Anteris Announces Results for the Third Quarter of 2025

MINNEAPOLIS, United States and **BRISBANE, Australia 13 November 2025: Anteris Technologies Global Corp.** (**Anteris** or the **Company**) (NASDAQ: AVR, ASX: AVR) a global structural heart company committed to designing, developing, and commercializing cutting-edge medical devices to restore healthy heart function, today reported financial results for the quarter ended September 30, 2025, and provided a corporate update.

Third Quarter 2025 Highlights

- Continued FDA engagement during the Quarter to advance the IDE for the PARADIGM Trial, with FDA approval to commence U.S. recruitment* announced in November 2025
- Advanced European regulatory activities to initiate the PARADIGM Trial across multiple countries, with the first PARADIGM patients treated in Denmark following regulatory approval from the Danish Medicines Agency in October 2025
- Progressed site and operational readiness across the United States, Europe and Canada ahead of anticipated trial enrolment
- Strengthened operational and quality systems while advancing manufacturing scale-up to support clinical activities including ISO 13485 certification for DurAVR® THV production
- Received approval from the Company's stockholders for ASX Limited's grant to the Company of a waiver from ASX Listing Rule 7.1

"Third Quarter activities were critical to set the company on its path for the rest of the year and into 2026. The company made significant progress on the regulatory front with approvals to start the PARADIGM pivotal study being achieved in both Europe and the U.S. in Q4 as a result," said Wayne Paterson, Vice Chairman and Chief Executive Officer of Anteris.

Business & Operations

DurAVR® THV Commercialisation Update

Activities supporting the launch of the PARADIGM Trial

During the third quarter of 2025, the company maintained positive engagement with the United States Food and Drug Administration (**FDA**) to advance the Investigational Device Exemption (**IDE**) for the PARADIGM Trial, submitting a formal response to address requests for additional information, including a completed simulated use study. FDA approval to commence patient recruitment* in the United States was subsequently announced in November 2025.

Anteris also advanced European regulatory activities aimed at securing approval to commence the PARADIGM Trial in countries including Germany, France and the Netherlands, with the first European approval secured in Denmark in October 2025. In parallel, cross-functional teams completed site and operational readiness activities, namely investigator training, study material preparation, and logistical set up, ahead of anticipated enrolment and pending receipt of regulatory clearance and Institutional Review Board (**IRB**) approval. The first PARADIGM patients were enrolled and treated in Denmark following regulatory approval from the Danish Medicines Agency in October 2025.

The Company continued strengthening its operational infrastructure during the quarter, advancing quality management system (**QMS**) buildout to support upcoming clinical activities and future ISO 13485 certification. Key quality procedures and standard operating documents were released to establish the framework for a mature, compliant system and to mitigate audit risk. In parallel, manufacturing scale-up activities progressed, including cross-training of inspection personnel, expansion of clean room capacity, and ongoing process development initiatives for projected DurAVR® THV demand.

The financial results for Anteris for the quarter ended September 30, 2025, are reviewed below. All amounts in $ refer to U.S. dollars.

The Company's net operating cash outflows for the nine months ended September 30, 2025, were $59.3 million, in line with the increase in clinical, regulatory and manufacturing requirements to support the PARADIGM Trial. Reflecting this clinical focus, the key areas of the Company's operating expenditure for the three months ended September 30, 2025, were as follows:

- R&D expenses were $16.8 million.

  The key activities undertaken were the preparatory activities linked to the PARADIGM Trial, including regulatory work regarding the IDE and extensive engagement with planned investigators at clinical trial sites by the Clinical Specialist Team, who work directly with physicians in the Cath Lab to support appropriate use of the device and procedural success. Additionally, there were further costs associated with upscaling of manufacturing capabilities, including completion of design validation processes and documentation, and continued portfolio development aimed at driving long-term growth beyond the current products.

- Selling, general and administrative expenses were $5.8 million.

The Company held $9.1 million of cash and cash equivalents as of September 30, 2025.

Anteris refers to the detailed Financial Information contained in its Form 10-Q filing including the Management Discussion & Analysis and the Risks.

About the PARADIGM Trial

The PARADIGM Trial is a prospective randomized controlled trial (RCT) which will evaluate the safety and effectiveness of the DurAVR® THV compared to commercially available transcatheter aortic valve replacements (TAVRs).

This head-to-head study will enrol approximately 1,000 patients across the United States, Europe and Canada in the 'All Comers Randomized Cohort' with 1:1 randomization of patients who will receive either the DurAVR® THV or TAVR using commercially available and approved THVs. The PARADIGM Trial will assess non-inferiority on a primary composite endpoint of all-cause mortality, all stroke and cardiovascular hospitalization at one year post procedure.

The PARADIGM Trial is designed to provide the robust clinical evidence required to support an application to the FDA for Premarket Approval (PMA) in the United States, with CE Mark approval anticipated to progress in parallel to the PMA.

For further information about the PARADIGM Trial, please refer to ClinicalTrials.gov (ClinicalTrials.gov ID NCT07194265).

*Subject to Institutional Review Board (IRB) approval

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About Anteris

Anteris Technologies Global Corp. (NASDAQ: AVR, ASX: AVR) is a global structural heart company committed to designing, developing, and commercializing cutting-edge medical devices to restore healthy heart function. Founded in Australia, with a significant presence in Minneapolis, USA, Anteris is a science-driven company with an experienced team of multidisciplinary professionals delivering restorative solutions to structural heart disease patients.

Anteris' lead product, the DurAVR® Transcatheter Heart Valve (**THV**), was designed in collaboration with the world's leading interventional cardiologists and cardiac surgeons to treat aortic stenosis – a potentially life-threatening condition resulting from the narrowing of the aortic valve. The balloon-expandable DurAVR® THV is the first biomimetic valve, which is shaped to mimic the performance of a healthy human aortic valve and aims to replicate normal aortic blood flow. DurAVR® THV is made using a single piece of molded ADAPT® tissue, Anteris' patented anti-calcification tissue technology. ADAPT® tissue, which is FDA-cleared, has been used clinically for over 10 years and distributed for use in over 55,000 patients worldwide. The DurAVR® THV System is comprised of the DurAVR® valve, the ADAPT® tissue, and the balloon-expandable ComASUR® Delivery System.

Forward-Looking Statements

This announcement contains forward-looking statements. Forward-looking statements include all statements that are not historical facts, including the objectives of, plans for and size of Anteris' studies and trials. Forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "budget," "target," "aim," "strategy," "plan," "guidance," "outlook," "may," "should," "could," "will," "would," "will be," "will continue," "will likely result" and similar expressions, although not all forward-looking statements contain these identifying words. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions, including those described under "Risk Factors" in Anteris' Annual Report on Form 10-K for the fiscal period ended December 31, 2024 that was filed with the Securities and Exchange Commission and ASX. Readers are cautioned not to put undue reliance on forward-looking statements, and except as required by law, Anteris does not assume any obligation to update any of these forward-looking statements to conform these statements to actual results or revised expectations.

Authorisation and Additional information

This announcement was authorised for release on the ASX by the Board of Directors.

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