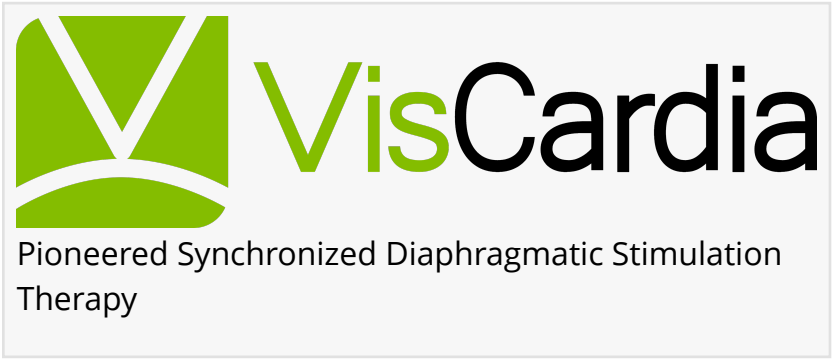
VisCardia Secures $40 Million Growth Financing to Advance VisONE™ Heart Failure Therapy Toward PMA Approval

PORTLAND, OR, UNITED STATES, December 2, 2025 /EINPresswire.com/ -- VisCardia, Inc., a medical device company pioneering a novel cardiac-support therapy for patients with heart failure, today announced it has secured $40 million in growth financing to advance the company's path toward Premarket Approval (PMA) for its VisONE™ Synchronized Diaphragmatic Stimulation (SDS) Therapy.



The financing will support the execution of the company's pivotal RECOVER-HF clinical study, and key milestones on the path to PMA. VisCardia expects to achieve the first implant early in 2026. Multiple leading U.S. institutions have already passed site qualification and are nearing patient enrollment, with a strong pipeline of both national and international institutions to follow.

"Closing this $40 million financing marks a transformative milestone for VisCardia," said Peter Bauer, Ph.D., President & CEO of VisCardia. "We are now positioned to execute our U.S. IDE pivotal trial and accelerate development of a minimally invasive therapy designed to offer a new treatment pathway for millions of heart failure patients who remain symptomatic despite guideline-directed medical therapy. The strong support from our investors underscores the magnitude of this unmet need and the differentiated potential of VisONE Therapy."

Dr. Lee Goldberg, Section Chief for Advanced Heart Failure and Cardiac Transplant at the University of Pennsylvania, will serve as Principal Investigator for RECOVER-HF. "I am very excited to be leading this pivotal trial," said Dr. Goldberg. "VisONE represents a promising and intuitive therapy for the substantial population of heart failure patients who continue to struggle despite adherence to established medical therapy. The mechanism of action leverages the diaphragm's natural physiologic contribution to cardiac function in a low-risk, minimally invasive manner. This unique approach aligns with the long-term treatment and economic goals in this complex patient population."

VisONE is a truly novel Heart Failure device therapy designed to augment cardiac function by

stimulating the diaphragm in synchrony with the cardiac cycle, thereby using it as an ancillary cardiac pump to improve blood circulation. The therapy does not interfere with respiration and is imperceptible to the patient. The extra-cardiac/thoracic placement VisONE enables a minimally invasive laparoscopic implant procedure that can be performed by a wide range of surgeons in an outpatient setting.

The RECOVER-HF pivotal trial will be a randomized, double-blinded study enrolling approximately 270 patients with moderate to severe heart failure who remain symptomatic despite optimized medical therapy and preserved ventricular synchrony. VisCardia has completed multiple OUS feasibility studies demonstrating clinically meaningful improvements in symptoms, functional capacity, and hemodynamic parameters.

About VisCardia

VisCardia, Inc. is a privately held medical device company based in Portland, Oregon, dedicated to developing minimally invasive solutions for the millions of patients suffering from heart failure. The company's breakthrough VisONE™ Synchronized Diaphragmatic Stimulation Therapy has completed extensive preclinical and early human clinical evaluation, and has been granted Breakthrough Device designation by the U.S. FDA. VisCardia is preparing to launch its pivotal RECOVER-HF trial, enrolling up to 30 sites across the U.S. and Europe, as it advances toward PMA approval.

For more information, visit: www.viscardia.com

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