

# ASX ANNOUNCEMENT

16 October 2020

## QUARTERLY ACTIVITY REPORT FOR THE PERIOD TO 30 SEPTEMBER 2020

Anteris Technologies Ltd (ASX:AVR) (**Anteris** or the **Company**) releases its Appendix 4C – Quarterly Cash Flow report and commentary for the period ended 30 September 2020 (Q3, 2020).

### HIGHLIGHTS

- Five patients successfully implanted in First-In-Human SAVR (surgical aortic valve replacement) trial.
- The DurAVR™ valve continues to produce consistent and superior performance results across key bench, animal and human studies, delivering normalised hemodynamics and promising to be the first TAVR valve to deliver a functional cure for severe aortic stenosis patients.
- \$US1M received from 4C Medical Technologies, Inc.
- \$1.8M of revenue, largely made up of manufacturing for LeMaitre Vascular, Inc.
- \$3.5M in cash receipts for the quarter.
- \$4.8M cash balance.

### COMMENTARY ON THE QUARTER

Anteris continued to make significant progress on key research and development programs, particularly on the development of its 3D single-piece DurAVR™ aortic valve.

The First-In-Human SAVR trial now has five patients successfully implanted with the DurAVR™ surgical aortic valve. The trial continues to demonstrate significantly improved valve function and blood flow, with results indicating the valve can achieve hemodynamics of a pre-disease valve.

The 15-patient study is on track and final results are expected between Q1 2021 and Q3 2021.

This month, Professor Bart Meuris MD, PhD, Chief of Cardiovascular Surgery at University Hospitals, Leuven, (Belgium) and lead surgeon on the FIH trial, presented key data and insights on the DurAVR™ valve from the trial at the European Association for Cardio-Thoracic Surgery Annual Conference. This highly recognised industry event and one of the world's largest cardio-thoracic meetings reinforced that the DurAVR™ valve provides a more effective treatment with improved valve function.

Anteris Technologies Ltd

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The Company is also progressing several key pre-clinical studies, including the anti-calcification comparison study against a currently marketed TAVR valve material and an early TAVR animal study. Results are expected to be available between Q4 2020 and Q1 2021. Data and experience from all studies provide important insights towards the next phase of development and commercialisation. This data will also be included in regulatory submissions (FDA, etc...) to demonstrate that the DurAVR™ valve provides a more effective treatment than other currently approved and marketed products.

Progress continues on the development of all aspects of our TAVR product including the catheter as the Company prepares for its FDA human TAVR study in 2021.

In July 2020, Anteris hosted a key opinion leader symposium on the next generation technologies for TAVR in younger, low-risk patients with aortic stenosis. The event provided investors and analysts with a comprehensive profile of current trends in TAVR use and the future of this technology. Mr Matt Miksic, Senior Analyst at Credit Suisse, moderated the forum featuring Dr Samir Kapadia, MD (Cleveland Clinic, Cleveland, OH), Dr Michael Reardon, MD (Houston Methodist, Houston, TX) and Dr Paul Sorajja, MD (Minneapolis Heart Institute, Minneapolis, MN).

Anteris has assembled highly regarded, global key opinion leaders to its TAVR Medical Advisory Board. During the quarter, Anteris welcomed Professor Bernard Prendergast, Chair of Cardiology at Cleveland Clinic in London and the Principal Course Director of PCR London Valves (the world's largest specialist meeting in valve intervention), to the Advisory Board. Professor Prendergast has performed over 1,000 TAVR procedures and will be instrumental as Anteris works towards European CE Mark approval for the DurAVR™ transcatheter valve in Europe.

In early September 2020, the Company was granted a patent in the United States for the sterilisation method employed in the manufacture of ADAPT® tissue. Expanding Anteris' intellectual property portfolio is an area of continual focus. This patent grant is essential to our value creation strategy.

Total quarterly revenue was \$1.8M, predominately from manufacturing for LeMaitre Vascular, Inc. ("LeMaitre"). To date, LeMaitre's purchase orders have remained solid. The Company also continues to supply ADAPT® tissue to 4C Medical Technologies, Inc. ("4C").

## **CASH RECEIPTS AND CASH FLOWS**

The closing cash balance as at 30 September 2020 was \$4.8M, down \$2.1M from 30 June 2020, and included:

- Net operating cash outflows of \$1.7M, including staff costs of \$2.1M, administration and corporate costs of \$1.3M, product manufacturing and operating costs of \$0.6M and research and development investment of \$1.2M. This was partly offset by customer receipts of \$2.2M and \$1.4M in proceeds from 4C for the previously recognised \$US1M associated with the validation of the sterilisation method licensed to 4C for its use with Anteris' ADAPT® tissue;
- Financing cash outflow of \$0.1M, relating to lease payments; and
- The effect of movements in exchange rates on cash held during the year was \$0.2M.

## CORPORATE ACTIVITY

Despite the COVID-19 pandemic, there has been no major impacts on Anteris to date. Anteris continues to closely monitor the situation, including the Company's manufacturing contingency plan and its capital reserves.

The Company has announced post quarter end, the extension of the maturity date on the outstanding loan balance with Sio Partners, LP through to 15 December 2021. The Company continues discussions with its strategic partners.

## IN SUMMARY

"We are making significant progress and attracting strong interest from potential strategic partners and prospective investors based on the data being generated. Benchtop and pre-clinical trials are providing critical insights and valuable data in the development of our 3D single-piece aortic valve. The results of these studies and the data generated to date in our First In Human study reinforce that DurAVR™ can deliver valve function that replicates a pre-diseased valve. If we keep generating these outcomes, it will provide a functional cure for those patients suffering from severe aortic stenosis," Wayne Paterson, Anteris CEO, said.

Yours faithfully,

A handwritten signature in black ink, appearing to be 'Wayne Paterson', written over a white background.

Wayne Paterson  
Chief Executive Officer

## About Anteris Technologies Ltd (ASX: AVR)

Anteris Technologies Ltd is a structural heart company delivering clinically superior solutions that help create life-changing outcomes for patients. Its focus is on developing next generation technologies with world class partners.

Its ADAPT® tissue platform, a next generation technology with zero DNA and zero glutaraldehyde, is the only bio-scaffold to demonstrate zero calcification after 10 years of use in complex cardiac surgery. With these advantages, Anteris' best-in-class ADAPT® tissue combined with its valve design has the potential to solve the problems of durability and valve degradation associated with current aortic valve replacement options.

## Authorisation and Additional information

This announcement was authorised by Mr Wayne Paterson, Chief Executive Officer.



**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 September 2020

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	2,186	5,966
1.2 Payments for		
(a) research and development	(1,207)	(3,422)
(b) product manufacturing and operating costs	(611)	(1,731)
(c) advertising and marketing	(100)	(465)
(d) leased assets	-	-
(e) staff costs	(2,057)	(9,042)
(f) administration and corporate costs	(1,300)	(4,528)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	96
1.5 Interest and other costs of finance paid	(58)	(170)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	38	823
1.8 Other		
-proceeds from licence for sterilisation process	1,360	1,360
-gain on derivative contract	-	154
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,748)</b>	<b>(10,959)</b>

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(26)	(266)
(d) investments	-	(400)
(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)	-	7,509
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(26)</b>	<b>6,843</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	-	-
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
3.9	Other (provide details if material)	(76)	(250)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(76)</b>	<b>(250)</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	6,896	8,968
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,748)	(10,959)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(26)	6,843
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(76)	(250)
4.5	Effect of movement in exchange rates on cash held	(231)	213
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>4,815</b>	<b>4,815</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	4,704	6,785
5.2	Call deposits	111	111
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>4,815</b>	<b>6,896</b>

<b>6. 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 and CEO remuneration	263
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	1,330	1,330
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	106	106
7.4 <b>Total financing facilities</b>	<b>1436</b>	<b>1436</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.		
<p>Loan facility from Sio Capital, capitalised interest at a rate of 12% per annum, maturing 15 December 2021.</p> <p>ANZ financial guarantee \$86k at an interest rate of 2.5%, maturing 30 June 2021.</p> <p>ANZ financial guarantee \$20k at an interest rate of 2.5%, open ended.</p>		

<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)	(1,748)
8.2	Cash and cash equivalents at quarter end (item 4.6)	4,815
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	<b>Total available funding (item 8.2 + item 8.3)</b>	<b>4,815</b>
8.5	<b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>2.75</b>

*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?
- 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?
- 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?

*Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.*

## 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: 16.10.2020

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.