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): September 20, 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.)**

303 Wyman Street, Suite 300
Waltham, Massachusetts **02451**
(Address of Principal Executive Offices) **(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 2.02 Results of Operations and Financial Condition.

On September 20, 2021, Adagio Therapeutics, Inc. (the "Company") provided a corporate update and announced its financial results for the quarter ended June 30, 2021 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 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 September 20, 2021.

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: September 20, 2021

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

Exhibit 99.1

Adagio Therapeutics Provides COVID-19 Antibody Program Updates as well as Business Highlights and Second Quarter 2021 Financial Results

New Data Supporting Potential of ADG20 for Both the Treatment and Prevention of COVID-19 to be Presented at IDWeek 2021

Patient Population in Global EVADE Phase 2/3 Clinical Trial of ADG20 Expanded following IDMC Assessment

$355.8 Million IPO Completed to Fund Continued Advancement of Portfolio of Antibody-based Solutions for Infectious Diseases with Pandemic Potential

Waltham, MA – Sept. 20, 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 reported updates on its lead COVID-19 antibody program, ADG20, as well as recent business highlights and second quarter 2021 financial results.

“Across the globe, COVID-19 continues to be a significant health crisis affecting nearly every age group. With the continued emergence of new variants, broadly neutralizing therapies that can be used for both the treatment and prevention of the disease are critical to address the current endemic as well as potential future outbreaks,” said Tillman Gerngross, Ph.D., co-founder and chief executive officer of Adagio. “Our team is working closely with our global CRO partners on the execution of our ongoing global clinical trials of ADG20, STAMP and EVADE, while also preparing for the anticipated worldwide commercialization of ADG20, if approved.

“ADG20 is a highly differentiated antibody that we are advancing through pivotal trials for both the treatment and prevention of COVID-19. We are pleased by the recent assessment of unblinded data by the IDMC for the EVADE trial, and their support of our plans to expand enrollment to include adolescents and pregnant or nursing women,” said Lynn Connolly, M.D., Ph.D., chief medical officer of Adagio. “To date, we have generated a compelling data package for ADG20 that includes broad neutralization of the original SARS-CoV-2 virus and the known variants of concerns in *in vitro* models as well as a favorable pharmacokinetic and tolerability profile in our Phase 1 trial. Further, at this year’s IDWeek, we will release additional data from our Phase 1 trial as well as details regarding our dose selection process for treatment and prevention, which we believe further support the important role this novel antibody can play in combatting the ongoing pandemic.”

ADG20 COVID-19 Program Highlights

- **New ADG20 Data to be Presented in Multiple Posters during IDWeek:** At the IDWeek 2021 Virtual Conference, Adagio plans to present additional data highlighting the potential for ADG20 to provide protection from COVID-19 for up to one year based on its extended half-life in humans combined with its broad and potent neutralizing ability demonstrated in laboratory testing. In addition, the data support the evaluation of a 300mg dose, delivered as a single intramuscular injection, in the ongoing Phase 2/3 STAMP (treatment) and EVADE (prevention) global clinical trials. The data will be presented in multiple posters, which will be available to registered attendees on the virtual platform throughout the duration of the conference, being held from September 29 – October 3, 2021. The presentations include:
    - **1086:** A Whole-Body Quantitative System Pharmacology Physicologically-Based Pharmacokinetic (QSP/PBPK) Model that a priori Predicts Intramuscular (IM) Pharmacokinetics of ADG20: an Extended Half-life Monoclonal Antibody Being Developed for the Treatment and Prevention of Coronavirus Disease (COVID-19)
    - **633:** Preliminary Results from a Phase 1 Single Ascending-Dose Study Assessing Safety, Serum Viral Neutralizing Antibody Titers (sVNA), and Pharmacokinetic (PK) Profile of ADG20: an Extended Half-Life Monoclonal Antibody Being Developed for the Treatment and Prevention of Coronavirus Disease (COVID-19)
    - **1089:** Use of a Whole-Body Quantitative System Pharmacology Physiologically-Based Pharmacokinetic (QSP/PBPK) Model to Support Dose Selection of ADG20: an Extended Half-Life Monoclonal Antibody Being Developed for the Prevention of Coronavirus Disease (COVID-19)
    - **1088:** A Whole-Body Quantitative System Pharmacology Physiologically-Based Pharmacokinetic (QSP/PBPK) Model to Support Dose Selection of ADG20: an Extended Half-Life Monoclonal Antibody Being Developed for the Treatment of Coronavirus Disease (COVID-19)
- **Patient Population Expanded in EVADE following IDMC Data Assessment:** The independent data monitoring committee (IDMC) for the EVADE Phase 2/3 trial of ADG20 for the prevention of COVID-19 recently provided a recommendation to expand Phase 3 trial enrollment to include adolescents 12 years and older and pregnant or nursing women, as well as a decrease in the protocol-specified, in-clinic post injection monitoring time. The IDMC's recommendations were based on their review of unblinded safety and tolerability data through the Day 28 post-treatment visit from 200 participants enrolled in the Phase 2 lead-in portion of the trial.
- **Partnership with Biocon Biologics Expands the Reach of a Potent and Broadly Neutralizing COVID-19 Antibody Treatment to Patients in India and Select Emerging Markets:** In the second quarter of 2021, Adagio partnered with Biocon Biologics Ltd. to combat the ongoing COVID-19 crisis in southern Asia. The partnership provides Biocon rights to manufacture and commercialize an antibody therapy based on ADG20 in India and additional select emerging markets based on the commercial manufacturing process developed for ADG20. As part of the agreement, Biocon will be granted access to data from Adagio's Phase 2/3 clinical trials as well as its anticipated Emergency Use Authorization package and other regulatory submissions to support approval or emergency authorization in India and other select emerging markets.

Recent Business Highlights

- **$355.8 Million Initial Public Offering (IPO) Successfully Completed**: In August 2021, Adagio sold 20,930,000 shares of common stock, including the full exercise of the underwriters' option to purchase an additional 2,730,000 shares of common stock at a public offering price of $17.00 per share. The gross proceeds of the offering, before underwriting discounts and commissions and other offering expenses payable by Adagio, were approximately $355.8 million.
- **David Hering, Global COVID-19 Vaccine Expert, Appointed as Chief Operating Officer:** Adagio recently appointed David Hering as the company's chief operating officer. Mr. Hering joins Adagio from Pfizer, where he most recently served as the global mRNA business lead, a business specifically created to manage global COVID-19 efforts as well as future vaccines utilizing mRNA technology, and led the launch of the first-ever COVID-19 vaccine in the United States. Prior to his most recent role at Pfizer, Mr. Hering was president, North America at Pfizer, where he led a 700-person organization across a portfolio of vaccine products for COVID-19 and meningococcal and pneumococcal diseases.

- **Collaboration with Scripps:** Adagio entered into an exclusive research agreement with The Scripps Research Institute to identify broadly protective vaccine candidates for the prevention of influenza and beta coronaviruses.
- **Board of Directors Expanded with Industry Leaders to Support Future Growth:** Adagio recently announced appointments of three industry veterans and area experts to its board of directors:
    - Tom Heyman, former president of the Johnson & Johnson Development Corporation (JJDC);
    - Anand Shah, M.D., former deputy commissioner for medical and scientific affairs at the U.S. Food and Drug Administration (FDA); and
    - Michael S. Wyzga, president of MSW Consulting, Inc. and former CFO of Genzyme

Second Quarter 2021 Financial Results

- As of June 30, 2021, Adagio had cash, cash equivalents and marketable securities of $392.5 million, which includes net proceeds from its Series C financing completed in April. Pro forma cash, cash equivalents and marketable securities as of June 30, 2021 is $719.6 million after giving effect to our initial public offering which closed on August 10, 2021.
- Research & development expenses including in-process research and development for the second quarter of 2021 were $37.6 million.
- Selling, general & administrative expenses for the second quarter of 2021 were $7.1 million.
- Net Loss for the second quarter was $44.7 million, or $0.18 per share.

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 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 antibody-based solutions for infectious diseases with pandemic potential. 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 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 through the completion of clinical trials and, if approved by regulatory authorities, through initial commercial launch. 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 IND submissions, 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 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, those risks described under the heading "Risk Factors" in Adagio's prospectus filed with the Securities and Exchange Commission ("SEC") on August 6, 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 June 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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ADAGIO THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(In thousands, except share and per share amounts)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents(1)	$ 392,509	$ 114,988
Prepaid expenses and other current assets	3,550	2,394
Total current assets	396,059	117,382
Deferred offering costs	1,933	—
Total assets	$ 397,992	$ 117,382
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 10,716	$ 8,153
Accrued expenses	27,181	4,919
Total current liabilities	37,897	13,072
Early-exercise liability	8	11
Total liabilities	37,905	13,083
Commitments and contingencies		
Convertible preferred stock (Series A, B and C) $0.0001 par value; 16,944,484 shares authorized, issued and outstanding at June 30, 2021; 12,647,934 shares authorized, issued and outstanding at December 31, 2020; aggregate liquidation preference of $505,399 and $169,900 at June 30, 2021 and December 31, 2020, respectively	504,711	169,548
Stockholders' deficit:		
Common stock, $0.0001 par value; 150,000,000 shares authorized at June 30, 2021 and December 31, 2020; 5,599,240 shares issued and outstanding at June 30, 2021; 28,193,240 shares issued and 5,593,240 shares outstanding at December 31, 2020	1	1
Treasury stock, at cost; 0 shares and 22,600,000 shares at June 30, 2021 and December 31, 2020, respectively	—	(85)
Additional paid-in capital	4,067	154
Accumulated deficit	(148,692)	(65,319)
Total stockholders' deficit	(144,624)	(65,249)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 397,992	$ 117,382

(1) Pro forma cash, cash equivalents and marketable securities as of June 30, 2021 is $719.6 million after giving effect to our issuance and sale of 20,930,000 shares of our common stock in our initial public offering at the price of $17.00 per share after deducting underwriting discounts, commissions and estimated offering costs which closed on August 10, 2021.

ADAGIO THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

(In thousands, except share and per share amounts)

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021	Period from June 3, 2020 (Inception) to June 30, 2020[3]
Operating expenses:			
Research and development[1]	$ 35,067	$ 69,204	$ 48
Acquired in-process research and development[2]	2,500	3,500	—
Selling, general and administrative	7,124	10,695	50
Total operating expenses	44,691	83,399	98
Loss from operations	(44,691)	(83,399)	(98)
Other income (expense):			
Interest income	23	32	—
Other expense	(5)	(6)	—
Total other income (expense), net	18	26	—
Net loss and comprehensive loss	$ (44,673)	$ (83,373)	$ (98)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.66)	$ —
Weighted-average common shares outstanding, basic and diluted	249,769	125,574	21,250,000

(1) Includes related-party amounts of $247 for the three months ended June 30, 2021, $435 for the six months ended June 30, 2021 and $0 for the period from June 3, 2020 (inception) to June 30, 2020.

(2) Includes related-party amounts of $2,500 for the three months ended June 30, 2021, $3,500 for the six months ended June 30, 2021 and $0 for the period from June 3, 2020 (inception) to June 30, 2020.

(3) The results for the period from June 3, 2020 (inception) to June 30, 2020 are the same for the three and six months ended June 30, 2020.