



Adagio Medical Highlights Recent Successful Expanded Access Cases with vCLAS™ System, Including Patients with Premature Ventricular Contractions (PVC)

March 19, 2026

vCLAS™ Used to Treat Patients with No Satisfactory Approved Treatment and/or Failed RF or PFA

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Mar. 19, 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 completion of 13 ventricular ablation procedures at leading institutions using the Company's proprietary Ultra-Low Temperature Ablation (ULTA) technology under Expanded Access authorization from the U.S. Food and Drug Administration (FDA). The procedures addressed recurrent, symptomatic ventricular tachycardia (VT) or premature ventricular contractions (PVC) in patients who had previously failed ablations with conventional and/or experimental modalities including radiofrequency (RF), venous ethanol and pulsed field ablation (PFA).

The Expanded Access Program (EAP), also called "Compassionate Use," is a potential pathway for patients with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. FDA guidelines state that approval for Expanded Access may be appropriate when all the following apply:

- Patient has a serious or immediate life-threatening disease or condition.
- There is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition.
- Patient enrollment in a clinical trial is not possible; and
- Potential patient benefit justifies the potential risks of treatment.

"Our experience during the FULCRUM-VT pivotal study treating a wide range of patients with VTs due to structural heart disease demonstrated that the combination of catheter stability, lesion depth and the ability to safely navigate around sensitive structures with Adagio's ULTA technology can be advantageous compared to other ablation technologies," said Dr. Gregory Supple, Director of Inpatient EP Services at the Hospital of University of Pennsylvania and one of the treating physicians. "Through that experience we recognized that ULTA is a promising option when managing some of our most challenging patients who have failed other ablation approaches, including those with symptomatic PVCs. Similar to structural heart VTs, PVCs may have a deep site of origin close to coronary arteries or be associated with highly mobile structures. These locations make the VT more difficult to treat using RF or PFA, which have intrinsic limitations on lesion depth, present risk of coronary injury or are highly sensitive to continuous contact between the catheter and tissue – the areas where ULTA may have a significant advantage. We are grateful to have had the opportunity to treat these patients with ULTA under the EAP."

Physicians reported favorable acute procedural outcomes and effective workflow integration in the electrophysiology lab for these patients, which included both structural VTs and symptomatic PVCs. A structural VT is a rapid, often dangerous heart rhythm originating in the ventricles, occurring specifically in patients with underlying heart damage, such as scarring from a heart attack, cardiomyopathy, or heart failure. PVCs are extra, abnormal heartbeats that begin in the heart's ventricles, and can be highly symptomatic. While there is currently no ablation technology approved in the United States for PVCs, it is estimated that PVC ablations represent approximately 50% of the total addressable market for VT ablation.

"We believe these compassionate use cases represent an important milestone for Adagio Medical and underscore the clinical need and differentiation of our proprietary ULTA platform. While initial clinical experience with ULTA in both the clinical studies and early compassionate use cases was limited to patients with structural heart disease, the recent inclusion of PVC patients under the EAP highlight the ability for ULTA to treat the full spectrum of ventricular arrhythmias, all through an endocardial approach," said Todd Usen, Chief Executive Officer of Adagio Medical. "We are first and foremost thrilled that our technology can help patients who have no other option to treat their condition and we are grateful to the physicians and patients who put their trust in our technology. We look forward to continuing to generate clinical evidence to support the advancement of our ULTA platform and to sharing the results of our FULCRUM-VT pivotal trial at the Heart Rhythm Society scientific meeting in April."

Adagio's FULCRUM-VT IDE study, which fully enrolled in October 2025, is designed to support U.S. regulatory approval of Adagio's vCLAS™ Cryoablation System, which the Company expects by year-end 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 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. 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. 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 of Adagio's ULTC technology, including the reproducibility and durability of any favorable results seen during use pursuant to the EAP; Adagio's strategy, future operations, the expected timing and results of clinical trials, prospects, plans and objectives of management; and the potential for FDA approval and commercialization of Adagio's product candidates and whether, if approved, these product candidates will be successfully distributed and marketed. 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, 2024 and Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, 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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