ASX ANNOUNCEMENT

31 October 2023

QUARTERLY ACTIVITY REPORT FOR THE PERIOD TO 30 SEPTEMBER 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 September 2023 (Q3).

Highlights

- The US FDA approved Early Feasibility Study (EFS) of DurAVR™ THV started with first patients treated successfully. Enrolment was completed after quarter end.
- The first valve-in-valve (ViV) procedure using the DurAVR™ Transcatheter Heart Valve (THV) under the Compassionate Use Program approved by Health Canada at end of July 2023.
- Established a sponsored Level 1 American Depository Receipt (ADR) program in the United States.
- As of 30 September 2023, the Company had a cash balance of $7.2 million.

Operational Performance and Activities

During the quarter, key clinical milestones were hit with the EFS starting in early August in the United States. Seven patients were implanted with DurAVR™ during the quarter, with the full initial enrolment of 15 patients completed during October 2023.

In addition, the first-in-human ViV procedures using DurAVR™ THV was done successfully in Canada under Health Canada's Special Access Program. A ViV procedure is required for patients with a life-threatening situation wherein their current bioprosthetic aortic valve is failing due to calcification or structural deterioration and a new heart valve must be implanted inside the failing valve. These patients are at high risk for another surgery and require a less invasive treatment option.

Since the first five patients were successfully implanted with the DurAVR™ THV in Tbilisi, Georgia, in November 2021, 39 patients (including three ViV cases and 15 EFS enrolments) have now been treated for severe aortic stenosis. Published results including 12 month data from the first two cohorts of Tbilisi patients demonstrated superior performance to current competitor products.

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

Aside, the Centers for Medicare & Medicaid Services (CMS) fully approved reimbursement of both the device and procedure for the ongoing *DurAVR™ THV System in Subjects with Severe Aortic Stenosis: Early Feasibility Study (EFS).* This followed the previously reported FDA category B recommendation for device reimbursement for the EFS.

Anteris continued to stimulate corporate and institutional interest with the CEO, Wayne Paterson, presenting the latest clinical results for the DurAVR™ THV at the Cantor Fitzgerald Global Health Conference held in New York on 26–28 September 2023.

This followed the establishment of a Deutsche Bank sponsored Level 1 American Depository Receipt (ADR) program in the United States. The ADR program (denominated in $US) was set up to improve US investor access to Anteris' ordinary shares. The program intends to simplify and streamline US investors' access to investing in Anteris by eliminating the need to deal with foreign currencies or the complexities of trading on foreign stock exchanges.

In addition to the clinical outcomes for the quarter, Anteris extended the Transition Services Agreement with LeMaitre Vascular, Inc. and will continue to manufacture and sell CardioCel™ and VascuCel™ products to LeMaitre Vascular, Inc. through to January 2025.

Financial Performance Overview

Anteris continues to invest in R&D activities as it works toward bringing the Company's DurAVR™ THV technology to market. Net cash outflows for the quarter were $13.0m and consisted of the following:

- Net operating cash outflows increased 4% on the prior quarter. Operating cashflows included the following items:
    - Research and development expenditure was $5.7m up on the prior quarter of $4.3m. During the period, the Company commenced its enrolment in its FDA approved Early Feasibility Study including site and patient enrolment costs. In addition the Company continued its R&D activities related to valve, frame and catheter development. Additionally, Anteris sponsored three ViV compassionate use procedures in Canada.
    - Staff costs of $5.7m was marginally higher than the prior quarter expenditure of $5.4m. Headcount increased from 73 to 95 since year-end with five additional personnel in quarter three. The headcount increase for the quarter is across R&D and upscaling of US manufacturing capabilities. The lower Australian dollar exchange rate relative to the US dollar during the quarter also had the effect of increasing employee costs.
    - Administration and corporate costs of $2.3m were down on the prior quarter and included travel related to EFS and ViV studies, accounting and legal advisors, information technology and investor relations.
    - Customer receipts of $1.7m from the sale of tissue products increased on the prior quarter due to the timing of receipt of aged balances as well as advanced receipts.
- Investing net cash outflow of $1.1m related to payments for equipment acquisition.
- Financing net cash inflow of $0.4m predominately related to net proceeds of $1.0M from the exercise of options which were converted into ordinary shares partly offset by the repayment of $0.3m of funding relating to insurance as well as lease payments of $0.2m.

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:

For more information:

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ANTERIS A Structural Heart Company

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Anteris Technologies Ltd	

ABN	Quarter ended ("current quarter")
35 088 221 078	30 September 2023

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	1,682	3,848
1.2	Payments for		
	(a) research and development	(5,688)	(14,561)
	(b) product manufacturing and operating costs	(198)	(849)
	(c) advertising and marketing	(435)	(1,073)
	(d) leased assets	-	-
	(e) staff costs	(5,659)	(18,730)
	(f) administration and corporate costs	(2,250)	(6,490)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	134	442
1.5	Interest and other costs of finance paid	(110)	(266)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other	-	-
1.9	**Net cash from / (used in) operating activities**	**(12,524)**	**(37,679)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(1,109)	(2,879)
	(d) investments	-	-
	(e) intellectual property	-	(388)
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
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**	**(1,109)**	**(3,229)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	35,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	957	2,649
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(2,259)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	(316)	(897)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	(236)	(630)
3.10	**Net cash from / (used in) financing activities**	**405**	**33,863**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	20,256	13,805
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(12,524)	(37,679)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,109)	(3,229)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	405	33,863

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.5	Effect of movement in exchange rates on cash held	186	454
4.6	**Cash and cash equivalents at end of period**	**7,214**	**7,214**

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	4,801	12,624
5.2	Call deposits	2,413	7,632
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)**	**7,214**	**20,256**

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	407
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** *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.*	**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)	340	340
7.4	**Total financing facilities**	**340**	**340**

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 $254k 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)	(12,524)
8.2	Cash and cash equivalents at quarter end (item 4.6)	7,214
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	7,214

8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	0.6

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:

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 the quarter, the Company raised gross proceeds of $957k from the conversion of unlisted options. Since 30 September 2023, the Company has raised a further $500k from the conversion of unlisted options.
- On 26 October 2023 Anteris announced a capital raise for the issue of 2,000,000 new shares raising $40m proceeds. These funds will be used for the preparation of the FDA Pivotal trial of the Company's DurAVR™ THV for treating severe aortic stenosis, continued ViV trials and general working capital expenses.
- In October 2023, the Company received $1.4m under the Australian Government's Research and Development (R&D) Tax Incentive Scheme.
- At the date of this report, 1,973,599 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 $22.2m of capital for the Company. It is anticipated that some of these options will be converted prior to maturity.

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 with Anteris completing 15 enrolments in its FDA approved EFS in the United States. Interim analysis reports show successful results.
- Anteris has also performed three cohorts of first-in-human studies using the Company's DurAVR™ THV with no device-related complications and positive clinical outcomes.
- The first three valve in valve procedures using the DurAVR™ THV under the Compassionate Use Program was successfully completed during the quarter.
- The Company continues the development of new products. This includes the development of an innovative heart valve repair device for the treatment of mitral and tricuspid valve regurgitation with v2vmedtech, inc.

On this basis, the Company considers it will be able to continue its operations and meet business objectives.

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 October 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