



Adagio Medical Announces Strategic Restructuring to Accelerate US Pivotal IDE Trial and Product Innovation

March 1, 2025

LAGUNA HILLS, CA, February 28, 2025 – Adagio Medical Holdings, Inc. (Nasdaq: ADGM; the “Company”), a leading innovator in catheter ablation technologies for treatment of cardiac arrhythmias, today announced a corporate restructuring and realignment of resources to prioritize its FULCRUM-VT US pivotal investigational device exemption (“Pivotal IDE”) clinical trial activities and its new product design optimization program. “After a comprehensive strategic review, we are doubling down on the priorities that will drive the most meaningful impact for physicians, patients, and shareholders,” said Todd Usen, the Chief Executive Officer of Adagio. “Our resources are now focused on the completion of the FULCRUM-VT Pivotal IDE trial and subsequent premarket approval of the VT Cryoablation System with vCLAS™ catheter from the U.S. Food and Drug Administration (“FDA”). With over 35% enrollment complete, we, along with our physicians, are very encouraged by the system’s performance and early outcomes. In addition, we will dedicate the appropriate resources to our product design optimization program, which allows us to design, iterate and innovate more efficiently. We believe that this focused approach is crucial to position Adagio as a leader in ventricular tachycardia solutions, which has been a historically underserved market.”

The streamlining of the Company operations includes a pause in the limited European launch of the vCLAS catheter, while the product design optimization program is instituted. The limited launch provided valuable insights from European electrophysiology professionals, including gaining a more in-depth understanding of the broad applicability and unique clinical benefits of Adagio’s proprietary ultra-low temperature cryoablation technology.

With a narrower focus on key initiatives, the restructuring includes a reduction in force, effective February 28, 2025. This is expected to enable additional investment in the aforementioned critical priorities.

“The decision to part with valued colleagues is difficult, and we have deep gratitude for their contributions,” continued Mr. Usen. “We wish them the very best and will strive to build upon their efforts. I have tremendous confidence in Adagio’s future, and believe that our highly differentiated and validated technology will drive the best clinical results for our physicians and, ultimately, the best outcomes for ventricular tachycardia patients.”

About FULCRUM-VT

FULCRUM-VT (Feasibility of Ultra-Low Temperature Cryoablation in Recurring Monomorphic Ventricular Tachycardia, NCT05675865) 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 ventricular tachycardia (“VT”) in accordance with current treatment guidelines. The results of the study will be used to obtain premarket approval from the FDA for Adagio’s VT Cryoablation System with the vCLAS™ cryoablation catheter with industry’s broadest indication for purely endocardial ablation of scar-mediated VT.

About Adagio Medical Holdings, Inc.

Adagio Medical Holdings, Inc. (Nasdaq: ADGM) is an early commercial stage medical device company located in Laguna Hills, California focused on developing proprietary Ultra-Low Temperature Cryoablation technology that creates contiguous, transmural lesions to treat cardiac arrhythmias, with an emphasis on ventricular tachycardia.

Forward-Looking Statements

Certain statements in this press release (this “Press Release”) may be considered “forward-looking statements” within the meaning of the “safe harbor” provisions of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements generally relate to future events or future financial or operating performance of the Company. For example, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forecast,” “future,” “intend,” “may,” “might,” “plan,” “possible,” “potential,” “predict,” “project,” “propose,” “seek,” “should,” “strive,” “will,” or “would” or the negatives of these terms or variations of them or similar terminology. Such forward-looking statements are subject to risks, uncertainties, and other factors which may be beyond the control of the Company and could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon estimates and assumptions that, while considered reasonable by the Company and its management, are inherently uncertain. The Company cautions you that these statements are based on a combination of facts and factors currently known and projections of the future, which are inherently uncertain. There are risks and uncertainties described in the documents and reports, which was filed by the Company with the U.S. Securities and Exchange Commission (the “SEC”) and will be filed by the Company from time to time with the SEC. These filings may identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements.

The Company cannot assure you that the forward-looking statements in this communication will prove to be accurate.

Nothing in this Press Release should be regarded as a representation or warranty by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved, in any specified time frame, or at all. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made in this Press Release. Subsequent events and developments may cause those views to change. The Company does not undertake any duty to update these forward-looking statements.

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