



Adagio Medical Reports First Quarter 2025 Results

May 16, 2025

LAGUNA HILLS, CA, May 15, 2025 – 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, 2025.

Recent Business Highlights:

- Received Breakthrough Device Designation from the U.S. Food and Drug Administration (the “FDA”) for the vCLAS™ Cryoablation System (“vCLAS”), for the treatment of drug-refractory, recurrent, sustained monomorphic ventricular tachycardia (“VT”) in patients with ischemic or non-ischemic structural heart disease. The vCLAS™ Cryoablation System is currently the subject of the FULCRUM-VT Investigational Device Exemption (“IDE”) study designed to support FDA approval. The Breakthrough Device program allows for the FDA to potentially provide Adagio with priority review and interactive communication during the vCLAS™ review phase.
- Surpassed 50% enrollment in the FULCRUM-VT pivotal study. The study, which seeks to enroll 206 patients with ischemic and non-ischemic disease at 20 U.S. and Canadian centers, is on track for completion of patient enrollment in the second half of 2025.
- Adagio’s Ultra-Low Temperature Cryoablation (“ULTC”) and vCLAS technologies were showcased by leading electrophysiologists during multiple scientific sessions at the recent European Heart Rhythm Association (EHRA) and Heart Rhythm Society (HRS) industry meetings.
- Hired industry veteran Deborah Kaster, who has more than 25 years of leadership experience in the medical technology sector, as Chief Business Officer.
- Implemented a corporate prioritization initiative focusing all resources on the FULCRUM-VT clinical trial activities and the Company’s new product design optimization program, which has been designed to advance faster innovation and iteration to meet market demands.

“This has been a defining quarter for Adagio Medical and for our progress across the company. The FDA’s Breakthrough Device Designation, multiple impactful presentations at leading industry conferences, the introduction of our optimized smaller, faster next generation ULTC technology in development and the continued momentum in enrolling patients in our FULCRUM-VT trial all underscore the clinical promise and growing validation of our proprietary ULTC platform technology,” said Todd Usen, Chief Executive Officer of Adagio. “I am so proud of the Adagio team’s accomplishments as we remain resolute in our mission to transform patient treatment and outcomes with our purpose-built solution for the large, underserved population of patients suffering from ventricular tachycardia.”

First Quarter 2025 Financial Results

Cost of revenue was \$0.3 million for the three months ended March 31, 2025, compared to \$0.5 million for the three months ended March 31, 2024.

Research and development expenses were \$3.7 million for the three months ended March 31, 2025, compared to \$3.5 million for the three months ended March 31, 2024.

Selling, general and administrative expenses were \$3.5 million for the three months ended March 31, 2025, compared to \$4.8 million for the three months ended March 31, 2024.

Net loss for the three months ended, March 31, 2025 was \$7.7 million, or \$(0.50) per share, compared to a net loss of \$8.0 million, or \$(10.28) per share, for the three months ended, March 31, 2024.

Reported cash and cash equivalents of \$13.0 million as of March 31, 2025.

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 tachycardia (VT) with its purpose-built vCLAS™ Cryoablation System which is CE Marked and is currently under evaluation in the Company’s FULCRUM-VT U.S. IDE Pivotal Study.

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 study, enrolling 206 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 ventricular tachycardia 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 of our vCLAS™ Cryoablation System our research, development and regulatory plans for our product candidates, including the timing of initiating additional trials and reporting data from our trials; the regulatory pathway for our vCLAS™ Cryoablation System and the potential impacts of the Breakthrough Device Designation; the potential for our product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies; and our current cash resources and the impacts of our corporate prioritization initiative and realignment of resources. 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 our business are described in detail in our Securities and Exchange Commission (“SEC”) filings, including in our Annual Report on Form 10-K for the full-year ended December 31, 2024, which is available on the SEC’s website at www.sec.gov. Additional information will be made available in other filings that we make from time to time with the SEC. These forward-looking statements speak only as of the date hereof, and we disclaim any obligation to update these statements except as may be required by law.

Contact

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Adagio Medical Holdings, Inc.

Condensed Balance Sheets
(in thousands, except share and per share data)

	<u>Successor</u>	<u>Predecessor</u>
	<u>As of</u>	<u>As of</u>
	<u>3/31/2025</u>	<u>12/31/2024</u>
Cash and cash equivalents	\$ 12,963	\$ 20,586
Total assets	41,338	48,448
Total Liabilities	28,939	28,536
Total stockholders' equity	12,399	19,912

Condensed Statements of Operations

	<u>Three months ended March 31,</u>	
	<u>2025</u>	<u>2024</u>
Revenue	\$ -	\$ 26
Cost of revenue	253	542
Research and development	3,659	3,469
Selling, general, and administrative	3,485	4,830
Total cost of revenue and operating expenses	<u>7,397</u>	<u>8,841</u>
Loss from operations	(7,397)	(8,815)
Other (income) expenses:		
Convertible notes fair value adjustment	190	1,673
Warrant liabilities fair value adjustment	38	(80)
Interest expense	(662)	(754)
Interest income	164	1
Other income (expense), net	(46)	(43)
Total other income, net	<u>(316)</u>	<u>797</u>
Net loss	<u>\$ (7,713)</u>	<u>\$ (8,018)</u>
Basic net loss per share	\$ (0.50)	\$ (10.28)
Diluted net loss per share	\$ (0.51)	\$ (10.28)
Weighted average shares outstanding, basic and diluted	15,375,521	779,908