

# ASX ANNOUNCEMENT

31 January 2023

## QUARTERLY ACTIVITY REPORT FOR THE PERIOD TO 31 DECEMBER 2022

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 2022 (Q4).

### Highlights

- FDA approval for an Early Feasibility Study (EFS) for the DurAVR™ THV System received.
- Anteris presented detailed 30-day outcomes of the combined cohort of 13 patients, from the DurAVR™ THV First-In-Human (FIH) trial at the PCR London Valves conference demonstrating 100% procedural success, excellent haemodynamics and restoration of normal laminar flow dynamics.
- As at 31 December 2022 the Company had a cash balance of \$13.8 million.
- Shortly after the quarter end DurAVR™ Transcatheter Heart Valve (THV) 1-year follow-up results on the first cohort of five patients were released showing impressive and preserved valve performance with excellent safety.

### Operational Performance and Activities

On 28 November 2022 the Company announced that the U.S. Food and Drug Administration (FDA) conditionally approved the DurAVR™ THV System for investigational device exemption (IDE) application to commence an Early Feasibility Study (EFS). The EFS will enroll 15 subjects across seven Valve Centers of Excellence within the United States. The FDA has categorised the DurAVR™ in this study as a CMS Category B device which permits the device to be sold during the study.

Anteris presented at the TAVI: Late-Breaking Trials and Innovations session at the PCR London Valves conference in November 2023 bringing further awareness to the outcomes of the first-in-human study of the DurAVR™ transcatheter aortic valve. The conference was attended by more than 3,000 participants from over 100 countries.

In a further session at the conference the results of a comparative study investigating aortic flow physiology by cardiac MRI were presented by Dr Pankaj Garg, Associate Professor in Cardiology at the University of East Anglia and Consultant Cardiologist at Norfolk and Norwich University Hospital. The study compared aortic flow haemodynamics in five patients who had received a DurAVR™ valve against other transcatheter aortic valve implants (TAVI) and patients who had surgical aortic valve replacement (SAVR). The study results demonstrated the novel leaflet design of DurAVR™ THV restored ascending aortic flow haemodynamics, whereas SAVR and other TAVI valves did not demonstrate the same physiological advantage.

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Just following the quarter end the Company released the 1-year follow-up results on the first cohort of five patients implanted with DurAVR™ THV showing impressive and preserved valve performance and excellent safety. All performance endpoints of the study were met, and the data demonstrates the restoration of normal, pre-disease, laminar blood flow and a maintained large orifice which is paramount to improving long-term survival and exercise capacity. All safety endpoints were also met at 1 year: no mortality (all causes), no disabling stroke, no life-threatening bleeding, no myocardial infarction. The second cohort of patients will reach the twelve-month mark in May 2023.

### Financial Performance Overview

Anteris continues to invest in research and development and the growth of the business to support product development and the process of seeking regulatory approvals to bring the company's DurAVR™ Transcatheter Heart Valve (THV) technology to market.

- Net operating cash outflows were \$8.6m for the quarter, a decrease of 8% on the prior quarter. This included the receipt of an R&D rebate of \$1.6m. Operating cashflows included:
  - Research and development costs of \$3.8m. The Company continues to invest in its expanded valve, frame and catheter development and production activities. This quarter has seen an increase costs from the September 2022 quarter and an overall increase on prior year linked to the Early Feasibility Study readiness activities; the Yale study; and expansion of the US R&D operations.
  - Staff costs of \$4.3m. Overall staff costs in 2022 have increased due to recruitment of additional headcount as it prepares for the Early Feasibility Study in the United States. Headcount has increased from 57 to 73 over the last year. The lower Australian dollar exchange rate relative to the US dollar has contributed to an increase in employee costs.
  - Administration and corporate costs of \$2.2m. The quarter's Administration and corporate costs are down on the prior quarter and comprise travel costs for London Valves attendance, corporate and compliance costs including accounting, tax and legal advisors, information technology and investor relations. Costs have increased over prior year reflecting a recommencement of travel given the previous COVID travel restrictions, an expanded investor relation program and additional consulting costs exploring a possible Nasdaq listing.
  - Customer receipts of \$0.8m from the sale of tissue products; and
  - Receipt of \$1.6m under the Australian Government's Research and Development (R&D) Tax Incentive Scheme.
- Investing net cash inflow of \$0.3m predominately related to a deferred instalment receipt for the sale of Anteris' CardioCel® and VasculCel® patch business to LeMaitre Vascular Inc, partly offset by equipment acquisitions primarily for the expansion of facilities in the United States.
- Financing cash inflow of \$0.2m primarily related to lease payments.

Pursuant to ASX LR4.7C.3, at item 6.1 of the Appendix 4C, the company reported an aggregate amount to related parties of \$352k. These payments represent payment for non-executive directors' fees and directors' remuneration.

## Outlook

The commencement of the DurAVR™ EFS this year represents a critical milestone for Anteris achieving Pre-Market Approval in the United States, and the commercialisation of the DurAVR™ THV System.

## ENDS

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

Anteris Technologies Ltd is a structural heart company that delivers clinically superior and durable solutions through better science and better design.

Its focus is developing next-generation technologies that help healthcare professionals deliver consistent life-changing outcomes for patients.

Anteris' DurAVR™ 3D single-piece aortic heart valve replacement addresses the needs of today's younger and more active aortic stenosis patients by delivering superior performance and durability through innovations designed to last the remainder of a patient's lifetime.

The proven benefits of its patented ADAPT® tissue technology, paired with the unique design of our DurAVR™ 3D single-piece aortic heart valve, have the potential to deliver a game-changing treatment to aortic stenosis patients worldwide and provide a much-needed solution to the challenges facing doctors today.

### 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")

31 December 2022

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	823	4,196
1.2 Payments for		
(a) research and development	(3,807)	(13,213)
(b) product manufacturing and operating costs	(392)	(1,513)
(c) advertising and marketing	(369)	(1,047)
(d) leased assets	-	-
(e) staff costs	(4,337)	(17,606)
(f) administration and corporate costs	(2,228)	(11,453)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	103	228
1.5 Interest and other costs of finance paid	(34)	(205)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,596	1,618
1.8 Other	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(8,645)</b>	<b>(38,995)</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	(784)	(2,279)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 months) \$A'000
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	(130)
2.2	Proceeds from disposal of:	-	-
	(g) entities	-	-
	(h) businesses	1,044	1,044
	(i) property, plant and equipment	5	5
	(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 (maturing term deposit)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>265</b>	<b>(1,360)</b>
<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	27,600
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	19	7,294
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2)	(1,468)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	(1,350)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(197)	(713)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(180)</b>	<b>31,363</b>

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (12 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	22,801	21,300
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(8,645)	(38,995)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	265	(1,360)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(180)	31,363
4.5	Effect of movement in exchange rates on cash held	(436)	1,497
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>13,805</b>	<b>13,805</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	13,716	13,484
5.2	Call deposits	89	9,317
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>13,805</b>	<b>22,801</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 and CEO remuneration	352
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	-	-
7.3 Other (please specify)	13,762	636
<b>7.4 Total financing facilities</b>	<b>13,762</b>	<b>636</b>
<b>7.5 Unused financing facilities available at quarter end</b>		13,126
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:		
<p>a) Undrawn discretionary drawdown facility from Mercer to invest in new shares subject to certain terms and conditions. The Company has entered into a funding package with Mercer which includes a \$16.5M discretionary drawdown facility (\$0.6M drawn) for Mercer to invest in new shares subject to certain terms and conditions. These include that Mercer cannot be required to acquire an interest in fully paid ordinary shares in Anteris exceeding 4.99% unless Mercer gives its written consent and in that case it is not to exceed 9.99%. The facility expired on 6 January 2023.</p> <p>b) ANZ financial guarantee \$86k at an interest rate of 2.5%, expiring 30 April 2024.</p>		
*All amounts shown on a gross basis (prior to transaction costs).		

<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)	(8,645)
8.2 Cash and cash equivalents at quarter end (item 4.6)	13,805
8.3 Unused finance facilities available at quarter end (item 7.5)	13,126
8.4 Total available funding (item 8.2 + item 8.3)	26,931
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>3.1</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:

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 2023

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