

ASX ANNOUNCEMENT

21 April 2022

QUARTERLY ACTIVITY REPORT FOR THE PERIOD TO 31 MARCH 2022

Brisbane, Australia and Minneapolis, USA. Anteris Technologies Ltd (ASX: AVR) (Anteris or the Company) releases its Appendix 4C – Quarterly Cash Flow report for the quarter ended 31 March 2022 (Q1, 2022).

Highlights

- Anteris reports its strongest clinical quarter to date
- Milestone achievement with all five patients in its first in human DurAVR™ THV clinical study doing well with no adverse events
- 30 day follow up showed the first five patients met or exceeded interim study objectives
- Significant IP strengthening with additional patents filed to enhance ADAPT®, lengthen shelf life and increase DurAVR™ heart valve manufacturing capacity
- Leading Australian interventional cardiologist Dr Karl Poon joins the global Medical Advisory Board
- US\$20 million (A\$28 million) placement completed to Perceptive Life Sciences Master Fund with the issue of 1,840,000 at \$15 per share
- Merger proposal received from NASDAQ listed special purpose acquisition company, Medicus Sciences which was turned down

COMMENTARY ON THE QUARTER

In a milestone achievement Anteris delivered its strongest clinical quarter to date with exceptional results from the first five patients in its first-in-human DurAVR™ THV clinical study at the Tbilisi Heart and Vascular Clinic, Tbilisi, Georgia. These results met and exceeded the interim study objectives.

As announced in January 2022, at the 30 day follow up point, all patients continued to do well and no adverse events such as death, stroke, myocardial infarction, reintervention were reported.

Further results also showed;

- An average 86% improvement in mean gradient (standard measure of stenosis severity) from pre-treatment levels.
- Mean gradients were up to 50% lower than other TAVR devices when matched to annular size¹. All patients are in the normal or near normal range when compared to the general population with normal valve function.
- Average Effective Orifice Area (EOA) was up to 45% larger than those reported with other TAVR devices in matched annular sizes².

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- No conduction (heart rhythm) disturbances due to the procedure.
- No clinically significant paravalvular regurgitation despite very complex and heavily calcified anatomy.
- Echocardiographic and CT analysis reported normal leaflet mobility, no leaflet calcification or thrombus generation.
- Echocardiographic and CT imaging data showed consistent laminar flow throughout the valve and long coaptation length in all five patients. Ostensibly, these features indicate lower leaflet strain leading to long term durability.
- The system also allowed for excellent commissural alignment; a significant patient benefit if future coronary intervention were required.
- A 20% increase from baseline in 6 min walk test (a measure of patient exercise tolerance). This is a 170% greater improvement than observed in studies of other TAVR valves³.

This indicates a marked improvement in patients' functional status and exercise tolerance. The improvement in exercise capacity may be associated with the increased EOA (larger valve opening area due to its unique design) allowing optimal haemodynamics (blood flow) at rest and during exercise⁴. Exercise performance is a critical marker of cardiac health.

Anteris continues to work closely with cardiologists at the Tbilisi Heart and Vascular Clinic to recruit an additional five patients required to complete the next phase of this study.

Additionally, to continue strengthening its IP portfolio and maintain its competitive advantage, Anteris filed a provisional application for a new patent pertaining to its tissue treatment technology, ADAPT®. The new patent relates specifically to particular aspects of the sterilization process allowing the safe transfer of product to manufacturer of valves.

This enhancement will allow expanded manufacturing of DurAVR™ at additional sites with manufacturing beginning in Australia and completing in the USA, significantly reducing labour, manufacturing time, and costs. It will also enable Anteris to increase production of its DurAVR™ heart valve due to the ADAPT® extended shelf life.

CASH RECEIPTS AND CASHFLOW

The closing cash balance as at 31 March 2021 was \$42.1M, up \$20.8M from 31 December 2021, and included:

- Net operating cash outflows of \$10.2M, including staff costs of \$5.2M, administration and corporate costs of \$2.6M, product manufacturing and operating costs of \$0.3M and research and development investment of \$2.9M. This was partly offset by customer receipts of \$1.0M;
- Investing cash outflows of \$0.4M primarily relate to IT and laboratory equipment acquisitions; and
- Financing cash inflow of \$32.6M including proceeds from the issue of ordinary share capital and the conversion of options offset by transaction costs.
- Negative FX movements on USD denominated cash balances.

CORPORATE ACTIVITY

During the quarter, Anteris welcomed leading Australian interventional cardiologist Dr Karl Poon MB, BS, FRACP, CSANZ to its global Medical Advisory Board. Dr Poon is an experienced interventional cardiologist with expertise in structural heart disease interventions and among Australia's most prolific implanters of TAVI devices.

His Medical Advisory Board participation is a welcome addition as the Company continues building clinical validation for its novel DurAVR™ 3D single-piece transcatheter aortic heart valve.

Anteris completed a US\$20 million (A\$28 million) placement to Perceptive Life Sciences Master Fund, Ltd and managed by Perceptive Advisors with the issue of 1,840,000 ordinary shares at A\$15 per share.

The Company also received a Non-Binding letter of intent for a merger with NASDAQ-listed special purpose acquisition company Medicus Sciences Acquisition Corp. This proposal was subsequently rejected by Anteris as it was deemed to not be in best interests of the Company's shareholders at this time.

This comes as the Company remains focused on its core objectives to continue clinically developing its DurAVR™ THV system and ultimately deliver substantial return of investment for its valued shareholders.

ENDS

References

¹ Naidu et al. Measuring TAVR Prosthesis Gradient Immediately Post-Procedure May Underestimate its Significance. JACC CV Imag. 2021;15(1):120-121

² Hahn et al. Comprehensive Echocardiographic Assessment of Normal Transcatheter Valve Function. JACC CV Imag. 2019;12(1):25-34)

³ Mack et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients/Supplementary Appendix N Engl J Med 2019; 380:1695-1705

⁴ Gorlin et al. Dynamics of the circulation in aortic valvular disease., Am J Med. 1955 Jun;18(6):855-70

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 reproduce consistent life-changing outcomes for patients.

Anteris' DurAVR™ 3D single-piece aortic heart valve replacement addresses the needs of tomorrow'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")

31 March 2022

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	1,037	1,037
1.2 Payments for		
(a) research and development	(2,921)	(2,921)
(b) product manufacturing and operating costs	(336)	(336)
(c) advertising and marketing	(144)	(144)
(d) leased assets	-	-
(e) staff costs	(5,234)	(5,234)
(f) administration and corporate costs	(2,600)	(2,600)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	2	2
1.5 Interest and other costs of finance paid	(35)	(35)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other	-	-
1.9 Net cash from / (used in) operating activities	(10,231)	(10,231)
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 (3 months) \$A'000
	(c) property, plant and equipment	(431)	(431)
	(d) investments	-	-
	(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 (maturing term deposit)	-	-
2.6	Net cash from / (used in) investing activities	(431)	(431)
3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	27,600	27,600
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	6,408	6,408
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,286)	(1,286)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(152)	(152)
3.10	Net cash from / (used in) financing activities	32,570	32,570

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 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	21,300	21,300
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(10,231)	(10,231)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(431)	(431)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	32,570	32,570
4.5	Effect of movement in exchange rates on cash held	(1,129)	(1,129)
4.6	Cash and cash equivalents at end of period	42,079	42,079

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	14,606	21,211
5.2	Call deposits	27,473	89
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)	42,079	21,300

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 and CEO remuneration	981
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		
7.	Financing facilities <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>	Total facility amount at quarter end \$A'000
7.1	Loan facilities	-
7.2	Credit standby arrangements	-
7.3	Other (please specify)	16,344
7.4	Total financing facilities	16,344
7.5	Unused financing facilities available at quarter end	10,308
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.	
	<p>Other consists of:</p> <ul style="list-style-type: none"> a) Convertible notes to Mercer Street Global Opportunity Fund, LLC (Mercer) with a face value of \$5.4M. No interest is payable on unconverted drawn funds. The amounts drawn down are secured against Anteris' assets excluding the ADAPT intellectual property. Details of the convertible notes is disclosed below: <ul style="list-style-type: none"> ○ The first tranche of \$1.62M* face value entitles Mercer the right to convert the note into fully paid ordinary shares at 90% of the average five-day VWAP immediately prior to the issue of the conversion notice, subject to a floor price of \$2.50. Expiry 19 May 2022. ○ The second tranche of \$1.08M* face value entitles Mercer the right to convert the note into fully paid ordinary shares at 90% of the average five-day VWAP immediately prior to the issue of the conversion notice, subject to a floor price of \$2.50. Expiry 12 August 2022. ○ The third tranche of \$2.7M* face value entitles Mercer the right to convert the note into fully paid ordinary shares at 90% of the average five-day VWAP immediately prior to the issue of the conversion notice, subject to a floor price of \$4.00. Expiry 12 August 2022. 	

b) 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%.

c) ANZ financial guarantee \$86k at an interest rate of 2.5%, expiring 30 April 2024.

*All amounts shown on a gross basis (prior to transaction costs).

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(10,231)
8.2	Cash and cash equivalents at quarter end (item 4.6)	42,079
8.3	Unused finance facilities available at quarter end (item 7.5)	10,308
8.4	Total available funding (item 8.2 + item 8.3)	52,387
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	5.1

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.

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: 21 April 2022

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