

# ASX ANNOUNCEMENT

19 April 2023

## AGREEMENT TO DEVELOP NEW HEART VALVE REPAIR DEVICE

**BRISBANE, Australia** and **MINNEAPOLIS, USA**, Anteris Technologies Ltd (Anteris or the Company) (ASX: AVR) is pleased to announce that the Company has entered an agreement with v2vmedtech, inc. (“**Agreement**”) to partner with leading physicians to develop an innovative heart valve repair device for the minimally invasive treatment of mitral and tricuspid valve regurgitation (“**Devices**”) – also known as a leaky valve – a market expected to be \$A4.1 Bn by 2028<sup>1</sup>.

To date these Devices have been developed through physician-led research from New York Presbyterian/Columbia University Hospital, NYC and utilize a transcatheter edge-to-edge repair method. It is designed to address unmet needs within the mitral and tricuspid valve repair space. The technology complements the Company’s portfolio by entering a market adjacent to the transcatheter aortic valve replacement (TAVR) market in which the Company remains focused on developing the DurAVR™ TAVR system.

The mitral and tricuspid valve repair markets are underpenetrated with few competitors, and many patients do not receive treatment due to current technology limitations. Anteris sees this as an opportunity to work with highly credible physicians to bring innovation to an established but growing market within the structural heart space by developing a device that can expand the treatable patient population to include those unsuitable for today’s treatment options.

The agreement allows the Company to take a risk-adjusted approach to partner with leading experts under terms calibrated to milestone achievement.

“This strategic partnership allows us to tap into our core capabilities of innovation and existing network of physician advisors while broadening our portfolio and entering additional market segments where we can expect significant long-term growth,” said CEO Wayne Paterson.

## AGREEMENT DETAILS

A series of binding agreements have been entered into with v2vmedtech, inc., a Delaware corporation (“v2v”). v2v was established to hold an exclusive license from Columbia University to technology developed by Dr. Vinayak (Vinnie) Bapat while he was a cardiologist at New York Presbyterian/Columbia University Hospital, and the license represents its only material asset. v2v is currently owned by Dr. Vinayak (Vinnie) Bapat who is the existing controlling shareholder along with six other minority shareholders. Dr Vinnie Bapat is a practicing cardiologist with Allina Health Minneapolis Heart Institute, Chief of Cardiothoracic Surgery at Abbott Northwestern Hospital and also a member of the Anteris Global TAVR Medical Advisory Board.

The key terms are:

### Contribution by Anteris

- The Company will initially acquire a 30% interest in v2v.

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

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- Anteris will initially contribute cash up to \$US 213,000 together with a contractual commitment to be responsible for development of the Devices and it is anticipated that the Company will contribute between \$US3.6M and \$US8M in cash and in-kind contributions (“Development Contributions”). The Development Contributions will be provided over five stages linked to key development milestones from concept development (“Stage 1”) through first use of the Device in a First-in-human trial (“Stage 5”), with Anteris having the option to proceed or not proceed at the end of each of the five agreed stages of the development program and subject to Break rights (refer below). Stage 1 is anticipated to result in Development Contributions from Anteris of \$US 0.7M to \$US1.6M.
- Anteris will provide engineering, clinical, regulatory, marketing and executive management resources excluding medical and Chief Medical Officer services. All third party costs and expenses incurred by Anteris directly related to the development of Devices shall form part of the Development Contributions.
- Anteris will also pay all customary corporate, operational and legal costs (“**Operational Contributions**”) of v2v up to an amount determined by the Board of v2v each year.
- Anteris will utilise its existing working capital to complete the acquisition, commence the initial development activities and provide the Stage 1 Development Contributions. Ongoing funding for the Development Contributions and Operational Expenditures will form part of Anteris’ broader capital management plan.
- Post the earlier of the completion of Stage 5 of the development milestones (being the first use of a Device in a First-in-human trial) or Development Contributions reaching \$US 10M (“**Funding Threshold**”), Anteris ownership interest will be increased from 30% to between 58% and 60%. The Development Contributions and the Operational Contributions count towards the Funding Threshold.

#### **Board of Directors and Management**

- Following the transaction, the v2v Board of Directors shall consist of a maximum of three members with two appointed by Anteris. Certain matters specified in the shareholders agreement require the approval of the non-Anteris Director, Dr. Bapat (or his designee), before they can proceed including proceeding to First-in-Human for the device(s), a change of control and a change to the number of directors on the Board.
- Anteris appointees will fulfill the roles of Chair of the Board of Directors, Chief Executive Officer and Chief Financial Officer of v2v.

#### **Break rights**

- Anteris has the right to discontinue additional Development Contributions subject to a break fee of between \$US0.2M at the end of stage 1 increasing in set increments to \$US 1M at the end of stage 5.
- If Anteris chooses to discontinue with Development Contributions, the original shareholders will have the right to purchase the shares held by Anteris equivalent to the Development Contributions paid by Anteris or dilute the ownership interest held by Anteris down to 2% if before the completion of stage 1 increasing in set increments up to 10% if before the completion of stage 5.

### **Option to purchase shares**

- Anteris holds an option to purchase the shares of all the Initial shareholders (shareholders at the date of the Agreement) if v2v achieves First-in-human with the Device(s). The option can be exercised at the higher of fair market value and \$US150M.

### **Other terms**

- Anteris is the exclusive partner to develop the Devices.
- v2v will own all intellectual property rights to the developed technology and development data from the activities from the Development Contributions
- Anteris is granted a perpetual, worldwide, royalty free, fully paid up, sublicensable, transferable, exclusive license to the developed technology and development data for use outside of the v2v field of use.
- The shareholders agreement includes a royalty to Dr Vinnie Bapat (existing shareholder) and Shalaka Bapat (existing shareholder) of between 2.5% to 8% of annual net sales of the Devices.
- There are no material conditions that need to be satisfied before the contract becomes legally binding.
- Anteris has completed due diligence on v2v and obtained customary representations and warranties from the shareholders.
- The license between Columbia and v2v can be terminated if certain expenditure amounts, development milestones or regulatory approvals are not incurred/achieved from 31 March 2027 and onwards.

### **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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