

## **Anteris Technologies Ltd**

## **Annual General Meeting 2020**

**CEO** Presentation

15 July 2021



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# **ANTERIS**

# DurAVR<sup>™</sup> for lifetime management of Aortic Stenosis patients

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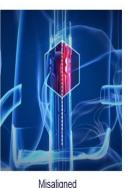


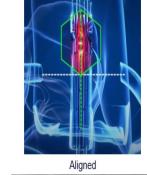
#### 2020 was an incredible year of progress, milestones and value creation

#### 2020 is the year DurAVR<sup>™</sup> moved from concept to product

- Commenced FIH DurAVR<sup>™</sup> study
- "Best Innovation" awarded at PCR London Valves
- Developed unique commissure attachment method to enhance stress reduction
- Finalized specific tissue valve leaflet design to optimize DurAVR<sup>™</sup> in THV setting
- Achieved concept lock on DurAVR<sup>™</sup> THV design
- Developed Unique catheter that allows both steering and precise commissure alignment
- Conducted successful pre-submission meeting for EFS with FDA – achieved alignment on testing required
- Head to Head study comparing Medtronic AOA with ADAPT<sup>®</sup> – study demonstrated significant benefit in the ADAPT<sup>®</sup> arm
- Opening of Minneapolis Innovation Center

#### Aligning the commissures







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Aligned and fully deployed

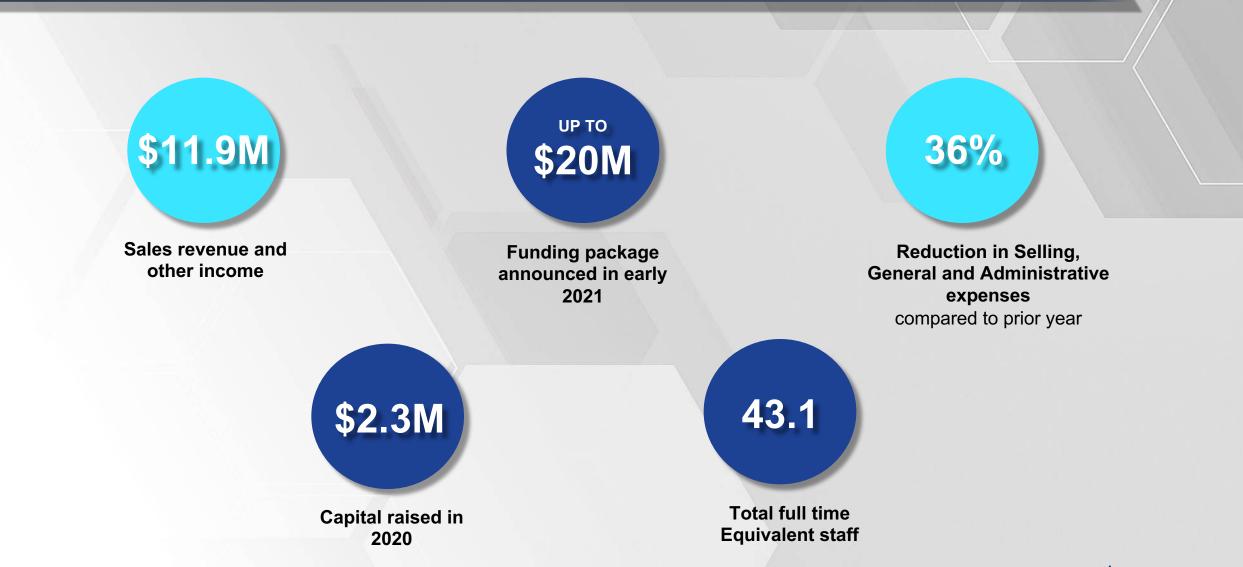
#### ComASUR™ Transfemoral Delivery System

- successful deployment and placement of DurAVR™ THV
- unique steerable catheter allowed for commissural alignment

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#### Financial highlights 2020



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## FY20 Financial information

\$ million	FY2019	FY2020 budget	FY2020 actual
ADAPT <sup>®</sup> revenue	10.2	6.8	6.2
Infusion revenue	6.9	-	0.9
	17.1	6.8	7.1
Gain on business divestments	24.9	-	-
Other income	0.6	2.1	4.8
	25.5	2.1	4.8
Other inventory costs	(6.4)	(2.1)	(2.7)
Selling, general and administrative costs	(34.5)	(23.6)	(22.1)
Impairment	(4.5)	-	-
Other	(3.4)	(1.8)	(2.4)
Net loss after tax	(6.2)	(18.6)	(15.3)

LeMaitre transaction in 2019 brought forward revenue/capital as well as reduced SG&A

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Ongoing 20% margin over costs

#### • Other income:

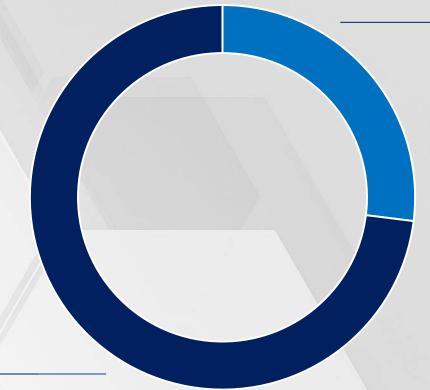
- Research & Development Tax Incentive
- 4C Licence income
- SG&A significantly reduced and primarily focused on production as well as Research & Development
- Covid-19 impacts
- Outperformance over internal budgets
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#### Breakdown of operational results

#### Research & Development \$11.1M

- DurAVR<sup>TM</sup> valve development program
- First-in-human trials
- Design of the TAVR delivery system
- Includes allocated Corporate costs

#### **Overall results \$15.3M loss**



#### Corporate & Operational \$4.2M

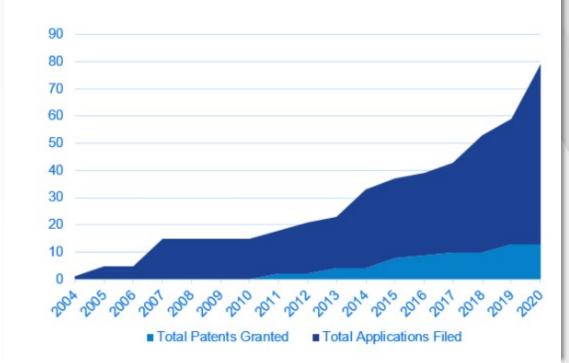
- Regulatory and Medical
- Capital raising costs
- Company compliance costs
- Insurance
- Financing costs
- Office administration
- IT support
- Net of R&D tax refund



# Due to the pace of development in 2020 patent applications increased dramatically

In 2020, Anteris:

- Filed **38** new applications throughout the world in 7 different patent families
- Received **2** issued patents (5% of pending applications)
- Received **1** notice of allowance in the United States







ADADT

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### Progress since code red - Our ability to pivot has been key



#### **Code Red Objectives**

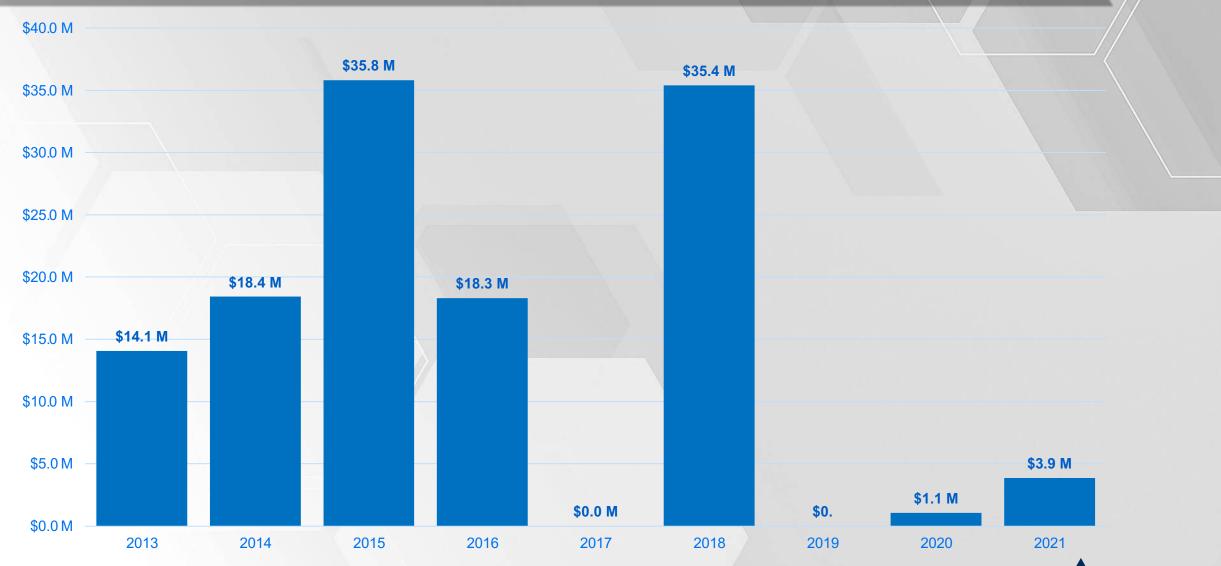
- Manufacturing pass rates to rise from a low of 22% to 75+%
- 250% increase in production output
- FTE reduction down 32% versus budget FY16/17
- CEO reports reduced by 50% more focused span of control
- Targeted expenditure reduction >\$12M per annum
- OPEX decrease >25%
- Total company sales rising >50% in FY17

#### Where we're at today

- Manufacturing pass rates have been consistently >70% since FY17 with pass rates of 76% in FY20
- Production output increased by 433% from 2,990 units in FY15 to 15,924 units in FY20
- FTE has reduced to 43.1 staff in FY20 which is 42% lower than the FY16/17 budget
- Executive management team has reduced by >50%
- Annual operating cash outflows in FY16 was \$39M. This was reduced to \$24M in FY20
- SG&A costs have decreased 26% from 2016
- ADAPT<sup>®</sup> sales have been restructured with LeMaitre transaction bringing forward many years of sales



#### Equity capital raised



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#### Capital raised through debt & equity



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### AVR share price and trading volumes





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Source: www.marketindex.com.au/asx/avr



# What is this disease and why are we competitive?



#### Aortic Stenosis has a high mortality rate within 2-3 years if left untreated

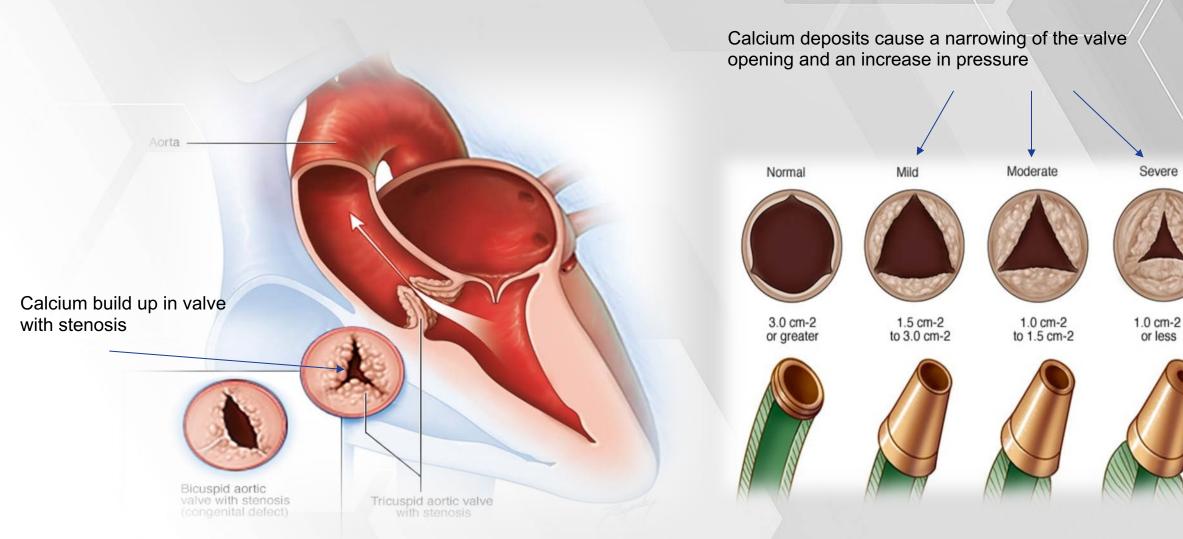
- It is estimated that 1 in 8 elderly Australians has Aortic Stenosis (AS).
- Calcific Aortic Stenosis is the most common cause of Aortic Stenosis.
- While up to 1.5 million people in the US suffer from AS, approximately 500,000 within this group of patients suffer from severe AS.
- Without an aortic valve replacement (AVR), as many as 50% of patients with severe AS will not survive more than an average of two years if they do not receive an aortic valve replacement.



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#### Aortic stenosis is a disease of calcification



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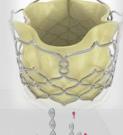
#### Anteris is focused on tissue science and valve technology

Three reasons Anteris will be the market leader in the future

DurAVR<sup>™</sup> is first and only 3D singlepiece aortic valve

Clinically proven ADAPT<sup>®</sup> anti-calcification treatment

DurAVR<sup>™</sup> THV Delivery System for Commissural Alignment





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DULAVE

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# What the experts are saying



# WHAT THE



#### Anteris 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



Paul Sorajja, MD Abbott Northwestern Hospital Minneapolis, MN







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

Alan Zajarias, MD

St. Louis, MO



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



Bernard Prendergast, MD St Thomas' Hospitals London

Samir Kapadia, MD

**Cleveland Clinic** 

Cleveland, OH

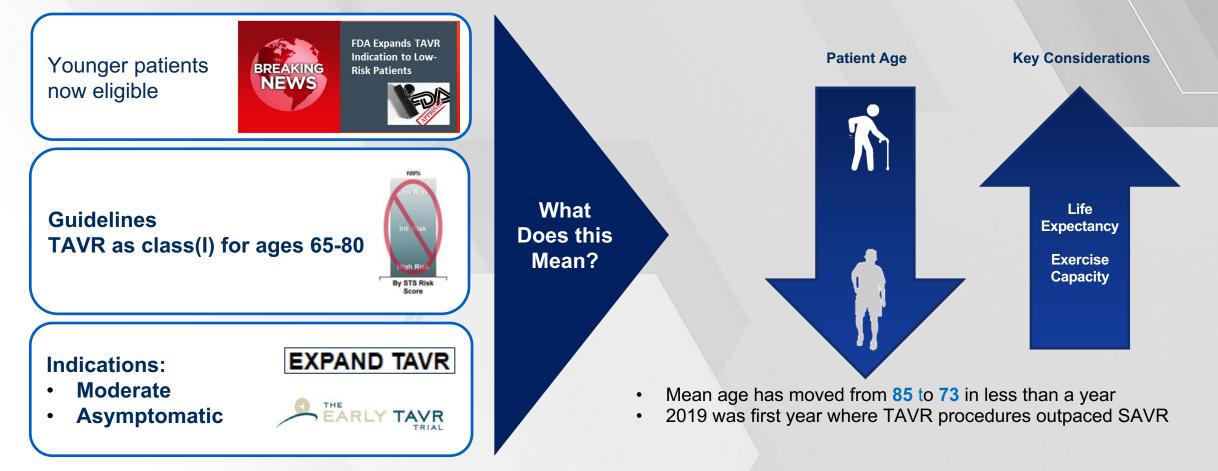


ADAPT for life



## Younger patients need new solutions

#### Younger patients need longer lasting next generation valve technology





ADAPT

Otto, et al. ACC/AHA Guideline, JACC,2021, 77, e25-197 Bagur R, et al. Heart. 2017;103:1756-1759 Carroll, et al STS ACC TVT Registry JACC

#### Current solutions attempt to address 4 key areas

#### **Current products fall short in two critical areas**





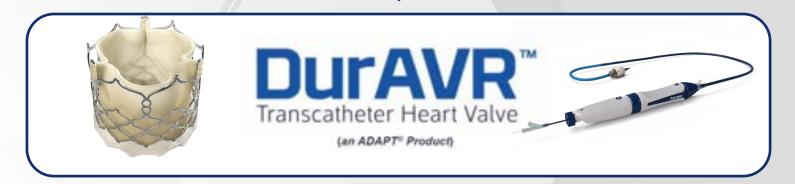
# DurAVR<sup>™</sup> THV satisfies all 4 key areas

ComASUR<sup>™</sup> delivery system is more predictable with commissural alignment Better hemodynamics at rest and during increased cardiac output (exercise) DurAVR's<sup>™</sup> 3D uni-body design has greater structural integrity + ADAPT<sup>®</sup> anticalcification treatment

Predictable Procedure Optimal Hemodynamic Performance

Low Incidence of Complications

Durability







# The Australian perspective





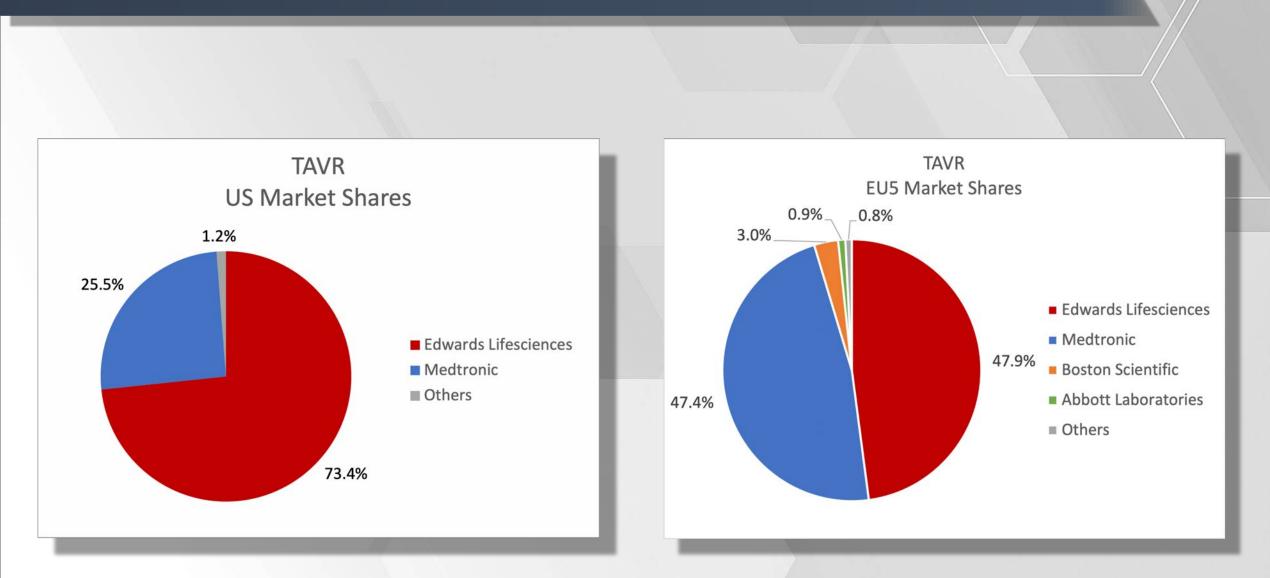
11-11 Contraction of the local division of the loc -A CONTRACTOR OF Karl Poon, MD rventional Cardiologi



# **The Competitors**

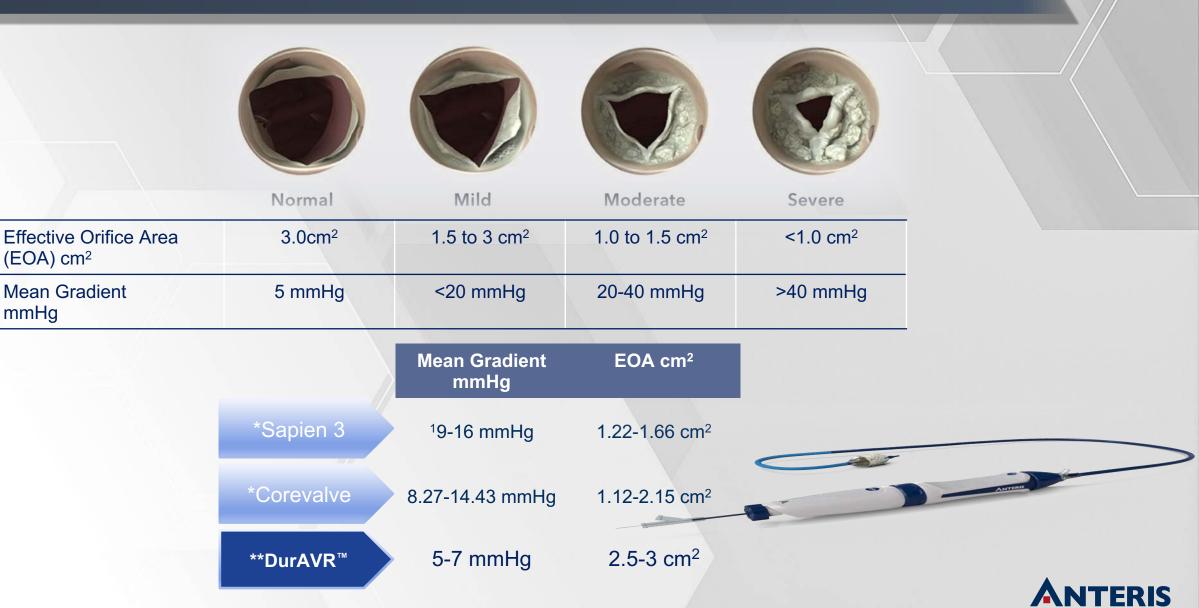


## TAVR Market Shares by Region (US & EU5)

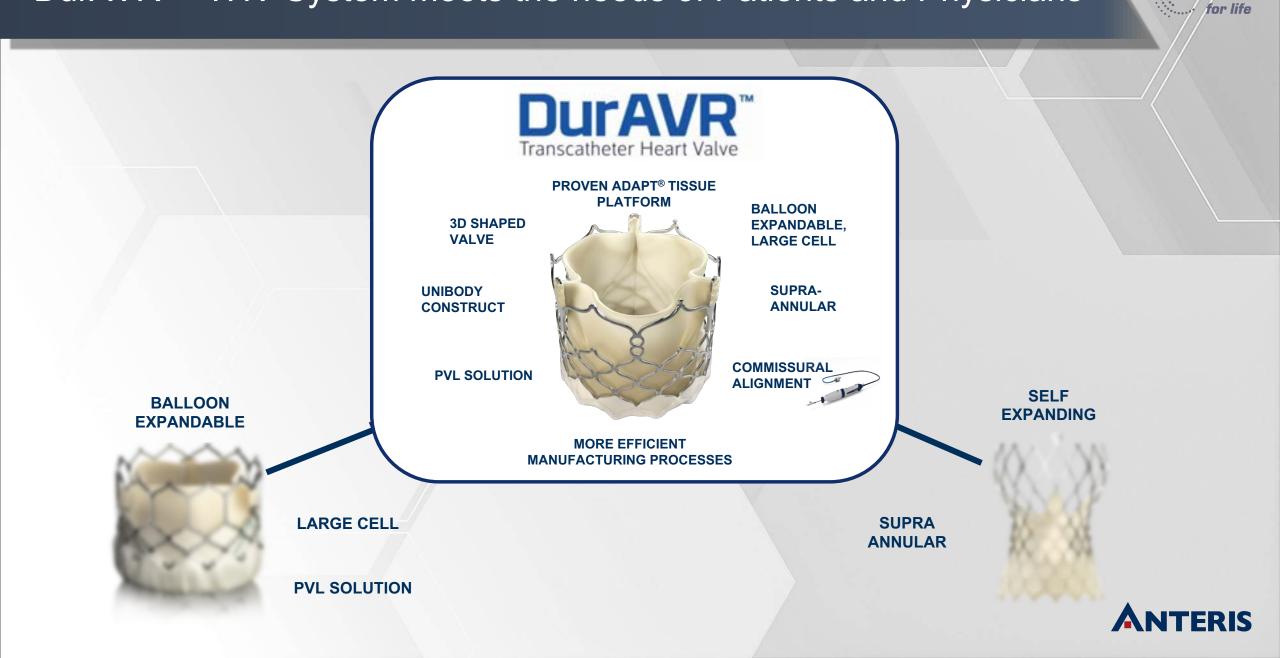




## DurAVR<sup>™</sup> better by design



#### DurAVR<sup>™</sup> THV System meets the needs of Patients and Physicians



## DurAVR<sup>™</sup> THV System designed to go the distance



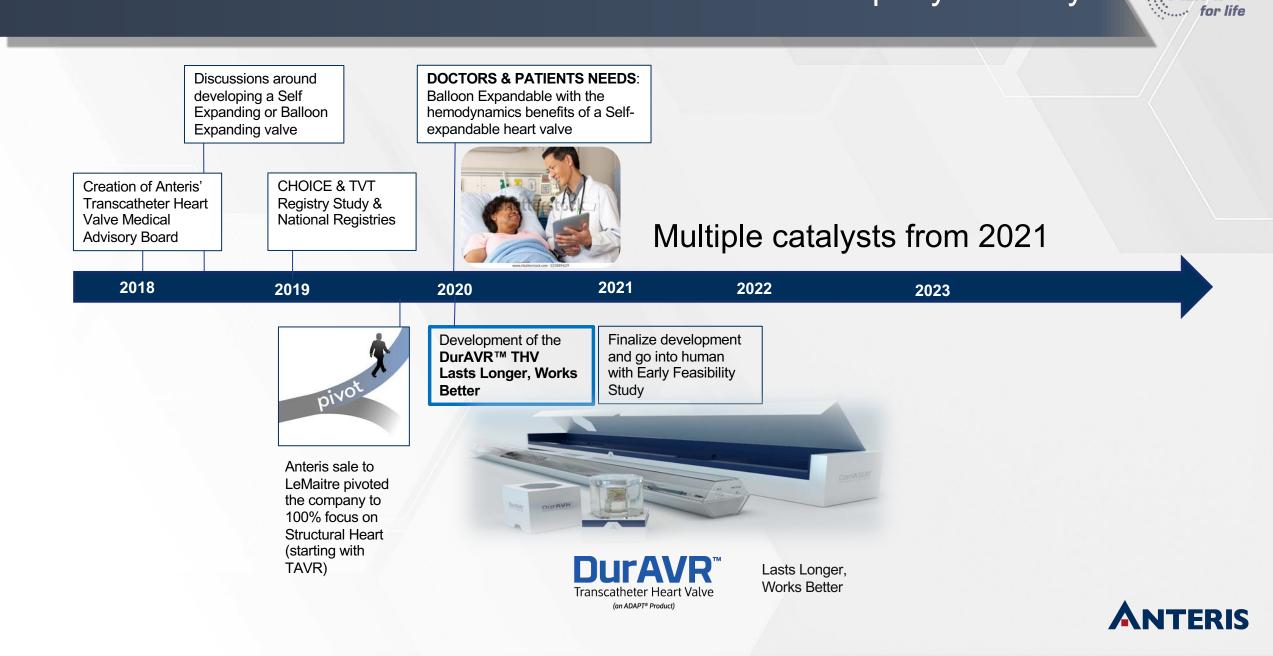
ADAPT

Data on file Hahn et al, JACC CV Imaging 2019 Fuchs, et al, J Am Coll Cardio Int 2018

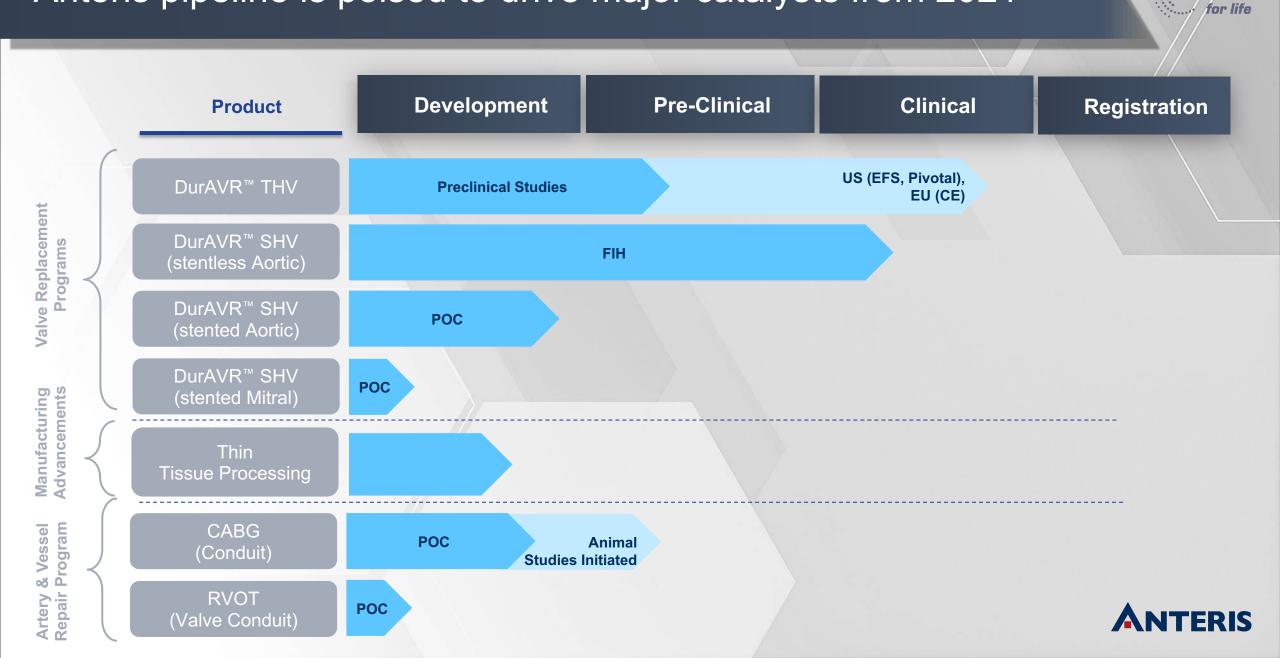
#### The road ahead



#### 2021/2022 will be the most transformational in the company's history



#### Anteris pipeline is poised to drive major catalysts from 2021



#### Shareholder questions

- When will you get a partnership?
- When can we get the licence fee deal implied in the MST report?
- If you need to go it alone how will you secure capital for this?
- When raising capital why do retail holders not get an option to participate ?
- Is Resilea a real competitor to ADAPT<sup>®</sup>?
- When do you expect the SAVR study to conclude?
- Is DurAVR<sup>™</sup> "better" or as good as the competitors ?
- Of the three key innovations which is more important, innovative and unique to ensure doctors use our products over the competitors?
- Do you think we are more likely to be (A) acquired, (B) partnered or (C) go it alone?
- When will we list on the NASDAQ?







DAPT

# A great team in the right locations

#### Exceptional individuals doing exceptional things **Biologics Manufacturing / R&D** Innovation Centre & Corporate HQ Strategic Hub in Europe (Malaga, Australia) (Minneapolis, USA) (Geneva, Switzerland) Finance & IT Team (Brisbane, Australia) ANTERIS



### Conclusions - We are now in the window of certainty

It's been an incredible year of progress and achievement – we now have a very competitive product ready to enter its registration studies

This is no longer a discussion about will we be able to develop a product, or if it's competitive

The risk clinical failure is very low

- We no longer need to speculate about whether this product will get to market. It will
- We don't need to speculate as to whether DurAVR<sup>™</sup> will capture market share in the USD 10b market year on year. It will
- We don't need to wonder if we have the support of the medical community, the health care analysts or major investors. We do

# UNCERTAIN



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## Mary is 72 years old and living with Aortic Stenosis





- Her stenosis has become so severe, she is no longer able to do things she loves, such as going for long walks with her grandkids
- Her doctor says she needs a new valve soon otherwise she may not live too much longer
- Recent approvals have made it possible for Mary to get her valve replaced without complicated and risky open-heart surgery – it's called TAVR, and it is proven just as safe and effective as surgery
- While her new valve will save her life, unfortunately it won't fully restore her level of physical activity, and will need to be replaced in 5-8 years – and perhaps even within 2 years
- Mary asks her doctor "why is there not a valve that works better and lasts longer?"







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

#### North America

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