

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 27, 2025

Anteris Technologies Global Corp.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of Incorporation)

001-42437
(Commission File Number)

99-1407174
(I.R.S. Employer Identification No.)

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

4066
(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 27, 2025, Anteris Technologies Global Corp. (the “Company”) issued a press release announcing that the first patients have been enrolled and successfully treated in the DurAVR[®] Transcatheter Heart Valve (THV) global pivotal trial for patients with severe calcific aortic stenosis (the “PARADIGM 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 27, 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 27, 2025

By:	<u>/s/ Wayne Paterson</u>
Name:	Wayne Paterson
Title:	Chief Executive Officer



Anteris Technologies Announces First Patients Treated in DurAVR® THV Global Pivotal Trial (the “PARADIGM Trial”)

MINNEAPOLIS, United States and BRISBANE, Australia 27 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, today announced the first patients have been enrolled and successfully treated in the DurAVR® Transcatheter Heart Valve (THV) global pivotal trial for patients with severe calcific aortic stenosis (the “PARADIGM Trial”). The procedures were performed by Prof. Dr. Ole De Backer at, The Heart Center, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark.

“We are proud to be the first enrolling center for this important trial,” said Prof. Dr. De Backer. “Our initial experience with the DurAVR® THV System has been very positive, and we look forward to providing definitive comparative evidence which could transform patient care.”

“With the first patients now randomized in the PARADIGM Trial, we are actively generating the clinical evidence required to advance the DurAVR® THV toward commercialisation, expanding treatment options for aortic stenosis patients,” said Anteris Chief Medical Officer, Chris Meduri, M.D. “This head-to-head study will provide robust comparative evidence across all surgical risk groups, which we believe will differentiate our platform based on efficacy, safety and ease of use.”

The PARADIGM Trial builds on Anteris’ existing clinical data set of 130 patients successfully treated with the DurAVR® THV, including de novo (first time) aortic stenosis cases, valve-in-valve (ViV) patients and complex anatomies such as bicuspid aortic valve patients. Anteris aims 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.

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 enroll approximately 1,000 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 (ClinicalTrials.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 minimize bias and allow a clear comparison between treatment groups.

ENDS

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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 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 results of the PARADIGM Trial, the quotes from Prof. Dr. De Backer and Chris Meduri, M.D, the contours of the PARADIGM Trial, and the expansion of the PARADIGM Trial to other countries and cohorts. 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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