

Anteris Reports 2024 Financial Results and Provides Corporate Update

Eagan, USA and Brisbane, Australia: 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 full year ended December 31, 2024, and provided a corporate update.

2024 Full Year Highlights & Recent Developments

- Achieved a successful U.S. Initial Public Offering (“IPO”) onto Nasdaq raising \$88.8m (AUD \$139.3m) before costs and commissions and excluding the underwriters option, which completed the Company’s re-domiciliation to the United States.
- Continued preparations to initiate the DurAVR[®] Transcatheter Heart Valve’s (“THV”) randomized global pivotal study (the “Pivotal Trial”) - request for Investigational Device Exemption (“IDE”) on track for submission to the U.S. Food and Drug Administration (“FDA”) in the first quarter of 2025.
- Generated additional positive patient data to support IDE submission for the DurAVR[®] THV – 86 cases treated to date.
- Performed first two cases of the DurAVR[®] THV’s European Early Feasibility Study (“EU-EFS”) at Structural Heart Copenhagen in Denmark (January 2025).
- Increased awareness of the DurAVR[®] THV system in the global medical community including multiple high profile podium presentations at key congresses such as New York Valves and the 36th TCT Conference.
- Finalized design optimization of the balloon-expandable ComASUR[®] delivery system and expanded manufacturing scale-up in Malaga, AU and Minneapolis, U.S. to support planned Pivotal Trial.
- Concluded 2024 with a strong cash position of \$70.5m (AUD \$113.3m).

“This has been a transformational year for Anteris as we made advancements across all aspects of our business, which positions us well to commence the Pivotal Trial of our DurAVR[®] THV system in 2025.” said Wayne Paterson, Vice Chairman and Chief Executive Officer of Anteris.

Business & Operations

DurAVR[®] THV Commercialization Update:

Preparations for Pivotal Trial

During 2024, the Company executed several key activities to facilitate obtaining approval from the FDA to commence a Pivotal Trial for the Company’s lead product, the DurAVR[®] THV system. The approval to commence the Pivotal Trial, if granted, requires submitting an IDE application to the FDA, which is planned for the first quarter of 2025. Multiple pre-submission meetings with the FDA occurred covering topics such as reviewing the Pivotal Trial’s clinical plan and statistical rationale. Other key preparatory activities included life cycle testing, test method creation and validation, human factors validation testing with physicians, sterilization and shipping validation, and simulated use testing.

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Expanded clinical experience

During 2024, Anteris advanced preparations for the DurAVR® THV's planned EU-EFS. The first two cases were performed in January 2025 at Structural Heart Copenhagen in Denmark by Dr Ole De Backer. Excellent outcomes were achieved in a native aortic valve stenosis and a degenerated surgical valve. The EU-EFS is planned to be carried out in Denmark, Sweden, the Netherlands, France and Germany, enrolling up to 40 patients, to provide both Valve-in-Valve ("ViV") data in a controlled setting as well as generate further feasibility and safety data in patients with severe aortic stenosis. The objective of these EU-EFS implants is to build awareness, understanding and experience with the DurAVR® THV system.

Clinical data presented at major medical conferences

Over the course of 2024, the Company attended several key industry conferences to promote awareness among clinicians of the DurAVR® THV system as a potential new treatment paradigm for aortic stenosis. These activities included podium presentations at Cardiovascular Research Technologies or CRT (March 2024), Sydney Valves (March 2024), Society for Cardiovascular Angiography & Interventions or SCAI (May 2024), Euro PCR (May 2024), New York Valves (June 2024), the 36th Annual Transcatheter Cardiovascular Therapeutics or TCT Conference (October 2024) and London Valves (Nov 2024).

Data presented during the year included US-EFS 30-day results, First-in-Human ("FIH") 1-year results demonstrating sustained hemodynamic performance, ViV data and a post-transcatheter aortic valve replacement ("TAVR") cardiac magnetic resonance ("CMR") imaging study demonstrating restoration of laminar flow and early left ventricular reverse remodelling following treatment with the DurAVR® THV.

Scaled up manufacturing to support Pivotal Trial

During 2024, the Company's team continued design optimizations to the DurAVR® THV system to optimise the procedure, support ease of use and lower manufacturing costs. Additionally, manufacturing scale-up progressed at both the Malaga, AU and Minneapolis, U.S. manufacturing facilities as well as outsourced suppliers of the key components and delivery system. Additionally, Anteris engaged a Contract Research Organisation and bolstered in-house resources to support planned requirements to initiate and manage the Pivotal Trial.

About the DurAVR® THV Pivotal Trial

This prospective Pivotal Trial is anticipated to be the first all-risk, head-to-head TAVR registration trial to date. The Pivotal Trial is expected to include up to 80 sites across the U.S. and other key markets with an estimated 1,000 to 1,200 patients having severe, calcific aortic stenosis, and subject to customary study exclusions. The Pivotal Trial will be on a 1:1 randomised basis with patients receiving either the DurAVR® THV or TAVR using a commercially available and approved THV from the SAPIEN series (Edwards Life Sciences) or the Evolut series (Medtronic). This is intended to generate the widest possible patient population from the Pivotal Trial, enabling direct comparison with existing therapy and support a claim to the FDA of non-inferiority of the DurAVR® THV. Patients with a failed surgical bio-prosthesis needing ViV TAVR will be enrolled in a separate parallel registry. This is intended to support the Company's plans for the ViV market opportunity. To date, 86 patients have been implanted with the DurAVR® THV with an expanding dataset over one year and overall promising performance across several haemodynamic measures.



2024 Financial Results

The financial results for Anteris for the year ended December 31, 2024 are reviewed below. All amounts in \$ refer to U.S. dollars.

- **Net Sales for 2024 were \$2.7 million**
- **Net Loss after Income Tax for 2024 was \$76.0 million**
- **Closing cash balance at December 31, 2024 was \$70.5 million**

In 2024, Net Sales were \$2.7 million relating to sales of our tissue products. In line with contractual arrangements, the manufacture of products for LeMaitre ceased in January 2025.

In 2024, the Net Loss after Income Tax of \$76.0 million was driven by the operating expenses principally related to research and development to support the planned launch of the Pivotal Trial in 2025 and increased selling, general and administrative expenses which includes the re-domiciliation, Nasdaq listing and the U.S. IPO.

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

Corporate and Financing Activities

In October 2024, Anteris entered an AUD \$25.0 million secured convertible note facility (the Bridging Facility) with Obsidian Global Partners, LLC (“Obsidian”) to provide funding, primarily for the period prior to the U.S. IPO. In total AUD \$7.5 million was drawn down under the Bridging Facility. The Bridging Facility was repaid in full in December 2024 from the proceeds of the U.S. IPO. This facility was subsequently terminated in February 2025.

In December 2024, Anteris completed its U.S IPO, through the offering of 14,800,000 shares of common stock (the “Common Stock”) in the U.S. at a price of \$6.00 per share (the “Offering”) raising \$79.6 million after costs and commissions. Anteris Common Stock were then listed on the Nasdaq Global Market from 13 December 2024 and on 17 December 2024, Anteris listed its CHESSE Depository Interests (CDIs) on a 1 CDI-for-1 share of Common Stock basis, on the ASX.

In January 2025, TD Cowen, Barclays and Cantor (the “IPO Underwriters”) partially exercised the underwriters’ option to purchase additional shares granted by Anteris in respect of 78,481 shares of Common Stock at the purchase price of \$6.00 per share, less underwriting discounts and commissions, to raise a further \$0.4 million.

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, U.S., 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 partnership 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. 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’ registration statement filed on 10 December 2024 with the SEC and ASX. Readers are cautioned not to put undue reliance on forward-looking statements, and except as required by law, neither ATL or Anteris 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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