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): August 11, 2026

ADAGIO MEDICAL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-42199**	**99-1151466**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

26051 Merit Circle, Suite 102 **Laguna Hills, CA**	**92653**
(Address of principal executive offices)	(Zip Code)

(949) 348-1188
(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:

☐ 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, par value $0.0001 per share	ADGM	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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 August 11, 2026, Adagio Medical Holdings, Inc. issued a press release announcing financial results for the quarter ended June 30, 2026, and providing a business update. A copy of this press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information furnished with this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for 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 into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as 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 August 11, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

Dated: August 11, 2026

Adagio Medical Holdings, Inc.

By: /s/ Deborah Kaster
Name: Deborah Kaster
Title: Chief Financial Officer and Chief Business Officer

Exhibit 99.1

Adagio Medical Reports Second Quarter 2026 Results

LAGUNA HILLS, CA, August 11, 2026 – Adagio Medical Holdings, Inc. (Nasdaq: ADGM) ("Adagio" or "the Company"), a leading innovator in catheter ablation technologies for the treatment of cardiac arrhythmias, today announced financial results for the second quarter ended June 30, 2026.

Recent Business Highlights:

- Announced the successful treatment at the Hospital of University of Pennsylvania of the first patient with the Company's next-generation vCLAS™ *Ultra* Ultra-Low temperature ablation catheter ("ULTA"), which is designed to be faster and more maneuverable than the first generation vCLAS™ Ventricular Ablation System catheter, under Expanded Access authorization from the U.S. Food and Drug Administration ("FDA")

- Announced pivotal results from the 209-patient FULCRUM-VT trial, which were presented in a late-breaking session at Heart Rhythm Society 2026, demonstrating a promising safety profile with only 2.4% protocol-defined Major Adverse Events and six-month results of 84% freedom from implantable cardioverter defibrillator ("ICD") shock and a 78% discontinuation or reduced dose of antiarrhythmic drugs, as well as equivalent results across both ischemic and non-ischemic cardiomyopathy patients with the Company's proprietary ULTA technology

- Submitted Premarket Approval ("PMA") application, supported by the FULCRUM-VT pivotal IDE trial, to the FDA for the vCLAS Ventricular Ablation System for the treatment of drug-refractory, recurrent, sustained monomorphic ventricular tachycardia ("VT") in patients with ischemic or non-ischemic structural heart disease

"This quarter marked an inflection point for Adagio as our team continues to execute and deliver on our critical milestones. The enthusiastic physician reception of our FULCRUM-VT late-breaking data at HRS reinforced what we have long believed about the potential for this technology, and the successful treatment of the first patient with vCLAS *Ultra* — a particularly complex case — was a powerful proof point for our next-generation system." said Todd Usen, Chief Executive Officer of Adagio Medical. "We believe our progress – combined with the breadth of our clinical evidence for both ischemic and non-ischemic patients - positions our fully-endocardial ULTA platform as a uniquely differentiated solution capable of treating the entire spectrum of cases in an addressable market that has long needed a purpose-built solution. We remain focused on executing against the milestones ahead as we work to bring our proprietary technology to the many patients who suffer from VT."

Second Quarter 2026 Financial Results

Cost of revenue was nil for the three months ended June 30, 2026, compared to $0.3 million for the three months ended June 30, 2025. The decrease was primarily attributable to the pause in commercial activity in Europe. Depreciation expense related to consoles loaned to customers is generally classified within cost of revenue; however, because the Company did not generate revenue during the three months ended June 30, 2026, such depreciation expense is reflected within research and development expenses for the period.

Research and development expenses were $2.5 million for the three months ended June 30, 2026 compared to $2.0 million for the three months ended June 30, 2025. The increase was primarily attributable to higher product development costs, including consulting and prototyping expenses, and higher operational costs, including the aforementioned depreciation expense, partially offset by lower clinical trial expenses.

Selling, general and administrative expenses were $2.5 million for the three months ended June 30, 2026, compared to $2.4 million for the three months ended June 30, 2025. The increase was primarily attributable to higher stock-based compensation expenses, partially offset by lower professional services expenses.

Net loss for the three months ended June 30, 2026, was $6.7 million, or $(0.30) per share (Basic), compared to a net loss of $3.9 million, or $(0.26) per share (Basic), for the three months ended June 30, 2025.

Weighted average shares of common stock outstanding, basic and diluted, were 22,210,459 as of June 30, 2026. The Company's fully diluted share count includes all outstanding warrants; however, for purposes of calculating net loss per share, warrants and certain other potentially dilutive securities are excluded as their inclusion would be anti-dilutive.

Cash and cash equivalents were $7.7 million as of June 30, 2026.

About Adagio Medical Holdings, Inc.

Adagio is a medical device company focused on developing and commercializing products for the treatment of cardiac arrhythmias utilizing its novel, proprietary, catheter-based Ultra-Low temperature ablation (“ULTA”, formerly known as ULTC) technology. ULTA is designed to create large footprint, titratable lesions extending through the depth of both diseased and healthy cardiac tissue, all through an endocardial approach. The Company is currently focused on the treatment of ventricular arrhythmias with its purpose-built vCLAS Ventricular Ablation System, which is CE Marked, and in May 2026 the Company submitted the results of the FULCRUM-VT pivotal study to support its PMA application to the FDA for the vCLAS Ventricular Ablation System. The Company is also developing a next-generation vCLAS *Ultra* catheter, designed to support faster ablation procedures with a smaller and more flexible form factor than its predecessor vCLAS device.

About FULCRUM VT

FULCRUM-VT (Feasibility of Ultra-Low Temperature Cryoablation in Recurring Monomorphic Ventricular Tachycardia) is a prospective, multi-center, open-label, single-arm trial, which has fully enrolled 209 patients with structural heart disease of both ischemic and non-ischemic cardiomyopathy, indicated for catheter ablation of drug refractory VT in accordance with current treatment guidelines. FULCRUM-VT 6-month primary chronic effectiveness was defined as freedom from sustained monomorphic VT lasting longer than 30 seconds or VT requiring appropriate ICD device therapy, in the absence of new or increase in antiarrhythmic drug therapy beyond previously failed dose.

The FDA has granted Investigational Device Exemption (IDE) approval to expand the Company’s FULCRUM-VT trial to evaluate the safety and effectiveness of the Company’s next-generation vCLAS *Ultra* catheter for the treatment of Sustained Monomorphic Ventricular Tachycardia (SMVT).

Adagio’s vCLAS™ Ventricular Ablation System is commercially available for the treatment of monomorphic VT in Europe and select other geographies but is limited to investigational use in the United States.

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," "plans," and "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning: Adagio's strategy, future operations, future financial position, and projected expenses; the expected timing and results of Adagio's clinical trials, including the reproducibility of the favorable results initially seen in Adagio's FULCRUM-VT pivotal data and the evaluation of the vCLAS Ultra catheter under the expanded IDE approval; the potential for ULTA technology to address unmet needs in the treatment of VT, including across both ischemic and non-ischemic cardiomyopathy substrates; and the potential for FDA approval of Adagio's product candidates, including the PMA application for the vCLAS Ventricular Ablation System. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements. Risks regarding Adagio's business are described in detail in Adagio's Securities and Exchange Commission ("SEC") filings, including in its Annual Report on Form 10-K for the full-year ended December 31, 2025 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, which are available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that Adagio makes from time to time with the SEC. These forward-looking statements speak only as of the date hereof, and Adagio disclaims any obligation to update these statements except as may be required by law.

Contact
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Chief Business Officer
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Adagio Medical Holdings Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2026	December 31, 2025
	(Unaudited)	(Audited)
Cash and cash equivalents	$ 7,740	$ 17,105
Total assets	33,884	43,253
Total liabilities	34,299	30,851
Total stockholders' (deficit) equity	(415)	12,402

Adagio Medical Holdings Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended June 30,	
	2026	2025
Revenue	$ —	$ —
Cost of revenue and operating expenses:		
Cost of revenue	—	342
Research and development	2,450	1,971
Selling, general, and administrative	2,484	2,404
Total cost of revenue and operating expenses	4,934	4,717
Loss from operations	(4,934)	(4,717)
Other (expense) income:		
Convertible notes fair value adjustment	(1,162)	1,427
Warrant liabilities fair value adjustment	181	(141)
Interest expense	(805)	(720)
Interest income	72	102
Other (expense) income, net	(69)	102
Total other (expense) income, net	(1,783)	770
Net loss	$ (6,717)	$ (3,947)
Other comprehensive loss:		
Foreign currency translation adjustment	153	(39)
Comprehensive loss	$ (6,564)	$ (3,986)
Basic net loss per share	$ (0.30)	$ (0.26)
Diluted net loss per share	$ (0.30)	$ (0.35)
Weighted-average shares outstanding – basic and diluted	22,210,459	15,381,565