

# ASX ANNOUNCEMENT

31 October 2024

## QUARTERLY ACTIVITY REPORT FOR THE PERIOD TO 30 SEPTEMBER 2024

**Anteris Technologies Ltd (ASX: AVR) (ATL or the Company)** submits the following Activities Report and Appendix 4C – Quarterly Cash Flow statement for the quarter ended 30 September 2024 (the **Quarter**). All financial results are in Australian dollars and unaudited.

### Highlights

- Preparations on track for global, pivotal clinical study – request for Investigational Device Exemption planned to be lodged with US FDA in Q1 2025.
- Engagement with numerous US sites underway to participate in the global, pivotal clinical trial.
- EFS implants in Europe planned Q4 2024 – potential to be global pivotal clinical study sites – European data will be used to support future FDA or CE Mark application.
- A total of 73 patients treated with the DurAVR® THV including another nine patients implanted during the quarter in Tbilisi, Georgia. Further data generated in Tbilisi to optimise our processes/procedures.
- Transaction to redomicile Anteris Group to the United States and conduct US IPO on NASDAQ continues to progress positively with strong and ongoing engagement. The Company anticipates to complete the Scheme subsequent condition end date of 20 December 2024 including the US IPO and an updated timetable will be released shortly.
- Cash balance of \$15.3M at 30 September 2024. As noted in the Scheme Booklet dated 2 September 2024, the US IPO is anticipated to raise between \$US 75M and \$US 100M.

### Operational Performance and Activities

#### ***Preparations for Global, pivotal, registration study***

During the Quarter, the Company continued to make good progress towards its primary goal of obtaining approval from the US Food and Drug Administration (**FDA**) to commence a global, pivotal registration study for its lead product the DurAVR® THV System in 2025 (the **Study**). This approval to commence the Study, if granted, requires submitting an Investigational Device Exemption (IDE) application to the FDA, planned for Q1 2025.

The Anteris clinical and regulatory team completed several Pre-Submission meetings with the FDA, to obtain guidance prior to submitting the complete IDE application, with the objective to expedite the regulatory process and minimise the risk of delays. Interactions with the FDA covered matters such as prior investigations, final study protocol and manufacturing details.

The Company's prospective study is anticipated to be the first all-risk, head-to-head transcatheter aortic valve replacement (**TAVR**) registration trial to date. The study is expected to include up to 80 sites across the United States and other key markets with an estimated 1,000 to 1,200 patients having severe, calcific aortic stenosis, and subject to customary study exclusions. The study will be on a 1:1 randomised basis with patients receiving either the Anteris DurAVR® THV or **TAVR** using any commercially available and approved transcatheter heart valve (**THV**) from the SAPIEN series (Edwards Life Sciences) or the Evolut series (Medtronic). This is intended to generate the widest possible patient population from the study, enabling direct comparison with existing therapy and support a claim to the FDA of non-inferiority of the

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DurAVR® THV System. The Study Co-Chairs are planned to be Dr. Martin B. Leon and Dr. Michael J. Reardon.

Patients with a failed surgical bio-prosthesis needing valve-in-valve (ViV) TAVR will be enrolled in a separate parallel registry. This is intended to support the Company's plans for the ViV market opportunity.

Additional preparatory steps completed for the IDE this quarter included extensive work on the clinical and pre-clinical submission packages, as well as engagement with many planned US study sites to assess feasibility, site commitment and recruitment capability. Undertaking this process prior to submission will assist the Company with its readiness to commence implants at these study sites as soon as the IDE is granted and the relevant institutional review board (ethics committee) approvals are received.

Also, this Quarter, manufacturing scale-up progressed at both the Malaga and Minneapolis manufacturing facilities as well as outsourced suppliers of the key components and delivery system. This work is well on track to support FDA requirements as well as ensuring the timely delivery of all DurAVR® THV Systems required for the study over the next 18 to 24 months. The manufacturing team also finalised several design optimizations to the DurAVR® THV System to optimise the procedure, support ease of use and lower manufacturing costs.

### **European early feasibility study**

During the Quarter, the clinical and regulatory team also progressed preparations for a European DurAVR® THV System early feasibility study (**EU-EFS**) planned to be carried out in Denmark, Sweden, the Netherlands, France and Germany. The EU-EFS, enrolling up to 40 patients, will provide both valve-in-valve data in a controlled setting as well as generate further feasibility and safety data in patients with severe aortic stenosis.

The objective of these early EU sites is to build awareness, understanding and experience with the DurAVR® THV System. These hospitals will also become eligible to be included in the global, pivotal registration study which is expected to accelerate enrolment in the Study. The data collected from EU sites will also support separate regulatory applications under the EU MDR regulation or CE Mark.

### **Market awareness – presentation at 36<sup>th</sup> TCT Conference**

To date, 73 patients are implanted with the DurAVR® THV with 43 patients now out over one year and overall pleasing performance across several haemodynamic measures. Aspects of this data supported a podium presentation at the 36<sup>th</sup> Annual Transcatheter Cardiovascular Therapeutics or TCT Conference held 27-30 October 2024. Dr Amar Krishnaswamy gave a presentation on Monday 28 October 2024, titled '*DurAVR® THV System with Biomimetic Leaflet Design: Impact on Flow Dynamics and LV Mass Regression*'. The presentation took place during the 'Innovations in TAVR Systems and New Clinical Updates' session. A copy of the presentation is available on the Company's website ([links.anteristech.com/TCT2024](https://links.anteristech.com/TCT2024)). The Company's Chief Medical Officer, Dr Chris Meduri, moderated a panel discussion on TAVR Techniques.

### **Financial Overview & Performance**

During the Quarter, the key focus was on clinical and regulatory activities, manufacturing scale up, as well as research and development, in support of the upcoming global, pivotal registration study planned for mid-2025. Additionally, there was one-off legal and financial work associated with the proposed transaction to redomicile the Anteris Group to the United States, list on NASDAQ and conduct an IPO.

During the Quarter, the Company's cash flows consisted of:

- Operating cash inflow was \$1.2M from product sales.
- Net operating cash outflow was \$22.1M from the following key operating cash items:
  - Research and development expenditure of \$10.2M. This included preparatory and clinical costs related to nine patients treated at Tbilisi plus continued R&D activities as we plan for the DurAVR® transcatheter heart valve's FDA pivotal study, a key step to gain regulatory clearance for the US market. These costs continue to relate to our valve, frame



- and catheter development and include expenditure on key animal studies and simulation testing.
- Staff costs of \$7.9M reflecting an increased headcount from 133 to 145 over the quarter.
  - Administration and corporate costs of \$4.5M. This included expenditure related to the planned redomicile to the United States, list on NASDAQ and US IPO, travel to Tbilisi, American Depositary Receipt (ADR) facility closure costs and operational activities including accounting and legal advisors, information technology costs and investor relations.
  - Product manufacturing and operating costs of \$0.4M relating to products sold.
  - Marketing of \$0.3M included market research and global branding activities.
- Net cash outflow from investing activities was \$0.8M, primarily related to the acquisition of plant and equipment for manufacturing activities in Minneapolis.
  - Net financing cash inflow was \$28.0M including the \$30M placement in July 2024 less transaction costs, lease repayments as well as a small debt repayment.
  - Pursuant to ASX LR 4.7 C.3, the Company paid an aggregate amount of \$0.4M to related parties for non-executive directors' fees and CEO remuneration.

### Post Third Quarter Events

In October, Partners for Growth elected to put their 49,388 warrants to the Company, issued in October 2017 in connection with a loan facility to the Company. As a result, the Company will pay \$1.5M to Partners for Growth which will also close out this historic arrangement.

### *Bridging Facility*

Subsequent to the end of the Quarter, Anteris entered into a \$25M bridging facility with Obsidian Global Partners, LLC which includes an initial drawdown of \$7.5M and subsequent drawdowns subject to mutual agreement.

### Update on Re-domiciliation and IPO on NASDAQ

As announced in the Scheme Booklet dated 2 September 2024, the Anteris Group seeks to redomicile to the United States and list on NASDAQ. The re-domiciliation is proposed to be effected by schemes of arrangement between Anteris and its shareholders (**Share Scheme**) and Anteris and its optionholders (**Option Scheme**), and together with the Share Scheme, (the **Schemes**), pursuant to which Anteris Technologies Global Corp. (**ATGC**) will acquire 100% of Anteris' issued shares, Anteris optionholders will exchange their options in Anteris for equivalent securities in ATGC, and ATGC will become the new ultimate parent company of the Anteris Group effectively re-domiciling the Company to the United States. The re-domiciliation is conditional upon approval of the Schemes by ATL shareholders and optionholders, and approval by the Supreme Court of Queensland.

The Board maintains the advantages of the re-domiciliation significantly outweigh the disadvantages and risks as outlined in the Scheme Booklet.<sup>1</sup> Accordingly, the Board continues unanimously to recommend shareholders vote in favour of the Share Scheme, subject to the independent expert continuing to conclude the Share Scheme is in the best interests of ATL shareholders, and that ATL optionholders vote in favour of the Option Scheme, subject to the independent expert continuing to conclude the Option Scheme is in the best interests of ATL optionholders.<sup>2</sup>

While the Company made considerable progress with the re-domiciliation this quarter, this is a complex cross border and capital raising transaction; and the original timetable set out in the Scheme Booklet has been extended. For this reason, the Company deferred the planned Scheme meetings and EGM initially

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<sup>1</sup> ATL shareholders and ATL optionholders should refer to the Scheme Booklet for full details on the advantages and disadvantages of the Schemes.

<sup>2</sup> The interests of directors of ATL in ATL shares and ATL options are set out in section 4.5 of the Scheme Booklet. ATL shareholders and ATL optionholders should have regard to these interests when considering the recommendations of the directors of ATL in relation to the Schemes.



scheduled for 4 October 2024 in Brisbane. The Company apologises for any inconvenience to any shareholder or optionholder.

The updated timetable as well as updated materials are currently being finalised and will be provided shortly to shareholders and optionholders. As part of this process, and based on feedback received, the Company also intends to extend the participation on the Schemes to shareholders in additional jurisdictions including Canada, Switzerland, Denmark, Ireland, the Netherlands, Sweden, Belgium and Germany.

The Company will provide details in relation to any additional jurisdictions in which ATGC securities may be offered under the Share Scheme (if any), as well as supplementary disclosure on any other matters relevant to the Schemes, when the relevant information is available.

In connection with the proposed re-domiciliation process, the Company has terminated its American Depository Receipt program.

This announcement is not an offer to participate in the US IPO. No offers of ATGC securities in the US IPO may be made until the Registration Statement on Form S-1 has been publicly filed with the United States Securities and Exchange Commission. Written offers of ATGC securities in the US IPO will only be made pursuant to the Registration Statement on Form S-1.

The Company cannot guarantee that the US IPO will be successfully completed, including that there is no guarantee that an achieve issue price of ATGC securities under the US IPO will be acceptable to the ATGC board of directors.

**ENDS**

### **About Anteris Technologies Ltd (ASX: AVR)**

Anteris Technologies Ltd (ASX: AVR) is a structural heart company committed to designing, developing, and commercialising innovative medical devices. Founded in Australia, with a significant presence in Minneapolis, USA (a MedTech hub), Anteris is science-driven, with an experienced team of multidisciplinary professionals delivering transformative solutions to structural heart disease patients.

The Company's lead product, DurAVR<sup>®</sup>, is a transcatheter heart valve (THV) for treating aortic stenosis. DurAVR<sup>®</sup> THV was designed in partnership with the world's leading interventional cardiologists and cardiac surgeons. It is the first transcatheter aortic valve replacement (TAVR) to use a single piece of bioengineered tissue. This biomimetic valve is uniquely shaped to mimic the performance of a healthy human aortic valve.

DurAVR<sup>®</sup> THV is made using ADAPT<sup>®</sup> tissue, Anteris' patented anti-calcification tissue technology. ADAPT<sup>®</sup> tissue has been used clinically for over 10 years and distributed for use in over 55,000 patients worldwide.

The ComASUR<sup>®</sup> Delivery System was designed to provide controlled deployment and accurate placement of the DurAVR<sup>®</sup> THV with balloon-expandable delivery, allowing precise alignment with the heart's native commissures to achieve optimal valve positioning.

Anteris Technologies is set to revolutionise the structural heart market by delivering clinically superior solutions for significant unmet clinical needs.

### **Authorisation and Additional information**

This announcement was authorised by the Board of Directors.



**For more information:**

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## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

<b>Name of entity</b>
Anteris Technologies Ltd

<b>ABN</b>	<b>Quarter ended ("current quarter")</b>
35 088 221 078	30 September 2024

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	1,191	3,666
1.2 Payments for		
(a) research and development	(10,237)	(30,698)
(b) product manufacturing and operating costs	(381)	(875)
(c) advertising and marketing	(323)	(1,214)
(d) leased assets	-	-
(e) staff costs	(7,883)	(24,346)
(f) administration and corporate costs	(4,507)	(11,777)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	141	527
1.5 Interest and other costs of finance paid	(94)	(285)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(22,093)</b>	<b>(65,002)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(798)	(2,885)
(d) investments	-	-
(e) intellectual property	(20)	(20)



<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	-
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(818)</b>	<b>(2,905)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	30,000	53,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	15	4,036
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,564)	(3,221)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(249)	(769)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(214)	(678)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>27,988</b>	<b>52,368</b>
<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	10,844	30,832
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(22,093)	(65,002)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(818)	(2,905)





<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	27,988	52,368
4.5	Effect of movement in exchange rates on cash held	(604)	24
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>15,317</b>	<b>15,317</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	6,839	10,143
5.2	Call deposits	8,478	701
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>15,317</b>	<b>10,844</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1 - director fees, Company secretarial fees and CEO remuneration	413
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

*Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.*





<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	600	600
7.3 Other (please specify)	89	89
<b>7.4 Total financing facilities</b>	<b>689</b>	<b>689</b>
<b>7.5 Unused financing facilities available at quarter end</b>		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		
Other consists of:		
a) ANZ standby letter of credit of \$600k at an interest rate of 2.5%, expiring not before 24 April 2025.		
b) ANZ financial guarantee of \$89k at an interest rate of 2.5%, expiring not before 24 April 2025.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(22,093)
8.2 Cash and cash equivalents at quarter end (item 4.6)	15,317
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	15,317
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>0.7</b>
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: The Company continues to invest in research and development activities as it works toward bringing the Company's DurAVR® Transcatheter Heart Valve technology to market. This work program will continue to result in a net cash outflow from operating activities.	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	



Answer:

- During the quarter, the Company raised gross proceeds of \$15,000 from the conversion of unlisted options.
- During the quarter, Anteris issued 1.875 million new shares raising \$30M gross proceeds before transaction costs.
- On 31 October 2024, Anteris entered into a \$25M bridging facility with Obsidian Global Partners, LLC which includes an initial drawdown of \$7.5M and subsequent drawdowns subject to mutual agreement. These funds will primarily be used for the ongoing development of DurAVR® THV, preparatory activities for the DurAVR® THV pivotal registration study and additional first-in-human studies, upscaling in-house manufacturing and general working capital.
- At the date of this report, 1,070,599 options held by external investors, with expiry dates in 2024 and 2025, are in-the-money and could be exercised at any time. If all of these were converted, they would generate \$10.7M of capital for the Company. It is anticipated some of these options will be converted prior to maturity.
- The Company intends to redomicile to the United States via schemes of arrangement (Re-domiciliation) and will seek a primary listing on Nasdaq, and a secondary listing of its CDIs (representing common stock) on ASX. In connection with the Re-domiciliation, Anteris intends to undertake an initial public offering targeted at but not exclusive to US investors. This process is intended to be completed prior to the end of 2024.

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

The Company expects it will be able to continue its operations and to meet its business objectives after considering the following:

- Significant milestones and achievements continue with the development of DurAVR®, Anteris' 3D single-piece Aortic Valve with Anteris completing 15 enrolments in its FDA approved EFS in the United States. 30-day data shows positive results. Preparations are on track for a global, pivotal clinical study. A request for an Investigational Device Exemption is planned to be lodged with US FDA in Q1 2025.
- Anteris also performed six cohorts of first-in-human studies for 51 patients using the Company's DurAVR® THV with positive results.
- Anteris has completed six valve-in-valve procedures using the DurAVR® THV under Canada Health's Compassionate Use Program.
- The successful treatment of a high risk patient unsuitable for standard of care interventions using the DurAVR® THV in a Valve-in-Valve-in-Valve (ViViV) procedure.

On this basis, the Company considers it will be able to continue its operations and meet business objectives.



## Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 31 October 2024

Authorised by:  .....

Wayne Paterson  
Chief Executive Officer

### Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.

