

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 17, 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 November 16, 2025 (November 17, 2025 AEDT), Anteris Technologies Global Corp. (the “Company”) issued an ASX Announcement and on November 17, 2025 issued a press release presenting the 30-day clinical outcomes for the DurAVR[®] Transcatheter Heart Valve (THV) in one hundred severe aortic stenosis patients with small aortic annuli.

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	ASX announcement: Anteris Technologies Presents Data from 100 DurAVR [®] THV Patients at PCR London Valves
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 17, 2025

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



Anteris Technologies Presents Data from 100 DurAVR® THV Patients at PCR London Valves

MINNEAPOLIS, United States and BRISBANE, Australia 17 November 2025: Anteris Technologies Global Corp. (Anteris or the Company) (NASDAQ: AVR, ASX: AVR) today released 30-day clinical outcomes for the DurAVR® THV in one hundred severe aortic stenosis patients with small aortic annuli (aortic annulus area $404 \pm 37\text{mm}^2$). The DurAVR® THV demonstrated single digit mean gradients, large effective orifice areas (EOAs), no moderate or severe paravalvular leaks and no valve related mortality, with 97% freedom from moderate or severe prosthesis-patient mismatch* (PPM) in a cohort of small annuli patients similar to the one reported in the SMART Trial¹.

The late-breaking science was presented by Prof. Dr. Ole De Backer at the PCR London Valves conference in London, United Kingdom with simultaneous publication online in EuroIntervention - 'Thirty-day outcomes of a novel biomimetic balloon-expandable transcatheter heart valve in patients with small aortic annuli' (DOI: 10.4244/EIJ-D-25-01106).

30-day Results Highlights for 100 DurAVR® THV Patients

- DurAVR® THV delivered a favorable hemodynamic profile with a large EOA of $2.2 \pm 0.3\text{ cm}^2$ and a single digit mean pressure gradient (MPG) of $8.2 \pm 3.1\text{ mmHg}$.
- At 30-days, clinical safety outcomes were positive with no valve related mortality and no moderate or severe paravalvular leak (PVL).
- Prosthesis-patient mismatch was just 3.0% compared with 11.2% to 35.3%¹ for current commercial devices, highlighting a meaningful reduction in a key predictor of valve failure and disease progression.
- A technical success rate** of 100% was achieved in the last 50 consecutive patient implants.

“The DurAVR® THV demonstrated high rates of technical and device success with encouraging 30-day hemodynamic outcomes, including very low PPM in small annuli patients. These results reflect a unique balance of balloon-expandable benefits characterised by high device success and low pacemaker rates, combined with a hemodynamic profile typically associated with self-expanding platforms,” said Prof. Dr De Backer, The Heart Centre, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark.

“When PPM occurs, patients essentially exchange one obstruction for another. Moderate to severe PPM is independently associated with reduced survival and increased risk of structural valve deterioration^{2,3}. Achieving 97% freedom from moderate or severe PPM is clinically relevant, particularly in small annuli patients where the risk of PPM is amplified,” said Chris Meduri, M.D., Anteris Chief Medical Officer.

This pooled analysis of 100 patients derived from the ongoing EMBARK study and early feasibility studies (EFS) conducted in the United States and Europe, consists of patients with small aortic annuli (SAA) treated with the Small size DurAVR® THV.

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“When we look at the strength of the 30-day outcomes together with the 1-year results presented at TCT, we see a consistent clinical profile that serves as a potential proxy for the recently initiated PARADIGM Trial. This pooled analysis of 100 patients represents approximately 20% of the planned DurAVR® enrolment for the all-comers randomized cohort of PARADIGM. This consistency across earlier and longer-term patient outcomes reinforces our confidence in DurAVR®’s potential as we advance this life-saving technology toward anticipated commercialization,” said Vice Chairman and CEO, Wayne Paterson.

The global PARADIGM Trial (ClinicalTrials.gov ID NCT07194265) 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) in the treatment of severe aortic stenosis.

*Prosthesis-patient mismatch (PPM) happens when a prosthetic valve, after being implanted, doesn't have a large enough opening (EOA) to accommodate the patient's blood flow needs, based on their body size. The result is higher than expected gradients. PPM affects a significant proportion of transcatheter aortic valve (TAVR) patients, particularly patients with a small aortic annulus and has been associated with impaired long-term survival following surgical aortic valve replacement (SAVR).

**As defined in VARC-3.

1. Herrmann HC, Mehran R, Blackman DJ, Bailey S, Möllmann H, Abdel-Wahab M, Ben Ali W, Mahoney PD, Ruge H, Wood DA, Bleiziffer S, Ramlawi B, Gada H, Petronio AS, Resor CD, Merhi W, Garcia Del Blanco B, Attizzani GF, Batchelor WB, Gillam LD, Guerrero M, Rogers T, Rovin JD, Szerlip M, Whisenant B, Deeb GM, Grubb KJ, Padang R, Fan MT, Althouse AD, Tchétché D; SMART Trial Investigators. Self-Expanding or Balloon-Expandable TAVR in Patients with a Small Aortic Annulus. *N Engl J Med.* 2024 Jun 6;390(21):1959-1971. doi: 10.1056/NEJMoa2312573. Epub 2024 Apr 7. PMID: 38587261.
2. Ferrara J, Theron A, Porto A, Morera P, Luporsi P, Jaussaud N, Gariboldi V, Collart F, Cuisset T, Deharo P. Prosthesis-Patient Mismatch in Small Aortic Annuli: Self-Expandable vs. Balloon-Expandable Transcatheter Aortic Valve Replacement. *J Clin Med.* 2022 Apr 1;11(7):1959. doi: 10.3390/jcm11071959. PMID: 35407567; PMCID: PMC8999619.
3. Hahn RT, Pibarot P. Prosthesis-patient mismatch in transcatheter and surgical aortic valve replacement. *Ann Cardiothorac Surg.* 2024 May 31;13(3):211-223. doi: 10.21037/acs-2023-aac-0166. Epub 2024 Apr 28. PMID: 38841078; PMCID: PMC11148757.

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 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 Vice Chairman and Chief Executive Officer, Wayne Paterson.

For more information:

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