

# ASX ANNOUNCEMENT

31 July 2024

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

**Anteris Technologies Ltd (ASX: AVR) (“Anteris” or the “Company”)** submits the following Activities Report and Appendix 4C – Quarterly Cash Flow statement for the quarter ended 30 June 2024 (Q2).

### Highlights

- New data from the latest cohort of 13 patients in the DurAVR® THV First-in-Human (FIH) Study confirmed optimal valve positioning with the ComASUR® Delivery System.
- New cardiac MRI data on 41 patients from the DurAVR® THV FIH Study demonstrated the restoration of normal aortic flow and haemodynamics.
- First-in-human TAVR in SAVR using DurAVR® successfully completed.
- The Company received positive feedback from the US FDA on key elements of the pivotal, registration study (phase 3).
- \$23 million in gross proceeds raised from the placement of one million new ordinary shares.
- The Company held its AGM on 29 May 2024 in Sydney.
- The Company had a cash balance of \$10.8 million at 30 June 2024. A further \$30 million in gross proceeds was received in late July 2024 through a capital raise for the issue of 1.875m new shares.

### Operational Performance and Activities

A cynosure for the quarter was the successful treatment using the DurAVR® THV in a Valve-in-Valve-in-Valve (ViViV) procedure on a high risk patient unsuitable for standard of care interventions (being a SAVR or a TAVR with commercially available valves). Dr Andreas Rück, Dr Magnus Settergren and Dr Nawzad Saleh at the Karolinska University Hospital in Stockholm, Sweden, performed the procedure under compassionate use approval as no other viable alternative was available. It was the first time a DurAVR® THV was used in ViViV intervention.

Two new data sets from cohorts in the FIH Study which utilized the Company's proprietary balloon expandable ComASUR® Delivery System reinforced DurAVR® THV's clinical and competitive superiority compared to the market leader. The ComASUR® Delivery System enables controlled deployment and accurate placement of the DurAVR® THV, facilitating precise alignment with the patients' native aortic valve.

On 20 June 2024, Anteris published new thirty-day data from the recent cohort (13 patients) demonstrating improved haemodynamic (blood flow) performance relative to earlier favourable clinical results reported in the DurAVR® THV FIH Study (Cohorts 1-4) in addition to validating the predictability of the ComASUR® Delivery System.

At the New York Valves 2024 (11 June 2024) Dr João Cavalcante, Section Head, Cardiac Imaging, Allina Health Minneapolis Heart Institute and Scientific Director, Cardiovascular Imaging Core Lab and Research Center, presented new cardiac MRI data on 41 patients from the DurAVR® THV FIH Study. The data showed the restoration of normal laminar flow and haemodynamics, leading to significant left



ventricular mass regression in patients with symptomatic, severe aortic stenosis. Studies performed on commercially available transcatheter valves, either balloon-expandable or self-expanding, do not appear to restore normal aortic flow whereas DurAVR<sup>®</sup> restored laminar flow with near equivalence to a normal healthy aortic valve.

The Company maintained ongoing dialogue with the US FDA during the quarter including a pre-submission meeting where the agency indicated support for key design aspects of the global, pivotal study (phase 3). The study will be the first randomised, all risk, head-to-head registration trial for TAVR. The agency also indicated that a single-arm, valve-in-valve registry to run concurrently with the primary aortic stenosis arm is acceptable. Pre-submission meetings permit companies to receive guidance from FDA review teams prior to a premarket submission or Investigational Device Exemption (IDE) which allows the device to be used in a clinical study.

The Company held its Annual General Meeting on 29 May 2024 in Sydney following publication of the Annual Report on 15 April 2024.

Early in the quarter, Anteris placed one million new shares at \$23 each mainly to help fund preparation for the FDA pivotal study - its primary goal towards DurAVR<sup>®</sup> THV commercialization.

Anteris continued to engage in business development opportunities and discussions with potential strategic partners. There can be no guarantee any such opportunities and discussions will result in a binding transaction in a timely manner or at all.

Anteris continued to progress a potential dual listing of its (or a successor entity's) securities on the NASDAQ and the ASX. Any potential dual listing would be subject to market and other conditions, obtaining any necessary shareholder and/or court approval and obtaining any necessary approvals from regulatory authorities (in the United States and Australia). There can be no assurance Anteris will complete a dual listing in a timely manner or at all.

## Financial Performance Overview

Anteris continues investing in R&D to commercialise its DurAVR<sup>®</sup> THV technology. Net cash flows for the quarter consist of:

- Operating cashflows included the following items:
  - Research and development expenditure was \$10.7m, up on the prior quarter of \$9.8m. During the period, the Company incurred preparatory and clinical costs related to 13 patients treated at Tbilisi (Cohort 5) plus continued acceleration of R&D activities as we prepare for the DurAVR<sup>®</sup> transcatheter heart valve's FDA pivotal study (phase 3), 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. In addition, the Company reached concept lock on the first phase of its next generation Transcatheter Edge to Edge Repair system in partnership with v2vmedtech, inc.
  - Staff costs of \$6.5m. Headcount increased from 121 to 133 over the quarter.
  - Administration and corporate costs of \$4.2m, up on the prior quarter of \$3.1m, comprised corporate and compliance costs including the hosting of the AGM, expenditure related to evaluating a potential dual listing on the NASDAQ and ASX, Tbilisi, international conferences (EuroPCR and New York Valves) and operational activities plus accounting and legal advisors, information technology costs and investor relations.
  - Marketing activities of \$0.6m covering costs relating to the international conferences (as noted above) and global branding activities.
  - Customer receipts of \$1.3m from the sale of tissue products compared with \$1.2m for Q1 2024



- Investing net cash outflow of \$1.0m related to payments for equipment acquisitions.
- Financing net cash inflow of \$22.3m predominately related to proceeds of \$23m from the placement of one million new ordinary shares at \$23 each in April 2024 and \$1.3m from the exercise of options into ordinary shares partly offset by \$1.5m transaction costs relating to the above capital raise, the repayment of \$0.3m of funding relating to insurance as well as lease payments of \$0.2m.
- Pursuant to ASX LR4 4.7C.3, at item 6.1 of the Appendix 4C, the Company reported an aggregate amount paid to related parties of \$0.4m. These payments represent non-executive directors' fees and CEO remuneration.

**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®, is a transcatheter heart valve (THV) for treating aortic stenosis. DurAVR® 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® THV is made using ADAPT® tissue, Anteris' patented anti-calcification tissue technology. ADAPT® tissue has been used clinically for over 10 years and distributed for use in over 55,000 patients worldwide.

The ComASUR® Delivery System was designed to provide controlled deployment and accurate placement of the DurAVR® 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

**Name of entity**

Anteris Technologies Ltd

**ABN**

35 088 221 078

**Quarter ended ("current quarter")**

30 June 2024

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
<b>1.</b>	<b>Cash flows from operating activities</b>		
1.1	Receipts from customers	1,280	2,475
1.2	Payments for		
	(a) research and development	(10,699)	(20,461)
	(b) product manufacturing and operating costs	(201)	(494)
	(c) advertising and marketing	(561)	(891)
	(d) leased assets	-	-
	(e) staff costs	(6,543)	(16,463)
	(f) administration and corporate costs	(4,182)	(7,270)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	145	386
1.5	Interest and other costs of finance paid	(94)	(191)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other	-	-
<b>1.9</b>	<b>Net cash from / (used in) operating activities</b>	<b>(20,855)</b>	<b>(42,909)</b>
<b>2.</b>	<b>Cash flows from investing activities</b>		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(978)	(2,087)
	(d) investments	-	-



Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
	(e) intellectual property	-	-
	(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>(978)</b>	<b>(2,087)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	23,000	23,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1,270	4,021
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,500)	(1,657)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(286)	(520)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(229)	(464)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>22,255</b>	<b>24,380</b>



Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
<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	10,588	30,832
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(20,855)	(42,909)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(978)	(2,087)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	22,255	24,380
4.5	Effect of movement in exchange rates on cash held	(166)	628
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>10,844</b>	<b>10,844</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	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	10,143	5,828
5.2	Call deposits	701	4,760
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>10,844</b>	<b>10,588</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1 - director fees, Company secretarial fees and CEO remuneration	382
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> <i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i> <i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	600	600
7.3 Other (please specify)	338	338
7.4 <b>Total financing facilities</b>	<b>938</b>	<b>938</b>
7.5 <b>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. c) Short term financing arrangements of \$249k with Clearmatch Originate Pty Limited to fund the Company's insurances (secured against the rights, interests, and any receivables under the policy). Interest is being applied at an effective rate of 17.5%. The final payment instalment is due on 25 August 2024.		

<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)	(20,855)
8.2 Cash and cash equivalents at quarter end (item 4.6)	10,844
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	10,844
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	0.5
<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 \$1.27m from the conversion of unlisted options.
- During the quarter, Anteris issued one million new shares raising \$23m gross proceeds.
- On 24 July 2024, Anteris announced a \$30m capital raise to be settled and allotted by 30 July 2024.
- At the date of this report, 1,072,099 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.
- Anteris continued to progress a potential dual listing of its (or a successor entity's) securities on the NASDAQ and the ASX. Any potential dual listing would be subject to market and other conditions, obtaining any necessary shareholder and/or court approval and obtaining any necessary approvals from regulatory authorities (in the United States and Australia). There can be no assurance Anteris will complete a dual listing in a timely manner or at all.

- 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. The Company continues to progress towards its FDA pivotal study.
- Anteris has performed five cohorts of first-in-human studies for 42 patients (including one compassionate use) 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.
- The Company continues the development of new products. This includes the development of an innovative heart valve repair device for the treatment of mitral and tricuspid valve regurgitation with v2vmedtech, inc.

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 July 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.

