Adagio Medical Receives IDE Approval from the FDA to Investigate Next-Generation vCLAS® Ventricular Ablation System

April 8, 2026

Designed to Deliver Faster, More Efficient Ablation with Improved Usability on Established, Titratable, Endocardial-Approach ULTA Platform

LAGUNA HILLS, Calif.--(BUSINESS WIRE)--Apr. 8, 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 that the U.S. Food and Drug Administration (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-Low Temperature Ablation (ULTA) Ventricular Ablation System for the treatment of Sustained Monomorphic Ventricular Tachycardia (SMVT).

"Ventricular tachycardia remains one of the most difficult arrhythmias to treat, with current ablation approaches often limited by difficulty achieving sufficient lesion depth," said Dr. William Stevenson, M.D., Professor of Medicine, Principal Site Investigator, Vanderbilt University Medical Center. "We have been impressed with the safety and clinical results of the initial ULTA system for treating VT in patients with ischemic and nonischemic cardiomyopathies. We are looking forward to evaluating the next generation of the system, which we anticipate will have improved catheter maneuverability and allow shorter freeze times, both factors that should reduce procedure times."

The approval for IDE expansion enables Adagio to initiate a clinical sub-study designed to evaluate its next-generation vCLAS Ventricular Ablation System including the next generation vCLAS *Ultra* catheter, which has been built on the clinical foundation established by the Company's all-endocardial ULTA technology. Adagio's vCLAS *Ultra* catheter achieves ablation temperatures of approximately -170°C enabling highly efficient, single-freeze applications that have been shown to produce effective lesions with greater than 50% reduction in ablation time as demonstrated in pre-clinical models.

"The vCLAS *Ultra*, which was designed to improve energy delivery, navigation, lesion control, and overall procedural workflow efficiency, reflects our team's ability to expeditiously translate feedback from our physician partners into meaningful technological advancement. In parallel, the design incorporates improvements in manufacturability, supporting scalability and reducing overall system cost," said Alex Babkin, Chief Technology Officer of Adagio Medical. "Importantly, this advancement positions us to potentially offer the market a single, versatile catheter capable of treating the full range of VT substrates, all through an endocardial approach, with our clinically established ULTA platform technology. This IDE approval is an important step toward clinically validating what we believe could be a paradigm-shifting technological solution for VT."

The sub-study is a prospective, single-arm, multi-center, pre-market, clinical supplemental study designed to provide safety and efficacy data regarding the use of Adagio's next generation vCLAS Ventricular Ablation System in the treatment of scar-mediated SMVT in ischemic and non-ischemic patients, which is the same population treated in the pivotal phase of the IDE study. The IDE expansion approval is for a total of 55 proposed patients in a staged sub-study design.

"We are building on a strong and growing body of clinical evidence supporting the effectiveness of our ULTA technology, which has already demonstrated the ability to create deep, effective lesions through a fully endocardial approach," said Todd Usen, Chief Executive Officer of Adagio Medical. "IDE approval for this study expansion marks an important milestone as we continue to advance our vCLAS *Ultra* catheter, which we built to enable broader adoption across all electrophysiology practices. Our goal is to translate this proven technology into a highly scalable solution that can democratize the treatment of VT and become the go-to ablation catheter for treating the large, underserved population of patients who suffer from this disease. On behalf of the entire Adagio team, we would like to thank the FDA for their collaboration and partnership."

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 in an endocardial only 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.

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 ULTA technology, including the ability of Adagio's next-generation vCLAS™ ULTRA system to provide clinical advantages; Adagio's research, development and regulatory plans for its product candidates; the reproducibility and durability of any favorable results initially seen in pre-clinical trials; Adagio's strategy and future operations; the expected timing and results of clinical trials; the 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 and the potential market opportunity for Adagio's product candidates. 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/20260408341039/en/

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

Source: Adagio Medical Holdings, Inc.