

# Investor Presentation

www.anteristech.com | Follow us @anteristech 🈏 🗗 in

Copyright Anteris Technologies Ltd 2020



#### Disclaimer



This presentation contains general information which is current as at 21 May 2020. It is information given in summary form and does not purport to be complete. Information in this presentation is not intended to be relied upon as advice to investors or potential investors and does not take into account the financial situation, investment objectives or needs of any particular investor. Before making any investment or other decision, investors should consider these factors, and consult with their own legal, tax, business and/or financial advisors. This presentation should be read in conjunction with all other information concerning Anteris Technologies Ltd filed with the Australian Securities Exchange (ASX). The information in this presentation is for general information only. Anteris advises that this presentation and any related materials and cross -referenced information, may contain forward looking statements that are based on information and assumptions known to date and are subject to various risks and uncertainties outside of Anteris' control. No representation is made as to the accuracy or reliability of forward looking statements or the assumptions on which they are based. Actual future events may vary from these forward looking statements and you are cautioned not to place reliance on any forward looking statement. Anteris undertakes no obligation to update any forward-looking statement to reflect events or circumstances after the date of this presentation (subject to ASX disclosure requirements).

## Anteris<sup>™</sup> developing the world's most durable heart valve





#### Anteris<sup>™</sup> developing the world's most durable heart valve

- Anteris<sup>™</sup> is a structural heart company with unique technology (ADAPT<sup>®</sup> and DurAVR<sup>™</sup>) that solves critical issues with currently marketed heart valves.
- Anteris<sup>™</sup> is competing in a potential **USD \$8 BN market**
- ADAPT<sup>®</sup> is the unique anti-calcification treatment platform technology on which our structural heart products are built.
- ADAPT<sup>®</sup> has unique properties that are critical to longer lasting aortic valves and has been used in over **20,000** patients globally.
- DurAVR<sup>™</sup>, built with ADAPT<sup>®</sup> technology, is a novel and highly durable 3D singlepiece aortic valve for the treatment of aortic stenosis.
- DurAVR<sup>™</sup> has unique properties that are critical to longer lasting valves and is now in human clinical trials following successful preclinical studies.







#### The Transcatheter Aortic Valve Replacement (TAVR) market is growing rapidly





By 2025, Global Aortic Valve Replacement to reach \$8B USD\*

TAVR is expected to be 62% of procedure volume and 87% of market revenue.



#### Why a durable heart valve matters

- The FDA approved the use of TAVR in "low-risk" (younger) patients in 2019.
- As a result replacement valves need to be durable and long lasting.

Currently marketed TAVR valve showing significant calcification



#### LONG-TERM DURABILITY OF TAVR Our current understanding of the long-term durability of TAVR is limited. Recent assessment of PARTNER 2A 5-year outcomes suggests SAPIEN XT is associated with a higher rate of structural valve deterioration compared to SAVR. Although a similar mid-term trend has not been observed for SAPIEN 3, long-term follow up data are not available TAVR DURABILITY IS A LONG-TERM ASSESSMENT · The question of long-term durability is not feasible to address premarket - Durability is largely a function of structural valve deterioration, and biological responses cannot be accurately modeled in non-clinical testing - A premarket requirement for clinical studies to evaluate long-term durability would have prevented TAVR availability to patients in need To address long-term durability, FDA has mandated post-approval studies and surveillance for all TAVR devices (consistent with an appropriate balance of premarket and postmarket data requirements) **TVTR/CMS-linked surveillance** Continued follow-up of pivotal trial subjects of commercial use Extreme Risk 5 years 5 years High Risk 5 years 5 years Intermediate Risk 10 years 5 years Low Risk 10 years 10 years www.fda.gov

#### The 2019 FDA approval for low-risk (younger patients) is driving market expansion





\*Popma FF, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. N Engl J Med. 2019;380(18):1706-1715. \*Mack, MJ, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019;380(18):1695-1705



## ADAPT<sup>®</sup> TISSUE SCIENCE

First and only anti-calcification treatment demonstrating **zero** calcification in humans beyond 10 years

#### ADAPT<sup>®</sup> is widely studied and has been used in over 20,000 patients worldwide



- ✓ >20,000 implants in young patients with congenital heart disease
- 10-year clinical data with no calcification in pediatric patients
- ✓ Largest series is 500 patients

ADAPT



DurAVR<sup>™</sup> A unique 3D singlepiece Aortic Valve Replacement



#### DurAVR<sup>™</sup> addresses the key areas that lead to valve deterioration

Only DurAVR<sup>™</sup> is made from ADAPT<sup>®</sup> treated tissue with superior anti calcification properties

Other valves are constructed from tissue that has residual DNA which promotes inflammation and immune response that leads to calcification

> DurAVR<sup>™</sup> has no residual glutaraldehyde

Other valves have residual glutaraldehyde which is toxic and requires manual rinsing pre-implantation

DurAVR<sup>™</sup> is made from one piece of tissue resulting in 35% less stress on the leaflets



resulting in greater stress and sub-optimal coaptation



DurAVR<sup>™</sup> has 20-30 sutures = lower manufacturing costs

Other valves require 100's of sutures per valve during manufacturing

Addressing even one of these could be a significant competitive advantage... The DurAVR<sup>™</sup> 3D single-piece heart valve addresses <u>all</u> of these.

Ca<sup>+2</sup>

for life

## DurAVR<sup>™</sup> durability experiments continue to be positive



**Clean Margins** 

(Annulus)

#### ACCELERATED WEAR TESTING SHEEP CALCIFICATION MODEL Anteris Valve shows no wear at **400 million cycles** A hostile environment for valves Well Anchored Supple Day 1 200 million 400 million **Sutures** Cusps Competitor Valves demonstrate wear and may

Valves implanted in juvenile sheep and assessed at 6 months: ADAPT<sup>®</sup> aortic valves show no calcification

breakdown at 250 million cycles

### DurAVR<sup>™</sup> exhibits no wear over 12 years

No wear was observed beyond 500M Cycle (12-13 years)



for life

## DurAVR<sup>™</sup> First in Human study patient #1



	Patients with other surgical valves* (N>1400)	DurAVR™ Patient 1
Peak Gradient mmHg	23	11
Mean Gradient mmHg	11	5
EOA cm <sup>2</sup>	1.9	2.9



\* Average of 1400 patients implanted with commercially available surgical valves at Leuven University Hospitals Proprietary Material of Anteris Technologies Ltd.





#### ADAPT for life

#### DurAVR<sup>™</sup> is addressing the key issues impacting valve durability

- 1. We have a unique tissue science (ADAPT<sup>®</sup>) which has zero DNA and proven not to calcify over 10 years in humans.
- 3D single-piece Aortic Valve (DurAVR<sup>™</sup>) which has shown no signs of wear over 500 million cycles (approx. 12-13 years).
- 3. DurAVR<sup>™</sup> is now being studied in humans with excellent early results.
- 4. Evidence is building that indicates superior hemodynamics\*.
- DurAVR<sup>™</sup> has addressed the key variables that lead to longer lasting valves. The tissue science and valve design.



\* Data continues to show consistent results, however experiments and trials are ongoing





# 2020 – Setting up the future





### ADAPT<sup>®</sup> Portfolio Patent Filings



YTD in 2020, the Company has filed **18** applications worldwide for its 3D valve and its novel sterilized packaging system.

If all proposed additional filings due later in 2020 are filed, total patent applications filed on the ADAPT<sup>®</sup> portfolio will be **2X** their 2019 levels.

#### Anteris<sup>™</sup> is supported by a world class TAVR focused advisory board





Gorav Ailawadi, MD University of Virginia Health System Charlottesville, VA



Susheel Kodali, MD Columbia University Medical Center New York, NY



Jeffery Popma, MD Harvard Medical Boston, MA







Vinayak Bapat, MD New York-Presbyterian/Columbia Medical Center, New York, NY



Christopher Meduri, MD **Piedmont Heart Institute** Atlanta, GA



Samir Kapadia, MD **Cleveland Clinic** Cleveland, OH



Michael Reardon, MD Houston Methodist DeBakey Heart & Surgery Vascular Center, Houston, TX



Paul Sorajja, MD Abbott Northwestern Hospital Minneapolis, MN



Alan Zajarias, MD Center for Advance Medicine Heart & Vascular St. Louis, MO





## Developing the world's most durable heart valve

#### The right science

 ADAPT<sup>®</sup> anti-calcification treatment is proven over 10 years in humans, with zero calcification in published studies.

#### The right design

 The DurAVR<sup>™</sup> 3D single-piece valve is proven to have less wear at the leaflets than conventional valves.

#### The right time

• The FDA approved the use of TAVR in "low risk" (younger) patients in 2019. Replacement valves need to last longer.





Innovation to support life's journey is at the heart of our story...

#### North America

860 Blue Gentian Road, Suite 340 Eagan MN 55121 Europe Rte de Pre-Bois 20, PO BOX 1877, 1215 Geneva 15 Australia Toowong Tower Level 3, 9 Sherwood Rd, Toowong QLD 4066

