UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 15, 2025

Anteris Technologies Global Corp.

(Exact name of registrant as specified in its charter)

Delaware	**001-42437**	**99-1407174**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Toowong Tower, Level 3, Suite 302 **9 Sherwood Road** **Toowong, QLD** **Australia**	**4066**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: +61 7 3152 3200

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	AVR	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure

On October 15, 2025, Anteris Technologies Global Corp. (the "Company") issued a press release regarding the Company obtaining its first European regulatory clearance to commence the DurAVR® Transcatheter Heart Valve Global Trial.

The information in this Current Report on Form 8-K, including the exhibit attached hereto, is being furnished and shall not be deemed to be filed for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act"), or incorporated by reference into any filing under the Securities Act of 1933 (the "Securities Act") or the Exchange Act, unless such subsequent filing specifically references this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed with this Current Report on Form 8-K:

Exhibit No.	Description
99.1	Press release dated October 15, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Anteris Technologies Global Corp.

Date: October 15, 2025

By: /s/ Wayne Paterson
Name: Wayne Paterson
Title: Vice Chairman and Chief Executive Officer

Exhibit 99.1

Anteris Receives First European Regulatory Clearance to Commence DurAVR® THV Global Pivotal Trial (the "PARADIGM Trial")

MINNEAPOLIS, United States and **BRISBANE, Australia 15 October 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, announced today it has received regulatory clearance from the Danish Medicines Agency to initiate the DurAVR® Transcatheter Heart Valve (THV) global pivotal trial in patients with severe calcific aortic stenosis (the "PARADIGM Trial"). Patient recruitment at Danish centers is expected to begin in 4Q 2025.

***PARADIGM**: A **P**rospective r**A**ndomized t**R**ial **A**ssessing the safety and effectiveness of the **D**urAVR® b**I**omimetic valve designed for physiolo**G**ic flow compared to Co**M**mercial TAVR devices*

With the first regulatory clearance secured, Anteris is positioned to drive the global PARADIGM Trial through the addition of further countries and sites in the near term, with planned expansion across the United States, Europe and Canada. Management believes strong enthusiasm from investigators is expected to translate into efficient recruitment and timely study advancement.

"Receiving initial approval in Europe is an important milestone as it signals the launch of the global PARADIGM Trial. This groundbreaking study has been designed with world-leading experts and is attracting significant interest from clinicians globally, reflecting the potential for DurAVR® to transform care for patients with aortic stenosis," said Anteris Chief Medical Officer, Chris Meduri, M.D.

"The PARADIGM Trial enables us to bring promising new technology to patients across all surgical risk groups, building on the growing body of evidence supporting the DurAVR® THV's favorable hemodynamic performance. We look forward to contributing meaningful data which could support both PMA* and CE Mark approvals," said Dr. Michael Reardon and Professor Stephan Windecker, Study Co-Chairs of the global PARADIGM Trial.

"The PARADIGM trial is a multi center global study which, if successful, will result in multiple approvals and labels for the DurAVR® THV. This is a watershed moment in the company's life cycle and marks the beginning of the commercialization planning phase as we march towards global approvals. Anteris is excited to be able to allow access to an increasing pool of patients globally who will benefit from this life saving technology. The commencement of this trial reflects the commitment and tireless work of our talented Anteris team, as well as our Physician and Scientific Advisors. The company would like to express its gratitude to the physicians, patients and shareholders who have been fundamental in developing this important new therapy," said Vice Chairman and CEO, Wayne Paterson.

In parallel, an Investigational Device Exemption (IDE) application remains under review by the U.S. Food and Drug Administation (FDA). Anteris continues to expect FDA approval in the near term, which will allow initiation of study sites in the PARADIGM Trial in the United States, pending Institutional Review Board (IRB) approval.

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 aoric valve replacements (TAVRs).

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This head-to-head study will enroll approximately 1000 patients 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.

For further information, please refer to ClinicalTrials.gov (ClinicaTrials.gov ID NCT07194265). The planned expansion across other geographies includes additional cohorts.

*A Premarket Approval (PMA) application requires a high level of clinical evidence to demonstrate reasonable assurance of safety and effectiveness for the intended use. Randomized controlled trials are generally considered Level 1 evidence, the highest level for determining the effectiveness of interventions in evidence-based medicine given RCTs mimimize bias and allow a clear comparison between treatment groups.

ENDS

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 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, including statements regarding the planned expansion of the PARADIGM Trial, the reults of the PARADIGM Trial, the contours of the PARADIGM Trial, and the timing of the IDE approval. 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' Annual Report on Form 10-K for the fiscal period ended December 31, 2024 that was filed with the SEC 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.

For more information:

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