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): November 16, 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 November 16, 2026, Adagio Medical Holdings, Inc. issued a press release announcing financial results for the quarter ended September 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 November 16, 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: November 16, 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 Third Quarter 2026 Results

LAGUNA HILLS, CA, November 16, 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 third quarter ended September 30, 2026.

Recent Business Highlights:

- Ultra-Low temperature ablation ("ULTA") featured in four podium presentations at the VT Symposium 2026 held October 9-10 in New York, with topics spanning clinical experience, comparative preclinical research and insights from FULCRUM-VT, with particular physician interest centered on the next-generation vCLAS *Ultra* catheter's handling, streamlined workflow, and ability to create time efficient deep wide footprint lesions with predictable dimensions

- Highlighted the first patient treated in the Investigational Device Exemption ("IDE") sub-study evaluating the Company's next-generation vCLAS™ *Ultra* System for Ventricular Tachycardia, which was completed at Banner – University Medical Center Phoenix, kicking off enrollment across multiple sites to advance the faster, improved ULTA catheter for the broadest population of ventricular tachycardia ("VT") patients

- Announced that the Company's Board of Directors initiated a formal process to explore strategic alternatives focused on maximizing shareholder value

- Treated a total of 22 patients with the Company's vCLAS™ *Ultra* System in the United States and Canada, including 19 patients enrolled in the FULCRUM-VT IDE sub-study and 3 compassionate use cases

"The third quarter was defined by progress in the clinical and regulatory programs that we believe are the foundation for the value of Adagio and our ULTA platform. Our PMA application for the vCLAS Ventricular Ablation System remains under FDA review, and we initiated the vCLAS Ultra IDE study, which builds on the FULCRUM-VT results with a faster, more maneuverable next-generation catheter. We were also pleased to see ULTA featured in several podium presentations at the recent VT Symposium, reinforcing the clinical differentiation of a purpose-built, all-endocardial approach to VT," said Todd Usen, Chief Executive Officer of Adagio Medical. "As the Board's review of strategic alternatives continues, we have aligned our cost structure around these prioritized programs and remain focused on maximizing value for our shareholders."

Third Quarter 2026 Financial Results

Cost of revenue was nil for the three months ended September 30, 2026, compared to $31 thousand for the three months ended September 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 September 30, 2026, such depreciation expense is reflected within research and development expenses for the period.

Research and development expenses were $1.8 million for the three months ended September 30, 2026, compared to $2.8 million for the three months ended September 30, 2025. The decrease was primarily attributable to lower clinical trial expenses and lower operational costs.

Selling, general and administrative expenses were $2.6 million for the three months ended September 30, 2026, compared to $2.9 million for the three months ended September 30, 2025. The decrease was primarily attributable to lower professional services expenses and regulatory reporting expenses, partially offset by higher payroll and personnel expenses.

Net income for the three months ended September 30, 2026 was $17.8 million, or $2.40 per basic share, compared to a net loss of $10.1 million, or $(19.73) per basic and diluted share, for the three months ended September 30, 2025. Net income for the third quarter of 2026 was primarily driven by a $23.0 million noncash gain related to the change in fair value of the Company's 13% Senior Secured Convertible Notes (the "Notes"). Diluted net loss per share for the third quarter of 2026 was $(5.13), which primarily reflects the exclusion of the noncash fair-value gain associated with the Notes.

Weighted-average shares of common stock outstanding for the three months ended September 30, 2026 were 747,657 on a basic basis and 833,254 on a diluted basis. Certain outstanding warrants and other potentially dilutive securities were excluded from the diluted earnings per share calculation because their inclusion would have been anti-dilutive.[1] Cash and cash equivalents were $3.1 million as of September 30, 2026.

Reverse Stock Split

On November 6, 2026, the Company effected a one-for-thirty (1-for-30) reverse stock split of its issued and outstanding shares of common stock. The reverse stock split did not change the number of authorized shares of common stock or the par value per share. The reverse stock split was undertaken in connection with the Company's efforts to regain compliance with the minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). The Company's common stock began trading on The Nasdaq Capital Market on a split-adjusted basis on November 9, 2026. All share and per-share amounts presented in this press release have been retroactively adjusted to reflect the reverse stock split for all periods presented.

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 Premarket Approval ("PMA") application to the U.S. Food and Drug Administration ("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.

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[1] Results have been adjusted to reflect the one-for-thirty (1-for-30) reverse stock split effected in November 2026.

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; the potential for FDA approval of Adagio's product candidates, including the PMA application for the vCLAS Ventricular Ablation System; Adagio's pursuit of strategic alternatives and the entry into or completion of any strategic alternative transaction; and Adagio's ability to regain compliance with Nasdaq's continued listing requirements, including the Minimum Bid Price Requirement. 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 September 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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Adagio Medical Holdings, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2026	December 31, 2025
	(Unaudited)	(Audited)
Cash and cash equivalents	$ 3,095	$ 17,105
Total assets	29,860	43,253
Total liabilities	11,497	30,851
Total stockholder's equity	18,363	12,402

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

	Three Months Ended September 30,	
	2026	2025
Revenue	$ —	$ —
Cost of revenue and operating expenses:		
Cost of revenue	—	$ 31
Research and development	1,799	2,774
Selling, general, and administrative	2,572	2,916
Total cost of revenue and operating expenses	$ 4,371	$ 5,721
Loss from Operations	$ (4,371)	$ (5,721)
Other income (expense)		
Convertible notes fair value adjustment	22,950	$ (3,508)
Warrant liabilities fair value adjustment	66	$ (231)
Interest expense	(843)	(749)
Interest income	40	79
Other income (expense), net	(2)	12
Total Other Income (expense), net	$ 22,211	$ (4,397)
Net income (loss)	$ 17,840	$ (10,118)
Other comprehensive income (loss):		
Foreign currency translation adjustment	$ 4	$ 4
Comprehensive income (loss)	$ 17,844	$ (10,114)
Basic net income (loss) per share	$ 2.40	$ (19.73)
Diluted net income (loss) per share	$ (5.13)	$ (19.73)
Basic weighted average shares outstanding	747,657	512,718
Diluted weighted average shares outstanding	833,254	512,718