announced new *in vitro* data demonstrating retained neutralizing activity of its monoclonal antibody (mAb), ADG20, against a diverse panel of circulating SARS-CoV-2 variants, including the newly emerged Lambda and Mu variants. Notably, findings show that ADG20 demonstrated potent *in vitro* neutralizing activity against all SARS-CoV-2 variants of concern tested, including those with reduced susceptibility to mAb products currently available under Emergency Use Authorization (EUA) or in late-stage development. These data will be presented during a poster session at the 2021 ISIRV-WHO Virtual Conference, which is being held October 19-21, 2021. In addition, Adagio will present an encore poster highlighting <u>recently announced</u> data from the company's ongoing Phase 1 trial of ADG20 in healthy participants.

"These new variant data further underscore the potential of ADG20 to address the ongoing COVID-19 pandemic, as well as possible future outbreaks caused by other SARS-like viruses," said Laura Walker, Ph.D., co-founder and chief scientific officer of Adagio. "We have intentionally designed this mAb to have both broad and potent neutralizing activity as well as a half-life that extends its potential window of protection, critical features that may set it apart from other therapies available under EUA or in development today. With global Phase 2/3 prevention and treatment trials ongoing, we look forward to continuing our evaluation of ADG20 to assess the meaningful role it could potentially play in the arsenal of COVID-19 treatment options. Given as a single, intramuscular injection in clinical trials, ADG20 has been designed to offer protection for up to a year in the prevention setting and is being explored as a treatment for high-risk patients and/or as a vaccine supplement, including for immunocompromised individuals."

In addition to the Phase 1 healthy participant trial, Adagio is advancing two ongoing global Phase 2/3 trials with ADG20, a treatment trial (STAMP) and a prevention trial (EVADE). The company anticipates submitting an EUA application to the U.S. Food and Drug Administration for ADG20 in the first quarter of 2022.

#### **Presentation Details**

**Poster Title:** (130) Broad and Potent In Vitro Neutralization of SARS-CoV-2 Variants by ADG20, a Half-Life Extended Monoclonal Antibody in Development for the Prevention and Treatment of COVID-19

**Poster Title:** (131) Evaluating the Safety, Tolerability, and Pharmacokinetics of ADG20, a Half-Life–Extended Monoclonal Antibody (mAb) in Development for the Prevention and Treatment of COVID-19: a Preliminary Analysis of a Randomized Phase 1 Study





### About ADG20

ADG20, a monoclonal antibody targeting the spike protein of SARS-CoV-2 and related coronaviruses, is being developed 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 against SARS-CoV-2 and additional clade 1 sarbecoviruses, by targeting a highly conserved epitope in the receptor binding domain. ADG20 displays potent neutralizing activity *in vivo* against the original SARS-CoV-2 strain as well as all known variants of concern. ADG20 has the potential to impact viral replication and subsequent disease through multiple mechanisms of action, including direct blocking of viral entry into the host cell (neutralization) and elimination of infected host cells through Fc-mediated innate immune effector activity. ADG20 is administered by a single intramuscular injection, and was engineered to have a long half-life, with a goal of providing both rapid and durable protection. Adagio is advancing ADG20 through multiple clinical trials on a global basis.

#### **About Adagio Therapeutics**

Adagio (Nasdaq: ADGI) is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibodybased solutions for infectious diseases with pandemic potential. The company's portfolio of antibodies has been optimized using Adimab's industryleading antibody engineering capabilities and is designed to provide patients and clinicians with 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 broad accessibility to people around the world. For more information, please visit <u>www.adagiotx.com</u>.

#### **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," "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 application, initiation 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; our ability to obtain and maintain regulatory approvals for, our product candidates; our ability to identify patients with the diseases treated by our product candidates and to enroll these patients in our clinical trials; our manufacturing capabilities and strategy; 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, including, without limitation, those risks 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. 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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