
**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): May 12, 2026

ADAGIO MEDICAL HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-42199
(Commission File Number)

99-1151466
(I.R.S. Employer Identification No.)

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

92653
(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 May 12, 2026, Adagio Medical Holdings, Inc. issued a press release announcing financial results for the quarter ended March 31, 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
<u>99.1</u>	<u>Press Release, dated May 12, 2026</u>
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: May 12, 2026

Adagio Medical Holdings, Inc.

By: /s/ Deborah Kaster

Name: Deborah Kaster

Title: Chief Financial Officer and
Chief Business Officer

Adagio Medical Reports First Quarter 2026 Results and Meaningful Clinical Progress*Advancing Toward Submission for PMA Approval Following Late-Breaking FULCRUM-VT Data*

LAGUNA HILLS, CA, May 12, 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 first quarter ended March 31, 2026.

Recent Business Highlights:

- **Pivotal results from the FULCRUM-VT trial presented in late-breaking session at Heart Rhythm Society 2026** – the first large-scale, rigorously executed pivotal trial in patients with both ischemic and non-ischemic cardiomyopathies—which demonstrated 84% freedom from implantable cardioverter defibrillator (“ICD”) shock at six months, a promising safety profile with 2.4% protocol-defined Major Adverse Events, and a 72% 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 Ultra-Low Temperature Ablation (“ULTA”) technology
 - **Received Food and Drug Administration (“FDA”) Investigational Device Exemption (“IDE”) approval to expand the FULCRUM-VT trial** to evaluate the safety and effectiveness of the next-generation vCLAS Ultra System, which is designed to be faster, colder and deeper, with improved usability, compared to the first generation vCLAS catheter, underscoring the depth and durability of the Company's ULTA platform for the treatment of Sustained Monomorphic Ventricular Tachycardia
 - **Featured in over a dozen well-attended events, presentations, and posters at Heart Rhythm Society's 47th Annual Scientific Sessions—Heart Rhythm 2026**—highlighting ULTA as a purpose-built endocardial solution for ventricular tachycardia (“VT”)
 - **Announced the publication of pre-clinical results of the Company’s next generation ULTA technology** in the *Journal of Cardiovascular Electrophysiology*, which describe titratable lesion depth exceeding 10 millimeters as well as significant functional improvements in catheter performance compared to first-generation ULTA, including improved handling characteristics, better compatibility with standard laboratory practices and the potential for 50-75% reduction in ablation time
 - **Successfully completed 13 cases under FDA Expanded Access** using the vCLAS System in patients with recurrent VT and premature ventricular contractions who had previously failed conventional and experimental ablation therapies, including radio frequency (RF) and pulsed field ablation (PFA), demonstrating real-world applicability and versatility of the ULTA platform
 - **Reported cash and cash equivalents of \$12.9 million as of March 31, 2026**, with potential for up to an additional \$31 million of aggregate gross proceeds that may be received upon the cash exercise in full of milestone-based warrants
-

“The first quarter of 2026 was a landmark period for Adagio during which we made exceptional progress advancing our Ultra-Low Temperature Ablation platform across both clinical development and real-world use,” said Todd Usen, Chief Executive Officer of Adagio Medical. “The late-breaking results from the FULCRUM-VT trial represent a defining milestone for our endocardial-only ULTA platform, demonstrating best-in-class safety, 84% freedom from ICD shock at six months, meaningful reductions in antiarrhythmic drug use, and consistent results across both ischemic and non-ischemic cardiomyopathy patients—the broadest patient population studied in any VT ablation trial. The enthusiasm from physicians on the podium was remarkable, with leading electrophysiologists highlighting ULTA as a potentially transformative solution for ventricular tachycardia. As we look ahead, we have multiple additional meaningful milestones expected this year across our platform of technologies and we are more confident than ever in our mission to fundamentally change the treatment of VT with a safe, effective solution for a broad group of patients who suffer from this dangerous arrhythmia.”

First Quarter 2026 Financial Results

Cost of revenue was nil for the three months ended March 31, 2026, compared to \$0.3 million for the three months ended March 31, 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 March 31, 2026, such depreciation expense is now reflected within research and development expenses for the period.

Research and development expenses were \$2.7 million for the three months ended March 31, 2026, compared to \$3.7 million for the three months ended March 31, 2025. The decrease was primarily attributable to lower clinical trial expenses and lower product development costs, including consulting, prototyping, and project-related support, partially offset by higher operational costs, including the aforementioned depreciation expense.

Selling, general and administrative expenses were \$2.5 million for the three months ended March 31, 2026, compared to \$3.5 million for the three months ended March 31, 2025. Selling, general and administrative expenses decreased primarily due to lower professional services expenses, regulatory reporting expenses, and payroll and personnel expenses.

Net loss for the three months ended March 31, 2026 was \$7.0 million, compared to a net loss of \$7.7 million for the three months ended March 31, 2025.

22,210,459 weighted average shares of common stock outstanding, basic and diluted, as of March 31, 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.

Reported cash and cash equivalents of \$12.9 million as of March 31, 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 Cryoablation (ULTC) technology. ULTC is designed to create large, durable lesions extending through the depth of both diseased and healthy cardiac tissue. The Company is currently focused on the treatment of ventricular arrhythmias with its purpose-built vCLAS™ Cryoablation System, which is CE Marked and is currently under evaluation in the Company’s FULCRUM-VT U.S. Pivotal IDE Trial.

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, enrolling 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. The results of the study will be used to apply for FDA premarket approval (PMA) for Adagio's vCLAS™ Cryoablation System, potentially leading to the broadest industry indication for purely endocardial ablation of scar-mediated VT.

Adagio's vCLAS™ Cryoablation 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: the potential receipt of additional gross proceeds from the private placement if the issued warrants are exercised in full; Adagio's intended use of the proceeds from the private placement; Adagio's strategy, future operations, future financial position, projected expenses, expected timing and results of clinical trials, prospects, plans and objectives of management; the reproducibility of any favorable results initially seen in Adagio's FULCRUM-VT pivotal data; and the potential for FDA approval of Adagio's product candidates. 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 March 31, 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 Financial Officer and Chief Business Officer
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Adagio Medical Holdings Inc.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share data)

	March 31, 2026	December 31, 2025
	(Unaudited)	(Audited)
Cash and cash equivalents	\$ 12,909	\$ 17,105
Total assets	39,308	43,253
Total liabilities	33,583	30,851
Total stockholders' equity	5,725	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 March 31,	
	2026	2025
Revenue	\$ —	\$ —
Cost of revenue and operating expenses:		
Cost of revenue	—	253
Research and development	2,741	3,659
Selling, general, and administrative	2,459	3,485
Total cost of revenue and operating expenses	5,200	7,397
Loss from operations	(5,200)	(7,397)
Other income (expense):		
Convertible notes fair value adjustment	(1,063)	190
Warrant liabilities fair value adjustment	(131)	38
Interest expense	(778)	(662)
Interest income	107	164
Other income (expense), net	70	(46)
Total other loss, net	(1,795)	(316)
Net loss	\$ (6,995)	\$ (7,713)
Other comprehensive loss:		
Foreign currency translation adjustment	(44)	(61)
Comprehensive loss	\$ (7,039)	\$ (7,774)
Basic net loss per share	\$ (0.31)	\$ (0.50)
Diluted net loss per share	\$ (0.31)	\$ (0.51)
Weighted-average shares outstanding – basic and diluted	22,210,459	15,375,521