

ASX ANNOUNCEMENT

28 July 2023

QUARTERLY ACTIVITY REPORT FOR THE PERIOD TO 30 JUNE 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 30 June 2023 (Q2).

Highlights

- A third cohort of patients were implanted with DurAVR™ Transcatheter Heart Valve (THV) in the quarter taking total treated patients to twenty-one, including one compassionate case.
- Thirty-day follow up on the third cohort results during the quarter are now available for a total of twenty patients at thirty days. DurAVR™ THV was successfully implanted in 100% of the cases with all patients achieving outstanding clinical outcomes.
- DurAVR™ THV one-year follow-up results were released for both cohort one (five patients) and cohort two (eight patients) showing preserved valve performance with excellent results and safety maintained over one year.
- Patents issued for the DurAVR™ THV single-piece tissue design with molded biomimetic leaflets.
- Agreement signed with v2vmedtech Inc. to develop a repair device for mitral and bicuspid regurgitation.
- As of 30 June 2023, the Company had a cash balance of \$20.3 million.

Operational Performance and Activities

During the period, a further seven patients (cohort three) and one patient granted compassionate use were implanted with DurAVR™ THV as part of the first-in-human study, conducted at Tbilisi, Georgia. Thirty-day results for cohort three were the best set to date. There were no device-related complications and excellent haemodynamic performance. All three sets of data will be included with results from the US Early Feasibility Study (EFS), to support Anteris' application for premarket approval, required to market DurAVR™ THV commercially in the United States.

Twelve-month data was published for the 12 patients from cohorts one and two showing sustainable results with excellent flow dynamics. An outstanding safety profile was demonstrated with no mortality (all causes), no disabling stroke, no life-threatening bleeding, and no myocardial infarction reported.

Effective Orifice Area and Mean Pressure Gradient showed significant improvement. These are indicators of increased long-term survival and exercise capacity.

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Anteris was granted an additional utility patent for the DurAVR™ THV on 12 April 2023 around the Company's differentiated heart valve technology (based on its innovative single-piece, shaped-tissue design). A further utility patent for the DurAVR™ THV was announced on 17 May 2023. These patents provide additional IP protecting the innovative single piece valve construction and leaflet design. The enhanced IP protection for DurAVR™ strengthens our competitive position in the transcatheter heart valve replacement (TAVR) field.

Anteris entered into an agreement with v2vmedtech Inc. (v2v) to develop a repair device for mitral and bicuspid regurgitation. v2v was established to hold an exclusive license from Columbia University to technology developed by Dr. Vinayak Bapat (also on Anteris' Global Advisory Board). The partnership will see leading physicians work to develop an innovative heart valve repair device to address the unmet needs due to current technology limitation. The mitral and tricuspid valve repair market is expected to be worth \$A4.1bn by 2028¹.

Financial Performance Overview

Anteris continues to invest in research and development activities as it works toward bringing the Company's DurAVR™ Transcatheter Heart Valve technology to market. Net cash outflows for the quarter were \$11.5m and consisted of the following:

- Net operating cash outflows decreased 8% on the prior quarter. Operating cashflows included the following items:
 - Research and development expenditure was \$4.2m. During the period, the Company continued with its Early Feasibility Study activities including regulatory preparatory activities, various IRB and ethics committee approvals and CMS applications for reimbursement, as well as ongoing valve, frame and catheter production activities. In addition, Anteris prepared for and completed the third cohort of patients in the DurAVR™ THV first-in-human (FIH) patient study in Tbilisi, Georgia.
 - Staff costs of \$5.4m was down from the first quarter expenditure of \$7.7m which included annual staff incentive payments. The Company has continued to recruit additional personnel predominately engaged in Research and Development activities as we prepare for the Early Feasibility Study in the United States as well as longer term manufacturing capabilities. Headcount has increased from 73 to 90 since year-end with 11 additional personnel in quarter two. The lower Australian dollar exchange rate relative to the US dollar during the quarter had the effect of increasing employee costs.
 - Administration and corporate costs of \$2.3m were below the quarterly average for 2022 of \$2.9m. This expenditure comprised of corporate and compliance costs including the costs of holding the Annual General Meeting, travel to Tbilisi Georgia for the third Cohort FIH patient study and a medical conference, plus accounting and legal advisors, information technology and investor relations.
 - Customer receipts of \$0.7m from the sale of tissue products declined during the quarter following lower sales demand coupled with extended payment arrangements with a key customer.

¹ Wallace (2020) *Heart Valve Devices Market insights – US: DRG Clarivate*

- Investing net cash outflow of \$0.6m related to the intellectual property assets acquired through the v2vmedtech, inc. agreement and equipment acquisitions primarily for the expansion of facilities in the United States.
- Financing net cash inflow of \$0.9m predominately related to net proceeds of \$1.6M from the exercise of options which were converted into ordinary shares offset by the repayment of \$0.6M of funding relating to insurance.

Pursuant to ASX LR4 4.7C.3, at item 6.1 of the Appendix 4C, the company reported an aggregate amount to related parties of \$0.4m. These payments represent payment for non-executive directors' fees and CEO remuneration.

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.

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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 2023

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	723	2,166
1.2 Payments for		
(a) research and development	(4,303)	(8,873)
(b) product manufacturing and operating costs	(309)	(651)
(c) advertising and marketing	(540)	(638)
(d) leased assets	-	-
(e) staff costs	(5,409)	(13,071)
(f) administration and corporate costs	(2,342)	(4,240)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	243	308
1.5 Interest and other costs of finance paid	(92)	(156)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other	-	-
1.9 Net cash from / (used in) operating activities	(12,029)	(25,155)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
	(c) property, plant and equipment	(259)	(1,770)
	(d) investments	-	-
	(e) intellectual property	(388)	(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 (maturing term deposit)	-	-
2.6	Net cash from / (used in) investing activities	(647)	(2,120)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	100	35,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	1,691	1,692
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(91)	(2,259)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(581)	(581)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(211)	(394)
3.10	Net cash from / (used in) financing activities	908	33,458

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	31,765	13,805
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(12,029)	(25,155)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(647)	(2,120)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	908	33,458
4.5	Effect of movement in exchange rates on cash held	259	268
4.6	Cash and cash equivalents at end of period	20,256	20,256

5.	Reconciliation of cash and cash equivalents 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	12,624	9,512
5.2	Call deposits	7,632	22,253
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	20,256	31,765

6.	Payments to related parties of the entity and their associates	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	362
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.		

7.	Financing facilities <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>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	655	655
7.4	Total financing facilities	655	655
7.5	Unused financing facilities available at quarter end		-
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) Short term financing arrangements of \$569k 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 rates between 4.32% and 4.99%. The final payment instalment is due on 25 December 2023.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(12,029)
8.2	Cash and cash equivalents at quarter end (item 4.6)	20,256
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	20,256
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.7
	<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. It is anticipated 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 this quarter, the Company raised gross proceeds of \$1.7M primarily from the conversion of unlisted options. Since 30 June 2023, the Company has raised a further \$812k from the conversion of unlisted options.
- At the date of this report, 2,038,099 options held by external investors, with expiry dates between now and 2025, are in-the-money and could be exercised at any time. If all of these were converted, they would generate \$22.9m of capital for the Company. It is anticipated that some of these options will be converted prior to maturity.
- The Company has an established track record of successfully raising new capital and debt facilities. The Company has continued to demonstrate successful results with its Research and development program including the one-year results of the First-in-human trials for both cohorts 1 and 2 as well as the 30-day results for cohort 3. The Company is also preparing for an Early Feasibility Study in the United States. All these factors are anticipated to be supportive of continuing to be able to raise new capital and debt facilities in the future.

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 the ADAPT® technology and product pipeline including DurAVR™, Anteris' 3D single-piece Aortic Valve. This has been demonstrated through scientific testing and associated findings including human and animal trials, patient outcomes and the sale of commercial products produced utilising the ADAPT® technology.
- Anteris has now performed three cohorts of first-in-human studies using the Company's DurAVR™ THV with no device-related complications and outstanding clinical outcomes. Planning for the US Early Feasibility Study which is required to market DurAVR™ THV commercially in the United States, is continuing to move ahead.
- The Company continues the development of new products. This includes the recent announcement to develop an innovative heart valve repair device for the treatment of mitral and tricuspid valve regurgitation with v2vmedtech, inc.

On this basis, the Company considers the recapitalisation plan and business objectives will be successful.

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: 28 July 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