Adagio Medical Treats First Patient with Faster, Single-Freeze Next-Generation ULTA System

August 3, 2026

vCLAS Ultra System Designed to Optimize Usability and Workstream to Address Entire Spectrum of Ventricular Tachycardia Patients

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Aug. 3, 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 the successful treatment of the first patient with its next-generation vCLAS *Ultra* Ultra-Low Temperature Ablation ("ULTA") system under Expanded Access authorization from the U.S. Food and Drug Administration ("FDA").

The patient, who presented with non-ischemic cardiomyopathy and a recent history of failed radiofrequency ("RF") and coronary venous alcohol ablations to address the ventricular tachycardia ("VT"), was successfully treated at the Hospital of University of Pennsylvania ("HUP") by Dr. Gregory Supple, Director of Inpatient EP Services at HUP and an Investigator in the Company's FULCRUM-VT Pivotal Investigational Device Exemption ("IDE") trial. This milestone marks a significant step forward in Adagio's mission to transform the treatment of VT for the broadest patient population, including both ischemic and non-ischemic cardiomyopathy patients, with a fully endocardial solution that eliminates many of the compromises associated with alternative ablation technologies.

"Adagio's next generation vCLAS *Ultra* system represents a meaningful advancement in VT ablation by combining the proven Ultra-Low Temperature Ablation — or ULTA — energy platform with a faster, more maneuverable catheter, giving electrophysiologists a promising solution for the complex, deep-substrate cases that have long defied conventional energy sources. The proven safety profile of ULTA has allowed physicians to confidently ablate near critical structures — an increasingly important consideration in modern VT practice. This was particularly relevant in this case where the VT originated in the periaortic region, characterized by thick myocardium and proximity to the coronary arteries, a situation that presents a common challenge for other approved and experimental ablation technologies. Using the vCLAS *Ultra* system, we were able to successfully treat the patient, who remains free from VT recurrence approximately two months post-procedure," said Gregory Supple, MD. "The catheter flexibility and single-freeze design dramatically reduced procedure time compared to the first generation vCLAS device while still delivering the durable, transmural lesions that define this technology. Most importantly, vCLAS *Ultra* provides us with the potential for a single catheter capable of addressing the full range of substrates we encounter in real-world practice."

The vCLAS *Ultra* system represents the next generation of Adagio's proprietary ULTA technology, designed to deliver single-freeze ablations at approximately -170°C with pre-clinical data demonstrating a potential 50-75% reduction in ablation time and procedures up to 30 minutes shorter compared to the first-generation system. The FDA has granted IDE approval to expand the Company's FULCRUM-VT trial to evaluate the safety and effectiveness of the Company's next-generation vCLAS *Ultra* System for the treatment of Sustained Monomorphic Ventricular Tachycardia ("SMVT").

"Treating the first patient with our next-generation vCLAS *Ultra* system is not only a proud milestone for the entire Adagio team, but also for our physician partners and the patients they treat and reflects our continued commitment to advancing our ULTA technology platform as the only purpose-built solution for VT," said Todd Usen, Chief Executive Officer of Adagio Medical. "Building on the compelling pivotal data on ULTA presented at Heart Rhythm 2026 — including only 2.4% major adverse events and six-month results of 84% freedom from implantable cardioverter defibrillator shock and 78% relative reduction in amiodarone use across the broadest patient population in any VT ablation study — the next generation vCLAS*Ultra* System is designed to significantly reduce ablation time and further improve the overall procedural workflow for physicians. With FDA approval of our first-generation ULTA system expected in the coming months, this milestone underscores the depth of our pipeline and reaffirms our confidence in ULTA as a transformative platform to address the entire spectrum of patients eligible for ablation to treat their VT."

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, durable 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™ 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, 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 Ventricular Ablation System (ULTA) for the treatment of Sustained Monomorphic Ventricular Tachycardia (SMVT).

Adagio's vCLAS™ Ventricular Tachycardia 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," "potential," "future" or similar expressions are intended to identify forward-looking statements. Forward-looking statements include statements concerning: the potential for the vCLAS *Ultra* system, including its single-freeze design, to reduce ablation and procedure time and to provide a single catheter capable of addressing the full range of substrates encountered in VT ablation; the potential for pre-clinical data regarding the vCLAS Ultra system's performance to be realized in clinical or commercial use; the potential for data from the FULCRUM-VT study, including with respect to the next-generation vCLAS *Ultra* system, to support an application for FDA premarket approval and the anticipated timing and outcome thereof, including the expected timing of FDA approval of Adagio's first-generation ULTA system; the potential for ULTA technology to address unmet needs in the treatment of VT, including across both ischemic and non-ischemic cardiomyopathy substrates; and Adagio's research, development and regulatory plans, including communications with, and submissions to, the FDA. 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, which is 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20260803231067/en/

Debbie Kaster
Chief Financial Officer and Chief Business Officer
dkaster@adagiomedical.com

Source: Adagio Medical Holdings, Inc.