Adagio Medical Provides Business Update: 22 Patients Treated with Next-Generation vCLAS™ Ultra System as FULCRUM-VT IDE Sub-Study Advances

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Strategic Alternatives Review Continues to Progress

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Nov. 10, 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 provided a business update highlighting continued execution of its FULCRUM-VT IDE study and FULCRUM-VT IDE sub-study, as well as progress of its previously announced review of strategic alternatives.

Clinical Update

To date, the Company has treated a total of 22 patients with the Company's vCLAS *Ultra* Ultra-Low Temperature Ablation ("ULTA") Ventricular Ablation System at seven centers in the United States and Canada, including 19 patients enrolled in the FULCRUM-VT IDE sub-study and three compassionate use cases.

"Our experience with Adagio's next-generation *Ultra* platform has been extremely encouraging. Having performed eight procedures, more than any other center worldwide to date, we have seen meaningful advancements in procedural workflow, catheter performance, and the freeze profile, allowing for a more efficient and streamlined approach to treating complex ventricular arrhythmias compared to the first-generation ULTA product," said Vidal Essebag, MD, PhD, Director of Cardiac Electrophysiology, McGill University Health Centre. "From our earliest experience, we recognized the potential of ultra-low temperature ablation to address some of the most challenging aspects of VT treatment. We believe these improvements in the *Ultra* catheter, combined with the ability to create deep, durable lesions across a broad ablation footprint, represent an important step forward in advancing treatment options for patients with ventricular tachycardia."

Advancing the FULCRUM-VT *Ultra* sub-study remains a top corporate priority. Patient enrollment, data collection, clinical site support and product development have all continued through the Company's previously announced operational restructuring and concurrent strategic review, and the Company continues to dedicate capital and operational resources to maintain the integrity, timeline and execution of the study.

The Company also continues to work with the U.S. Food and Drug Administration ("FDA") on its Premarket Approval ("PMA") application for the first-generation vCLAS Ventricular Ablation System, which was submitted in May 2026.

Strategic Alternatives Review Process Update

The Company's previously announced review of strategic alternatives is progressing, and the Company's Board of Directors (the "Board") continues to actively evaluate a broad range of options to maximize shareholder value. The Board has not set a definitive timetable for the completion of this process, and there can be no assurance that the review will result in any specific transaction. The Company does not intend to disclose further developments regarding the strategic review until the Board has approved a specific course of action or determines that disclosure is otherwise required.

"Our team remains committed to optimizing our operations while prioritizing our focus on providing ULTA as a solution for the broadest population of patients suffering from VT. With 22 patients now treated with vCLAS *Ultra*, we believe the early clinical experience is validating what we designed this catheter to do, as physicians are seeing ablation times reduced by more than 60% compared to our first-generation system, with our smaller, more flexible next-generation catheter," said Todd Usen, CEO of Adagio Medical. "Throughout our operational restructuring and strategic review, we have continued to prioritize the FULCRUM-VT sub-study as we believe that this is the most important thing we can do for patients and for our shareholders. At the same time, our Board's review of strategic alternatives is progressing, and we remain focused on realizing the full value of our ULTA platform."

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.

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 ventricular tachycardia ("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 and Adagio's pursuit of strategic alternatives and the entry into or completion of any strategic alternative transaction. 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.

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