

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 12, 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 2.02. Results of Operations and Financial Condition.

On November 12, 2025 USA ET (November 13, 2025 AEST), Anteris Technologies Global Corp. (the “Company”) (i) filed the Form 10-Q for the quarter ended September 30, 2025 with a cover page (the “Results Announcement”) with the Australian Securities Exchange (“ASX”); and (ii) issued an ASX Announcement regarding the Company’s financial results for the quarter ended September 30, 2025, both of which include unaudited and other historical financial information for the quarter ended September 30, 2025. The Results Announcement has been prepared for the purpose of complying with the reporting requirements of the ASX. Copies of the Results Announcement and the ASX Announcement are attached as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K.

The information in this Item 2.02, including Exhibits 99.1 and 99.2 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	Results Announcement, as filed with the ASX, for the quarter ended September 30, 2025
99.2	ASX Announcement regarding financial results for the quarter ended September 30, 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: November 12, 2025

By: /s/ Wayne Paterson

Name: Wayne Paterson

Title: Vice Chairman and Chief Executive Officer



Results for announcement to the market

Name of entity: Anteris Technologies Global Corp. (“ATGC”)
ARBN: 677 960 235
Reporting period: For the quarter ended September 30, 2025

The attached Form 10-Q *Quarterly Report* for the quarter ended September 30, 2025 has been filed with the U.S. Securities and Exchange Commission. It includes the condensed consolidated financial statements which have been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S. GAAP”) and are denominated in U.S. dollars.

The following supplementary information is provided in connection with the Form 10-Q for the purposes of compliance with ASX Listing Rule 4.7C in relation to quarterly activity reports. This information should be read in conjunction with the Form 10-Q and is provided to satisfy the Company’s ongoing disclosure obligations under the ASX Listing Rules.

Details of business activities during the quarter:

Refer to the Form 10-Q and the “Anteris Announces Results for the Third Quarter of 2025” announcement lodged with the ASX on November 13, 2025.

Use of funds:

On December 12, 2024, our registration statement on Form S-1 relating to our initial public offering became effective pursuant to which we issued and sold 14,878,481 shares of Common Stock. We received net proceeds of US\$80.0 million, after deducting the underwriting discounts, commissions and offering expenses and giving effect to the exercise of the underwriters’ option to purchase additional shares. The use of proceeds from our initial public offering, as of September 30, 2025, was as follows:

- US\$52.7 million for the ongoing development of DurAVR® THV and the preparation and enrolment of the Pivotal Trial of DurAVR® THV for treating severe aortic stenosis; and
- US\$18.3 million net, comprising the repayment of US\$7.0 million of debt (including the Obsidian convertible notes and options), net working capital, v2v expenditures and other general corporate purposes, offset by receipts from tax incentives.

Aggregate amount of payments to related parties and their associates:

During the third quarter of 2025, the aggregate amount of payments to related parties and their associates (which includes director fees, Company secretarial fees, CEO, President and CFO remuneration) was US\$515 thousand. These payments were included in cash flows from operating activities.

There were no payments to related parties or their associates included in cash flows from investing activities.

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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 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.

Authorisation and Additional information

This announcement was authorised for release on the ASX by the Board of Directors.

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>





Anteris Announces Results for the Third Quarter of 2025

MINNEAPOLIS, United States and BRISBANE, Australia 13 November 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 reported financial results for the quarter ended September 30, 2025, and provided a corporate update.

Third Quarter 2025 Highlights

- Continued FDA engagement during the Quarter to advance the IDE for the PARADIGM Trial, with FDA approval to commence U.S. recruitment* announced in November 2025
- Advanced European regulatory activities to initiate the PARADIGM Trial across multiple countries, with the first PARADIGM patients treated in Denmark following regulatory approval from the Danish Medicines Agency in October 2025
- Progressed site and operational readiness across the United States, Europe and Canada ahead of anticipated trial enrolment
- Strengthened operational and quality systems while advancing manufacturing scale-up to support clinical activities including ISO 13485 certification for DurAVR® THV production
- Received approval from the Company's stockholders for ASX Limited's grant to the Company of a waiver from ASX Listing Rule 7.1

"Third Quarter activities were critical to set the company on its path for the rest of the year and into 2026. The company made significant progress on the regulatory front with approvals to start the PARADIGM pivotal study being achieved in both Europe and the U.S. in Q4 as a result," said Wayne Paterson, Vice Chairman and Chief Executive Officer of Anteris.

Business & Operations

DurAVR® THV Commercialisation Update

Activities supporting the launch of the PARADIGM Trial

During the third quarter of 2025, the company maintained positive engagement with the United States Food and Drug Administration (**FDA**) to advance the Investigational Device Exemption (**IDE**) for the PARADIGM Trial, submitting a formal response to address requests for additional information, including a completed simulated use study. FDA approval to commence patient recruitment* in the United States was subsequently announced in November 2025.

Anteris also advanced European regulatory activities aimed at securing approval to commence the PARADIGM Trial in countries including Germany, France and the Netherlands, with the first European approval secured in Denmark in October 2025. In parallel, cross-functional teams completed site and operational readiness activities, namely investigator training, study material preparation, and logistical set up, ahead of anticipated enrolment and pending receipt of regulatory clearance and Institutional Review Board (**IRB**) approval. The first PARADIGM patients were enrolled and treated in Denmark following regulatory approval from the Danish Medicines Agency in October 2025.

860 Blue Gentian Road,
Suite 340
Eagan, MN, 55121
United States
T: +1 651 493 0606
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Anteris Technologies Global Corp.
BRISBANE | MINNEAPOLIS | GENEVA | MALAGA



anteristech.com

Toowong Tower, Level 3, Suite 302
9 Sherwood Road, Toowong
QLD 4066, Australia
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The Company continued strengthening its operational infrastructure during the quarter, advancing quality management system (QMS) buildout to support upcoming clinical activities and future ISO 13485 certification. Key quality procedures and standard operating documents were released to establish the framework for a mature, compliant system and to mitigate audit risk. In parallel, manufacturing scale-up activities progressed, including cross-training of inspection personnel, expansion of clean room capacity, and ongoing process development initiatives for projected DurAVR® THV demand.

The financial results for Anteris for the quarter ended September 30, 2025, are reviewed below. All amounts in \$ refer to U.S. dollars.

The Company's net operating cash outflows for the nine months ended September 30, 2025, were \$59.3 million, in line with the increase in clinical, regulatory and manufacturing requirements to support the PARADIGM Trial. Reflecting this clinical focus, the key areas of the Company's operating expenditure for the three months ended September 30, 2025, were as follows:

- R&D expenses were \$16.8 million.

The key activities undertaken were the preparatory activities linked to the PARADIGM Trial, including regulatory work regarding the IDE and extensive engagement with planned investigators at clinical trial sites by the Clinical Specialist Team, who work directly with physicians in the Cath Lab to support appropriate use of the device and procedural success. Additionally, there were further costs associated with upscaling of manufacturing capabilities, including completion of design validation processes and documentation, and continued portfolio development aimed at driving long-term growth beyond the current products.

- Selling, general and administrative expenses were \$5.8 million.

The Company held \$9.1 million of cash and cash equivalents as of September 30, 2025.

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

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 enrol approximately 1,000 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 (PMA) in the United States, with CE Mark approval anticipated to progress in parallel to the PMA.

For further information about the PARADIGM Trial, please refer to ClinicalTrials.gov (ClinicalTrials.gov ID NCT07194265).

*Subject to Institutional Review Board (IRB) approval

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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 Board of Directors.

For more information:

Investor Relations

investors@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
LinkedIn	https://www.linkedin.com/company/anteristech

