

# ASX ANNOUNCEMENT

31 January 2024

## QUARTERLY ACTIVITY REPORT FOR THE PERIOD TO 31 DECEMBER 2023

**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 31 December 2023 (Q4).

### Highlights

- Enrolment for the 15-patient US FDA approved Early Feasibility Study (EFS) of DurAVR™ THV to treat severe aortic stenosis completed October 17.
- Preliminary results 30 days post-procedure from 14 out of the 15 enrolled patients (one awaiting scheduling) showing outstanding haemodynamic function, excellent safety data and no incidence of stroke, myocardial infarction, life-threatening bleeds or all-cause mortality.
- Eight patients with severe aortic stenosis were successfully treated with DurAVR™ THV at the Tbilisi Heart and Vascular Clinic, Tbilisi, Georgia (Tbilisi).
- \$41.3 million raised during the quarter with \$33.3 million placement of 1.664 million new shares at \$20 each in November and \$8.0 million in proceeds from the exercise of 550,000 options.
- The Company had a cash balance of \$30.8 million at 31 December 2023.

### Operational Performance and Activities

During the quarter, clinical outcomes for patients suffering severe aortic stenosis treated with DurAVR™ THV continued to be outstanding. Interim and 30-day data from the EFS consistently reinforced the DurAVR™ THV clinical superiority to competitive products across all measures.

Specifically, the 30-day haemodynamic results (for 14 out of the 15 enrolled patients) from the EFS proved:

- Mean Effective Orifice Area (EOA) = 2.18 cm<sup>2</sup>
- Mean Pressure Gradient (MPG) = 7.8 mmHg
- Doppler Velocity Index (DVI) = 0.63
- No paravalvular leaks (PVL) were observed at 30-day follow-up.

The 30-day haemodynamic results were consistent with those reported at patient discharge with no significant change in EOA or MPG values.

"These haemodynamics are unparalleled," Dr Chris Meduri, Anteris' Chief Medical Officer, commented at the time.

"This biomimetic valve not only allows us to have this acute improvement in flow from a classic haemodynamic performance but, also, we've seen (on cardiac MRI) normalisation of laminar flow out of the aorta. It's likely to have significant implications as we think about the long-term durability of the valve, stress on the leaflets but, also, aortopathies, potentially inflammation and other things as well."



Last year ended with 47 patients since November 2021 having been successfully treated for severe aortic stenosis using the DurAVR™ THV, including three valve-in-valve procedures conducted under Health Canada's Special Access Program. Published results including 12-month data from the Tbilisi patient cohorts demonstrated superior performance to current competitor products. An additional three valve-in-valve procedures were conducted under Health Canada's Special Access Program in January 2024.

All data sets will be included with results from the EFS to support Anteris' application for a pivotal trial to gain premarket approval, required to market DurAVR™ THV commercially in the United States.

Anteris received a \$1.4 million tax refund in October under the Australian Government's Research and Development (R&D) Tax Incentive Scheme for claims in FY22.

Anteris continues to evaluate a potential dual listing of its (or a successor entity's) securities on NASDAQ and ASX and has undertaken some preparatory work in relation to this. Any potential dual listing would be subject to customary conditions, which may include 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 that Anteris will complete a potential dual listing in a timely manner or at all.

### **Financial Performance Overview**

Anteris continues investing in R&D to commercialise its DurAVR™ THV technology. Net cash inflow for the quarter including FX movements was \$23.6 m, consisting of:

- Net operating cash outflows of \$13.8m. Operating cashflows included the following items:
  - Research and development expenditure was \$6.2m, up on the prior quarter of \$5.7m. During the period, the Company incurred preparatory and clinical costs related to the 15 patients treated in its US FDA approved Early Feasibility Study and the 8 patients treated at Tbilisi. In addition, the Company continued its R&D activities related to valve, frame and catheter development.
  - Staff costs of \$6.0m was 7% higher than the prior quarter expenditure of \$5.7m. Headcount increased from 73 to 103 since prior year-end with eight additional personnel in quarter four. The headcount increase for the quarter is related to upscaling of US manufacturing capabilities and R&D activities.
  - Administration and corporate costs of \$2.9m were up on the prior quarter of \$2.2m and comprise travel costs for the clinical trials incurred over the quarter as well as 2 medical conferences, accounting and legal advisors, information technology and investor relations.
  - Customer receipts of \$0.9m from the sale of tissue products.
  - Receipt of a \$1.4m tax rebate under the Australian Government's Research and Development (R&D) Tax Incentive Scheme.
- Financing net cash inflow of \$39.1m predominately related to proceeds of \$33.3m from the placement of new shares and \$8.0m from the exercise of options into ordinary shares, offset by the payment of capital raising transaction costs of \$1.8m, insurance and lease payments of \$0.5m.
- Investing net cash outflow of \$0.7m related to payments for equipment acquisitions.

Wayne Paterson CEO Commented, "Quarter 4 closed the most pivotal year in our history as a structural heart company. The European and US clinical results exceeded expectations and demonstrated the importance of DurAVR™ as the first new class of TAVR valve in over a decade. The clinical benefits are now well proven in dozens of patients globally".



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 50,000 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:**

##### **Investor Relations (US)**

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##### **Investor Relations**

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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")**

31 December 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	881	4,729
1.2 Payments for		
(a) research and development	(6,217)	(20,778)
(b) product manufacturing and operating costs	(238)	(1,087)
(c) advertising and marketing	(733)	(1,806)
(d) leased assets	-	-
(e) staff costs	(6,034)	(24,764)
(f) administration and corporate costs	(2,936)	(9,426)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	188	630
1.5 Interest and other costs of finance paid	(98)	(364)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,433	1,433
1.8 Other	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(13,754)</b>	<b>(51,433)</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	(673)	(3,552)
(d) investments	-	-



<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
	(e) intellectual property	-	(388)
	(f) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	-	38
	(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>(673)</b>	<b>(3,902)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	33,283	68,283
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	8,000	10,649
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,756)	(4,015)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(253)	(1,150)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(187)	(817)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>39,087</b>	<b>72,950</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	7,214	13,805
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(13,754)	(51,433)



<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (12 months) \$A'000</b>
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(673)	(3,902)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	39,087	72,950
4.5	Effect of movement in exchange rates on cash held	(1,043)	(589)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>30,831</b>	<b>30,831</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	19,024	4,801
5.2	Call deposits	11,807	2,413
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>30,831</b>	<b>7,214</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	370
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.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1	-	-
7.2	-	-
7.3	86	86
<b>7.4 Total financing facilities</b>	<b>86</b>	<b>86</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 financial guarantee \$86k at an interest rate of 2.5%, expiring 30 April 2024.	

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1	(13,754)
8.2	30,831
8.3	-
8.4	30,831
8.5	2.2
	<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: N/a
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: N/a
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: N/a



## 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 January 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 – e.g. 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

