

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): November 3, 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, Queensland
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 November 3, 2025, Anteris Technologies Global Corp. (the “Company”) lodged a press release, regarding the Company obtaining approval from the U.S. Food and Drug Administration (“FDA”) for the Company’s DurAVR® Transcatheter Heart Valve (“THV”) Global Pivotal Trial (the “PARADIGM Trial”). A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained 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 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: FDA Approves Anteris’s DurAVR® THV Global Pivotal Trial (the “PARADIGM Trial”)
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: November 3, 2025

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



FDA Approves Anteris's DurAVR® THV Global Pivotal Trial (the "PARADIGM Trial")

PARADIGM: *A Prospective Randomized Trial Assessing the safety and effectiveness of the DurAVR® biomimetic valve designed for physiologic flow compared to Commercial TAVR devices*

MINNEAPOLIS, United States and BRISBANE, Australia 3 November 2025: Anteris announced today it has received U.S. Food and Drug Administration (FDA) approval to initiate PARADIGM, its global Investigational Device Exemption (IDE) clinical trial which is designed to evaluate the DurAVR® Transcatheter Heart Valve (THV) in patients with severe calcific aortic stenosis and to support a future PMA* submission.

"We are extremely pleased to receive FDA approval for the PARADIGM Trial, which allows us to commence patient recruitment in the United States**." This milestone, together with the recent launch of the trial and first patients treated in Denmark, represents a significant achievement and a key step forward in advancing this life-saving technology worldwide for patients living with aortic stenosis, a debilitating and progressive condition," commented Vice Chairman and CEO, Wayne Paterson.

The PARADIGM Trial is co-chaired by Dr. Michael J. Reardon, Allison Family Distinguished Chair of Cardiovascular Research and Professor of Cardiothoracic Surgery at the Houston Methodist Hospital, Texas and Professor Stephan Windecker, Chairman of the Department of Cardiology at Bern University Hospital, Switzerland.

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 1000 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 in the United States, with CE Mark approval anticipated to progress in parallel to the PMA.

For further information, please refer to ClinicalTrials.gov (ClinicalTrials.gov ID NCT07194265).

*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.

**Subject to Institutional Review Board (IRB) approval

860 Blue Gentian Road,
Suite 340
Eagan, MN, 55121
United States
T: +1 651 493 0606
info.us@anteristech.com

Anteris Technologies Global Corp.
BRISBANE | MINNEAPOLIS | GENEVA | MALAGA



anteristech.com

Toowong Tower, Level 3, Suite 302
9 Sherwood Road, Toowong
QLD 4066, Australia
T: +61 1300 550 310
info.au@anteristech.com
ARBN: 677 960 235

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 intent for the PARADIGM Trial. 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, 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.

For more information:

Investor Relations

investor@anteristech.com
Debbie Ormsby
Anteris Technologies Global Corp.
+61 1300 550 310 | +61 7 3152 3200

Investor Relations (US)

mchatterjee@bplifescience.com
Malini Chatterjee, Ph.D.
Blueprint Life Science Group
+1 917 330 4269

Website www.anteristech.com
X [@AnterisTech](https://twitter.com/AnterisTech)
LinkedIn <https://www.linkedin.com/company/anteristech>

