

# ASX ANNOUNCEMENT

29 May 2024

## **Annual General Meeting Chairman's Address and Chief Executive Officer Presentation**

**SYDNEY**, 29 May 2024: Anteris Technologies Ltd (ASX: AVR) is pleased to provide the attached Chairman's Address and Chief Executive Officer Presentation to the Annual General Meeting being held today

**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 55,000 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.

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**Authorisation and Additional information**

This announcement was authorised by Mr Stephen Denaro, Company Secretary.

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Address by the Chairman Mr John Seaberg

As usual at our AGM meetings I make you suffer through a few minutes of Chairman ramblings before turning the mic over to the guy you really want to hear from, your CEO, Wayne Paterson. Thank you for indulging me and I promise to be brief.

First off, please know that your Board of Directors has been actively and effectively governing this company as an intact team for years now. So, many thanks to Steve Denaro, Wenyi Gu and Wayne Paterson for years of service on this Board. Each of these Directors brings unique and relevant backgrounds to this Board and we have developed a collegial and open dialogue that allows each of us to be heard and to eventually align on what we believe is best for shareholders.

About 15 years ago, I was on a Nasdaq board, amazingly enough, for a company that processed Bovine tissue used for various patching applications such as hernia repair, and we took some governance training. In that training it was emphasized that an important duty of Directors, acting on behalf of shareholders, is to Recruit and Retain a highly qualified CEO. I'm proud of the fact that we were able to recruit and retain Wayne because we are very pleased with his results so far. Not only has he re-focused the Company totally on Structural Heart markets but he has attracted a world class medical advisory board and a highly effective management team. Today, our product and our stellar clinical results are presented from numerous podiums at key conferences around the world.

I mention the above because I've come to think of our management team's responsibility as being like parents raising a gifted child. Now whether that child is gifted in sports, music or academics, the parent's job is to bring out the best in the child.

And of course, our gifted child is our DurAVR™ TAVR device. And it is not hyperbole to describe it as gifted. After 45 years in the Cardiovascular device space, I've never seen a device with the market potential of DurAVR™. We now have enough human data to feel confident that we'll do very well in our upcoming pivotal clinical trials. And once approved, we have a product to sell that can take majority market share in the \$10 Billion and growing TAVR market.

But feeling confident doesn't mean being reckless. Our ultimate success is too important to our future patients and our shareholders to cut any corners. Our management team and our Advisory Board are focused on doing it right because that's the only way to ensure great clinical outcomes. The world needs this product because it has the potential to save thousands of lives and to ensure a better quality of life for our patients. But the work gets harder now, the closer we get to success. And so, I thank Wayne, David St. Denis our Chief Operations Officer, Dr Chris Meduri our Chief Medical Officer and Matt McDonnell our CFO and the many others who are making all this happen. Your strong efforts are needed and appreciated!

I promised to be brief, so let me close by saying to you our shareholders, you are invested in a great product that is backed up by highly skilled people. If things continue as planned, you will be well rewarded!



# Annual General Meeting

Anteris Technologies Ltd

29 MAY 2024

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Anteris 2023/24 AGM



# Financial report

## Balance sheet

<b>Assets</b>	<b>1,734,826</b>
Current assets	88,905
Non-current assets	1,645,921
<b>Liabilities</b>	<b>166,630</b>
Current liabilities	110,327
Non-current liabilities	56,303
<b>Equity</b>	<b>74,393</b>
Paid-in capital	72,921
Retained earnings	1,472



## Equity statement

<b>Current year</b>	<b>1,774,576</b>
Comprehensive income	15,897
Issue of share capital	88,905
Dividends	23,853
<b>Previous year</b>	<b>166,630</b>
Comprehensive income	110,327
Issue of share capital	56,303
Dividends	67,676



## Income statement

<b>Revenues</b>	<b>12,978,516</b>
Net sales	12,873,892
Investment	104,624
<b>Expenses</b>	<b>6,372,535</b>
Research and Development	1,385,395
Operating expenses	4,439,118
Marketing	548,022
<b>Net income</b>	<b>6,505,981</b>



## Cash flow statement

<b>Operations</b>	<b>12,978,516</b>
Earnings	12,873,892
Depreciation	104,624
<b>Investing</b>	<b>6,372,535</b>
Real estate	1,385,395
Equipment	4,439,118
<b>Financing</b>	<b>6,505,981</b>
Dividends	6,505,981



2023 Financials

# FY2023 Key Numbers

CASH  
**\$30.8M\***  
COMPARED TO  
\$13.8M  
AT 31 DEC 2022

SALES REVENUE  
+ OTHER INCOME  
**\$7.0M**

CAPITAL RAISED  
IN 2023  
**\$78.9M**

R&D COSTS  
**\$45.8M**  
COMPARED TO  
\$25.1M IN 2022

**96.4\***  
FTE &  
CONTRACTORS  
supporting  
Anteris' business  
strategy

# Financial Highlights 2023

Key Financial Metrics	FY2022 Actual \$m	FY2023 Actual \$m
Market capitalization (31 Dec)	308.6	341.3
Cash position (31 Dec)	13.8	30.8
Capital raised (gross)	34.9	78.9
Sales revenue and Other income	6.7	7.0
Operating expenditure	(52.0)	(74.7)
FX and other	<u>1.0</u>	<u>(1.4)</u>
Net loss before tax	(44.3)	(69.1)

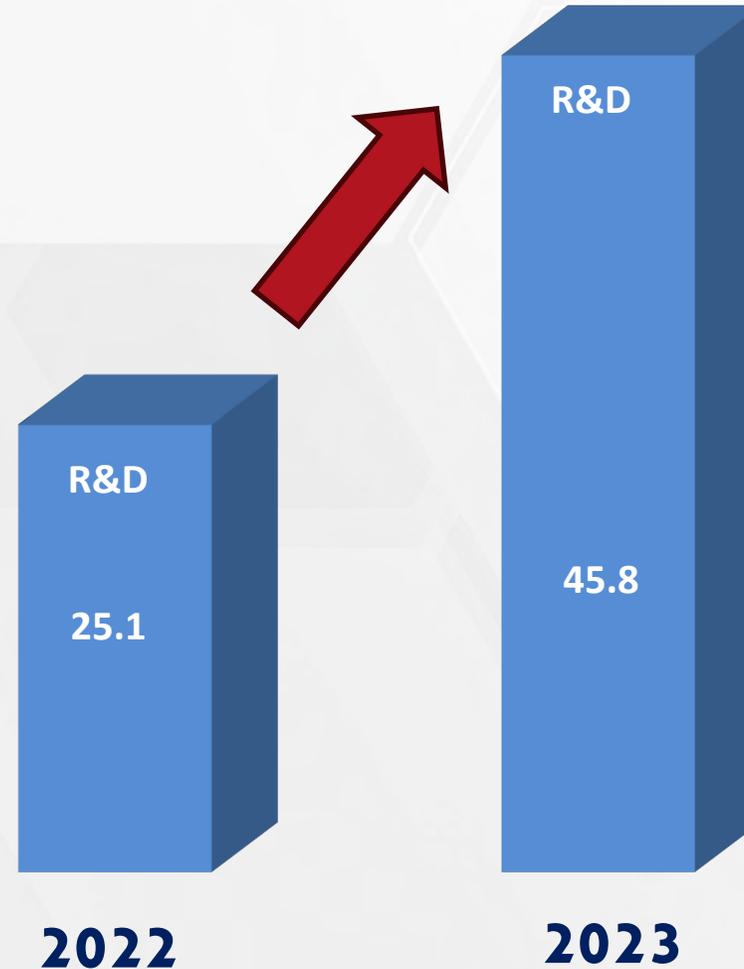
- Strengthened balance sheet at year-end following a successful capital raise
- Revenues and Other income include ADAPT® sales and R&D tax incentive income
- Operating expenditure includes significant R&D growth to support approval process



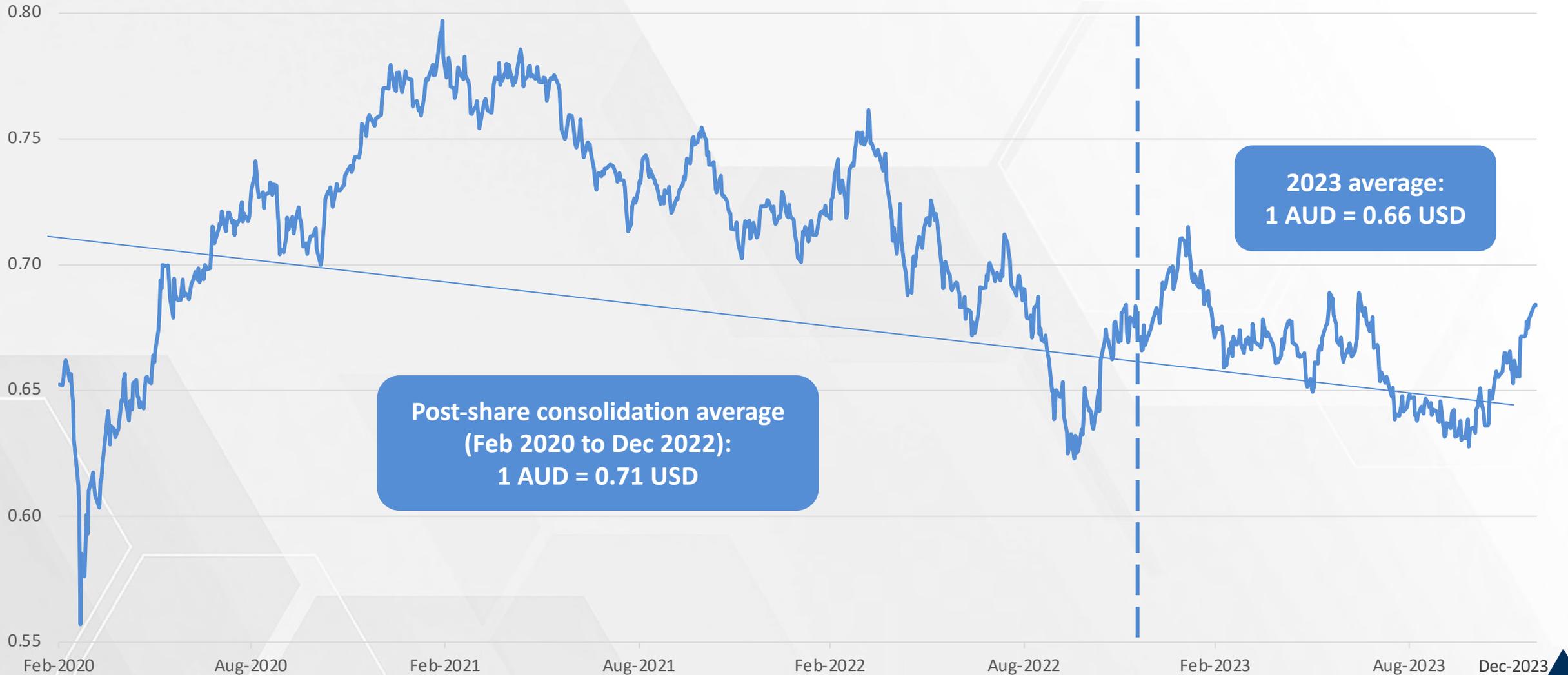
# Focused R&D Expenditures Driving the Path to Approval

## Research and development

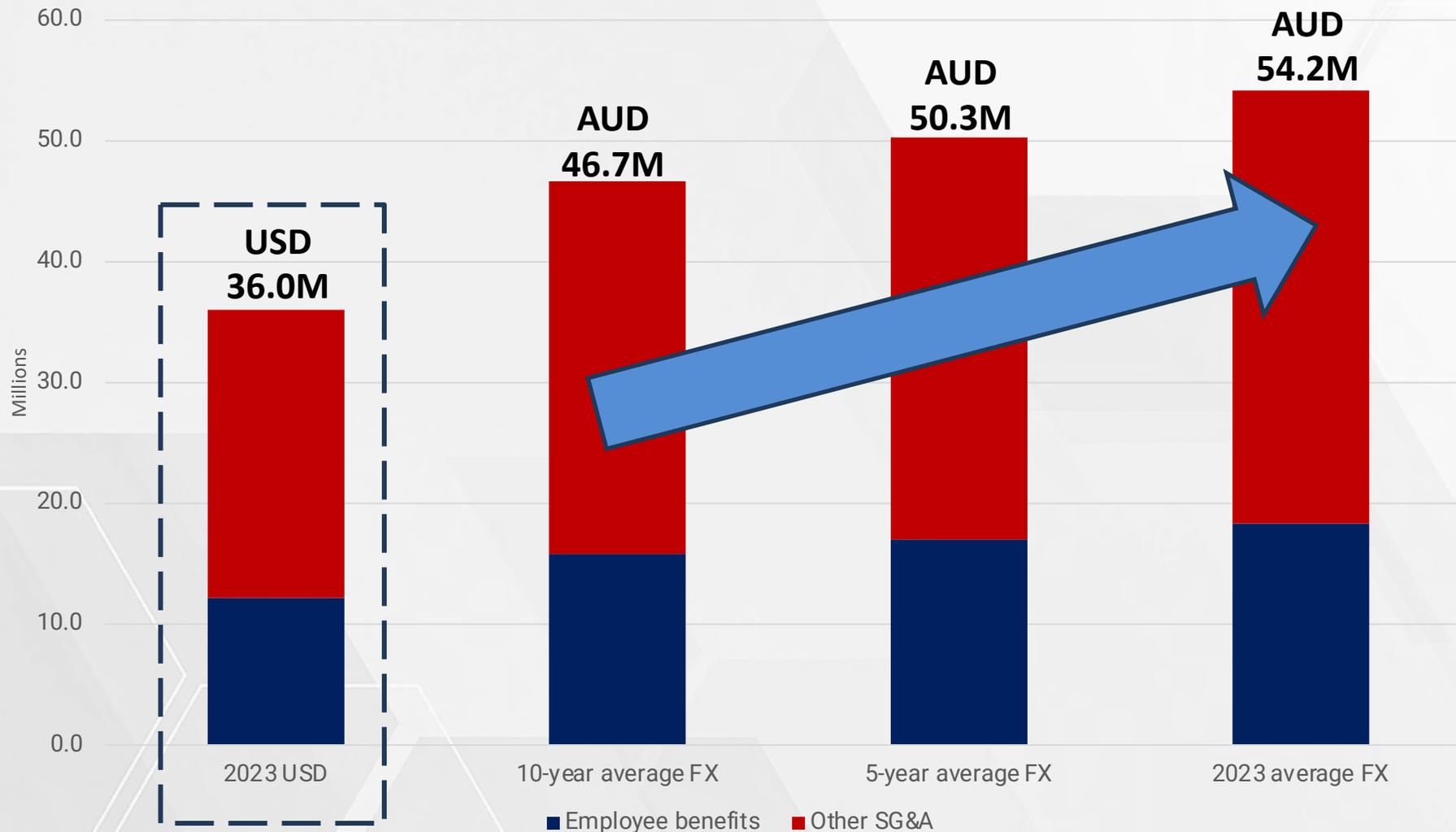
- DurAVR™ valve development program
- EFS
- Valve-in-valve procedures
- Valve science program
- Upscaling manufacturing capabilities
- Medical affairs
- Regulatory affairs



# Negative FX Impact Over the Past Years as AUD has Declined to USD



# USD Expenditures Translates to 50% Increase in AUD Costs



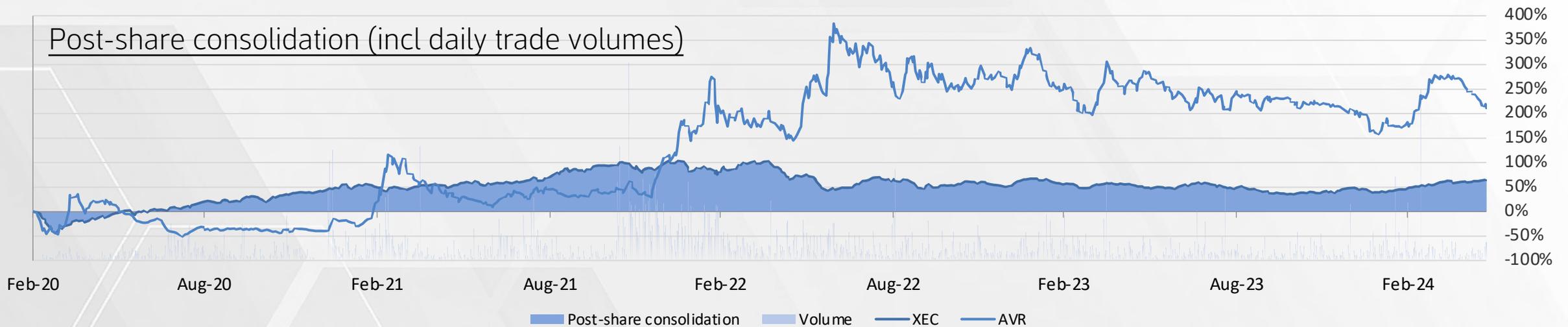
- USD \$36.0M of expenses incurred in 2023 converted into A\$54.2M
- The same USD \$36.0M using the prior 10-year average FX rate converts into A\$46.7M

# AVR has Returned 210% Since the Share Consolidation

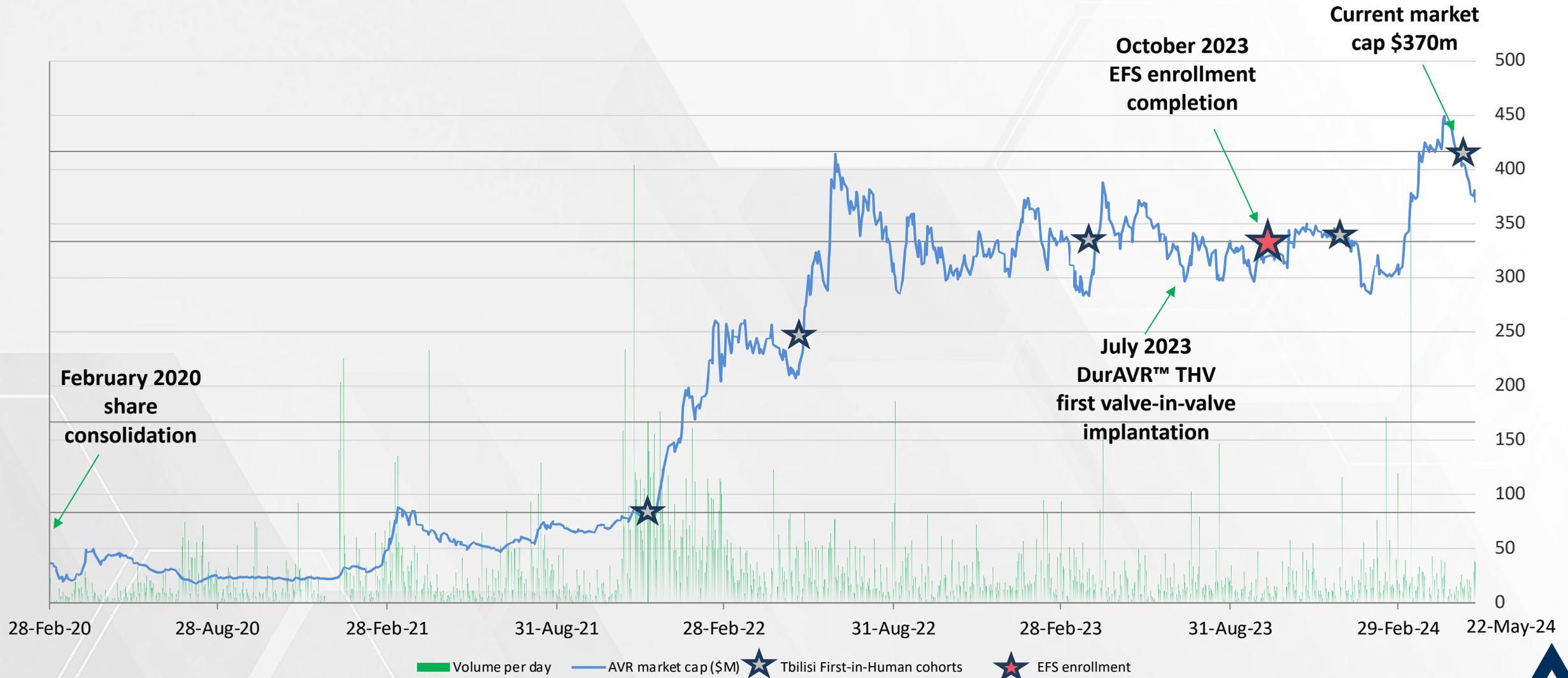
- The S&P/ASX Emerging Companies Index (XEC) is a benchmark consisting of 200 Australian microcap companies ranked anywhere between 350 to 600 by market capitalization
- The below graph compares the performance of the AVR share price vs XEC index since the CardioCel™ divestiture

	AVR return	XEC return
Post-share consolidation	210%	65%

Post-share consolidation (incl daily trade volumes)



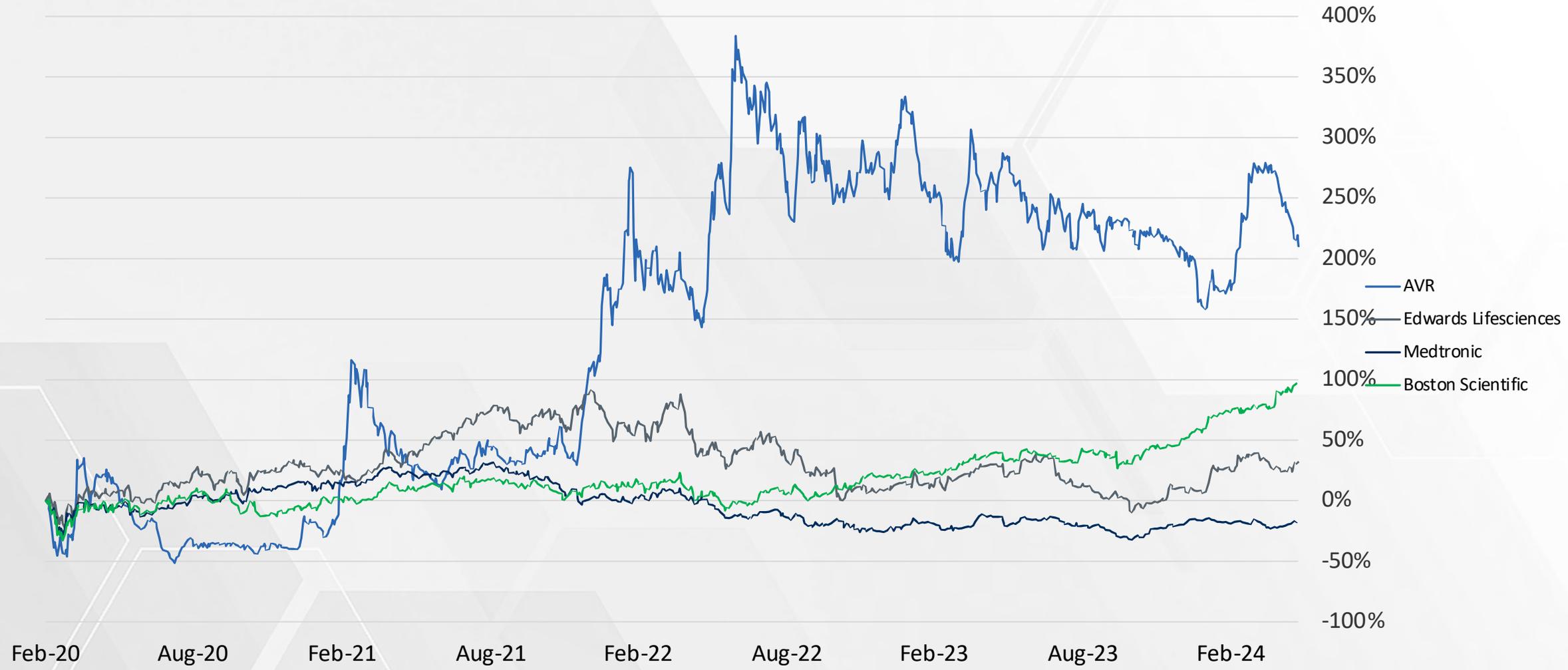
# Market Capitalization Increase of > 1800% since Consolidation



Volume per day AVR market cap (\$M) ★ Tbilisi First-in-Human cohorts ★ EFS enrollment

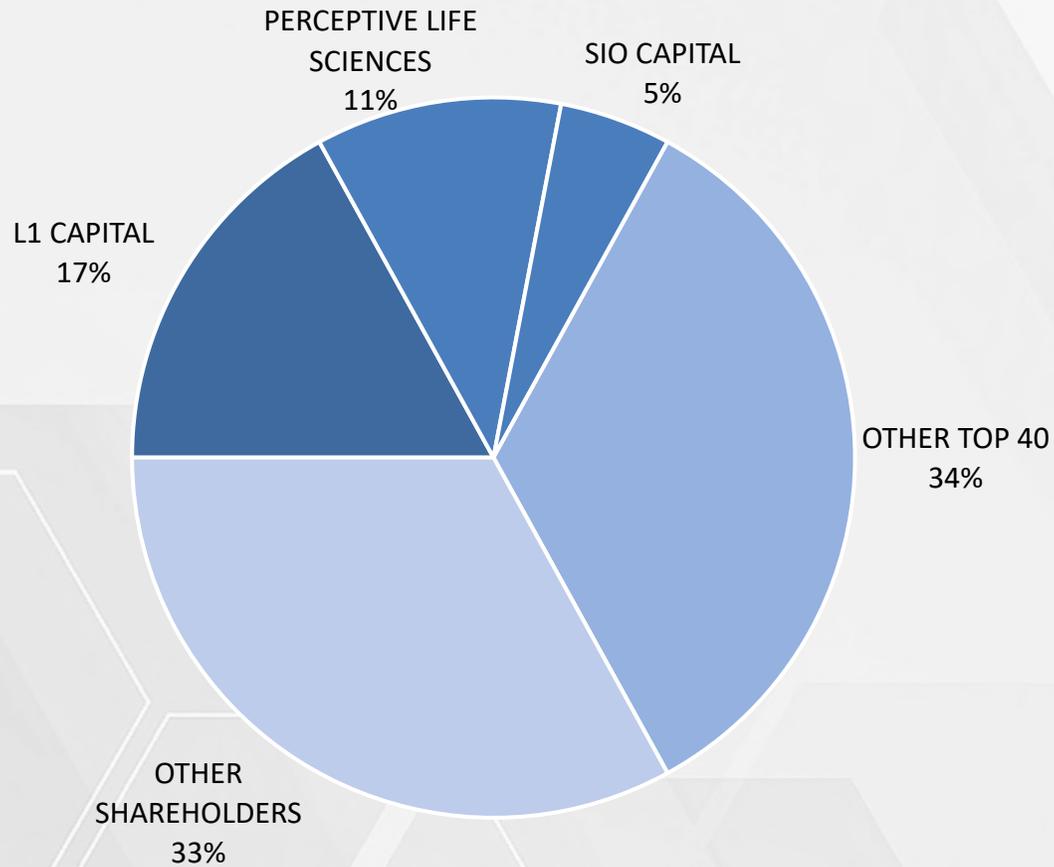


# AVR has Outperformed Major TAVR Competitors since First Patient Data

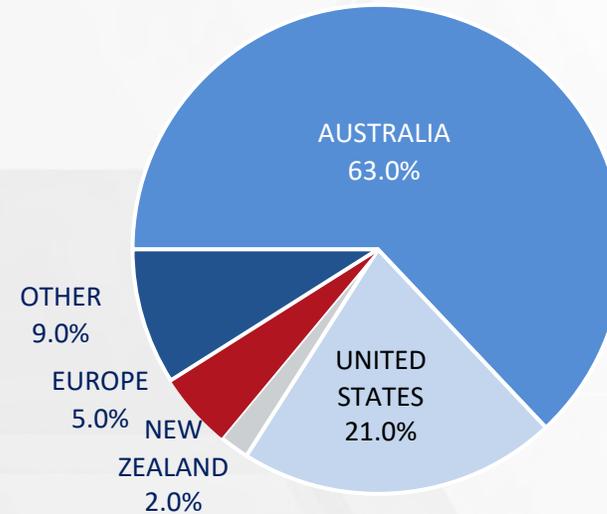


# Top 40 Investors Hold 68% of the Company

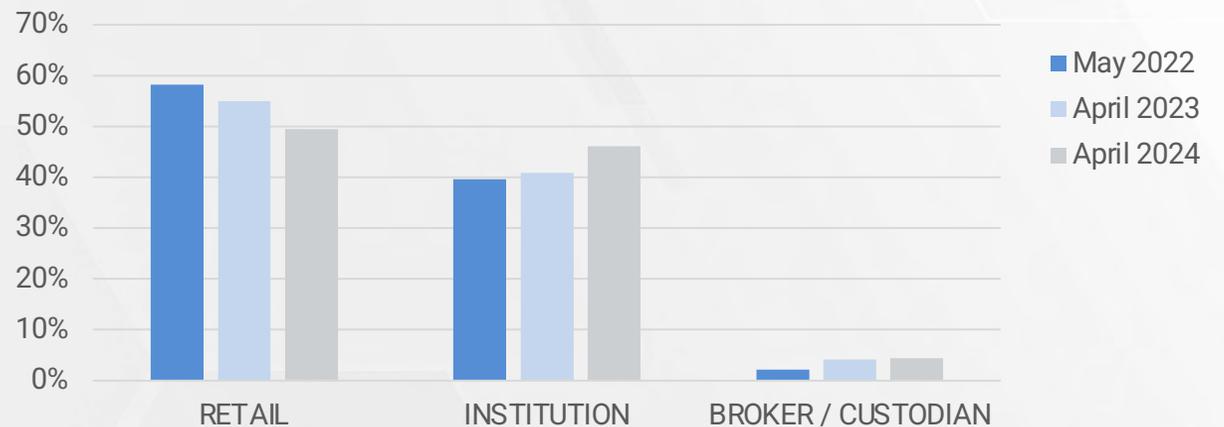
## SHAREHOLDER MIX



## OWNERSHIP COUNTRY

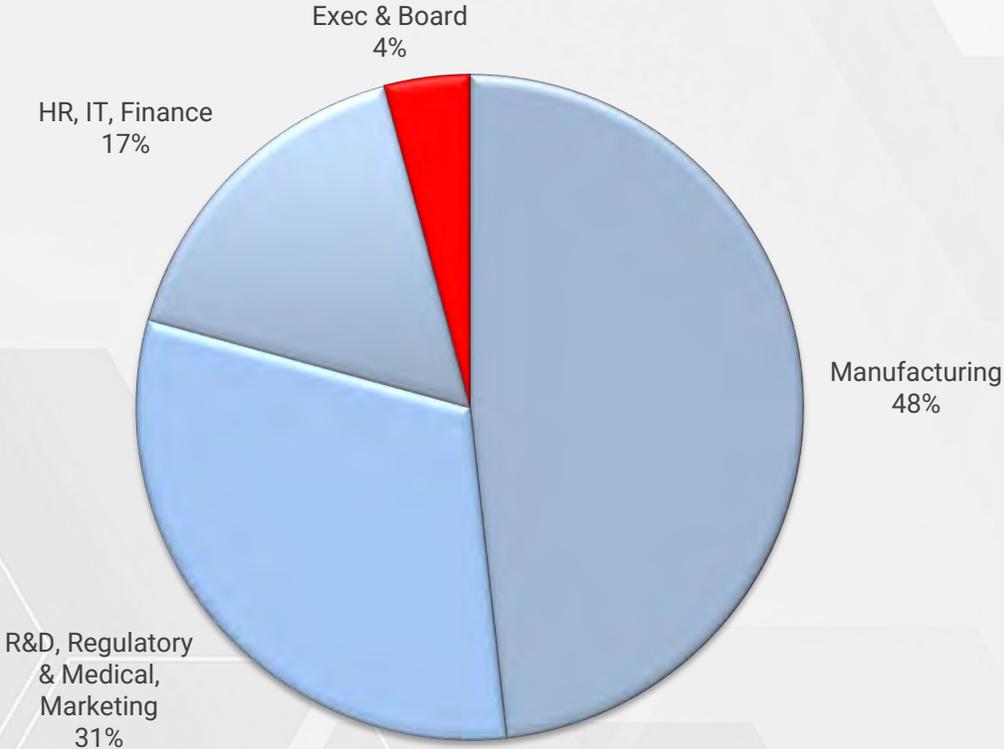


## INVESTOR TYPE HISTORY



# Anteris Has a Talented and Diverse Work Force

### FTE by Function

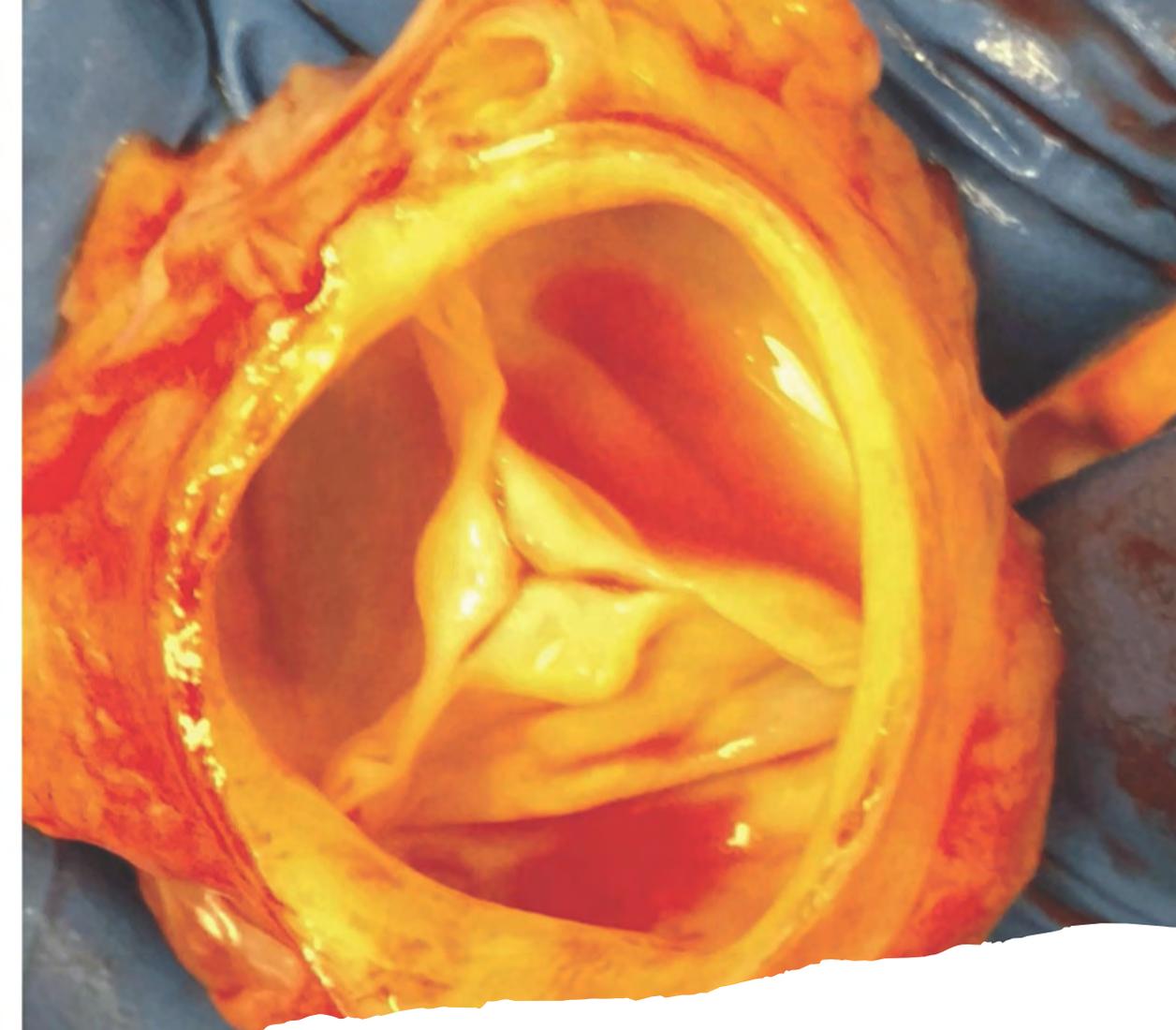


### Multicultural Workforce



\* Data as at 31 December 2023, including contractors



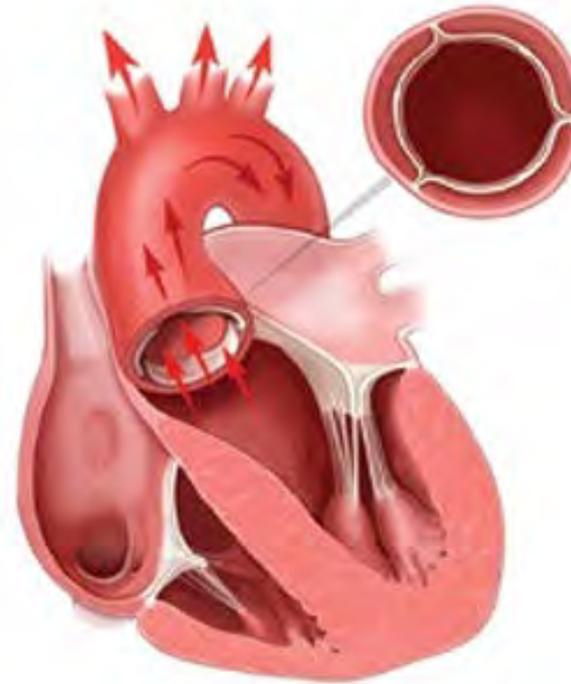


Let's talk about Aortic Stenosis

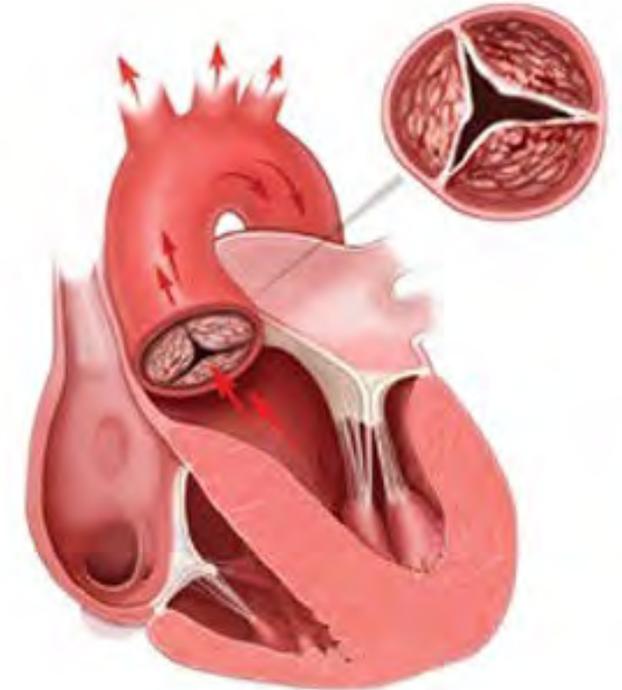


# Aortic Stenosis is a Life Threatening Disease

AS is a serious life threatening disease affecting 1 in 8 elderly Australians



*Aortic Valve opens widely*



*Aortic Stenosis opening restricted*



Anteris has significantly expanded its patient numbers to 64 in the past 12 months



# The TAVR Market

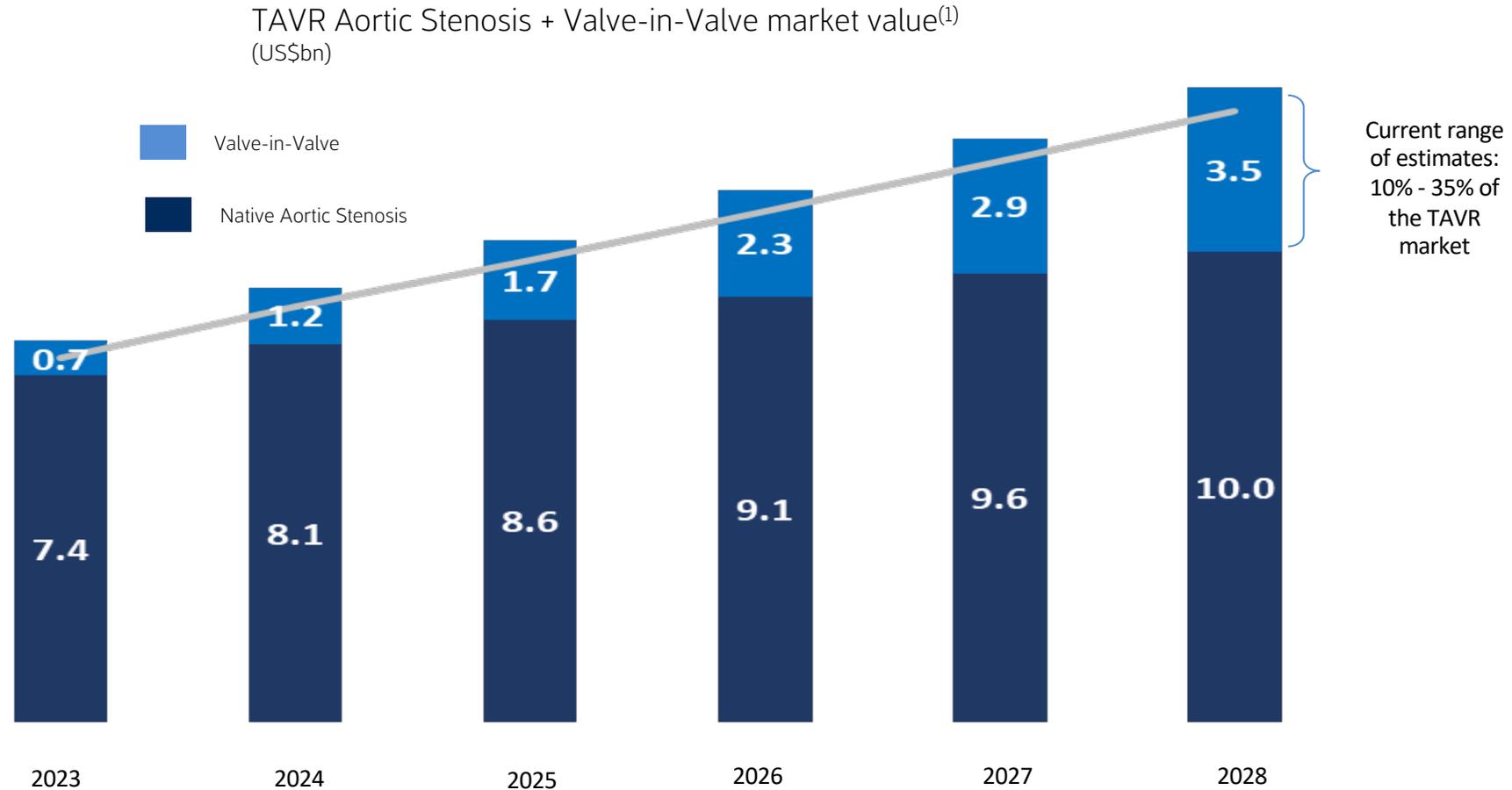
An anatomical illustration of the TAVR (Transcatheter Aortic Valve Replacement) procedure. The top half shows a catheter with a valve being inserted into the aorta. The bottom half shows the valve expanded and seated within the native aortic annulus. A blue arrow points to the valve's contact with the annulus.

## ADVANCED SEALING

Increased Surface Area  
Contacting Native Annulus

# TAVR is a US\$10 bn+ Market Opportunity

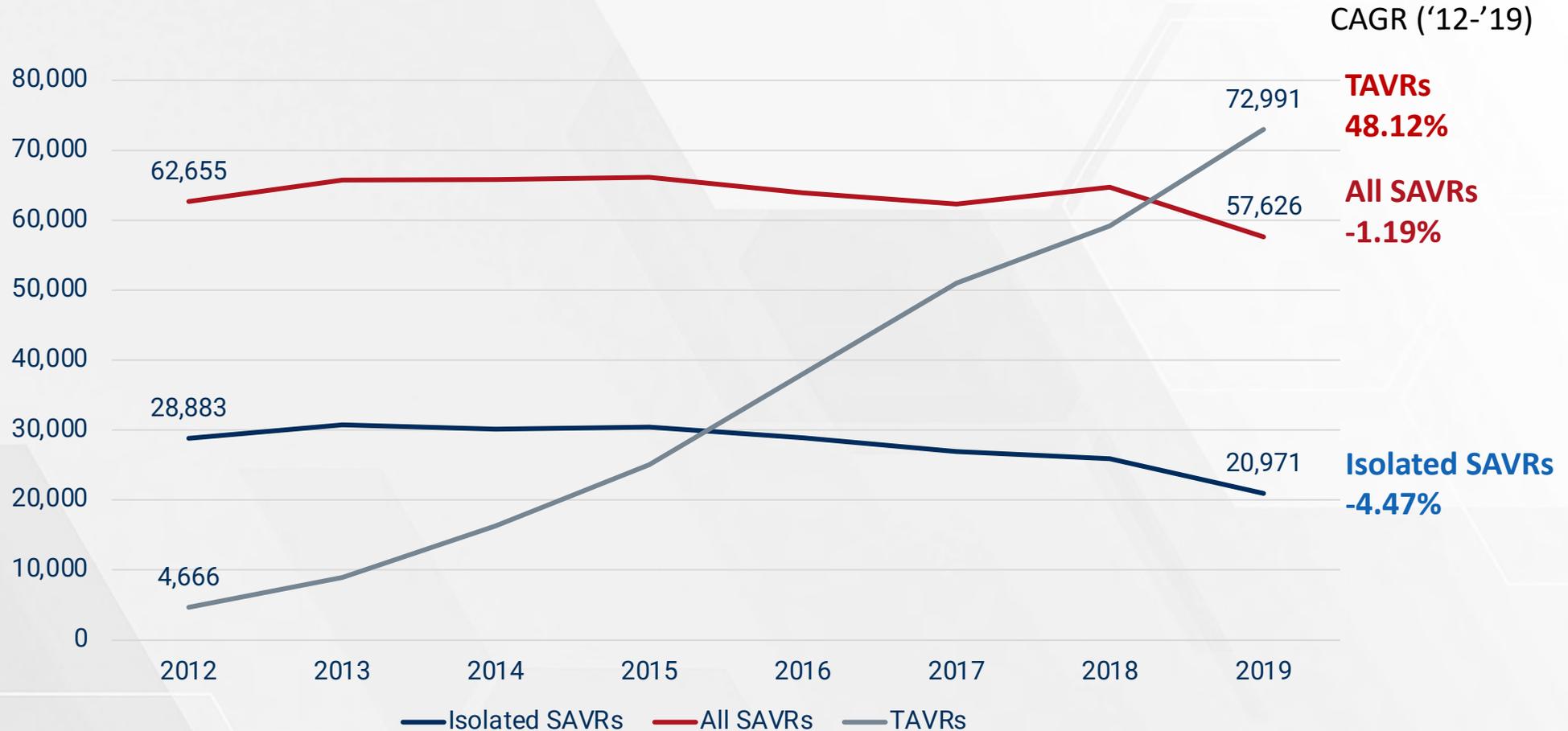
The aortic stenosis patient population is under penetrated, with only ~15-20% of severe AS cases treated today.



The world population continues to age rapidly and the incidence of aortic stenosis and severe aortic stenosis is growing with the population



# TAVR will Continue to Grow at a Significant Rate

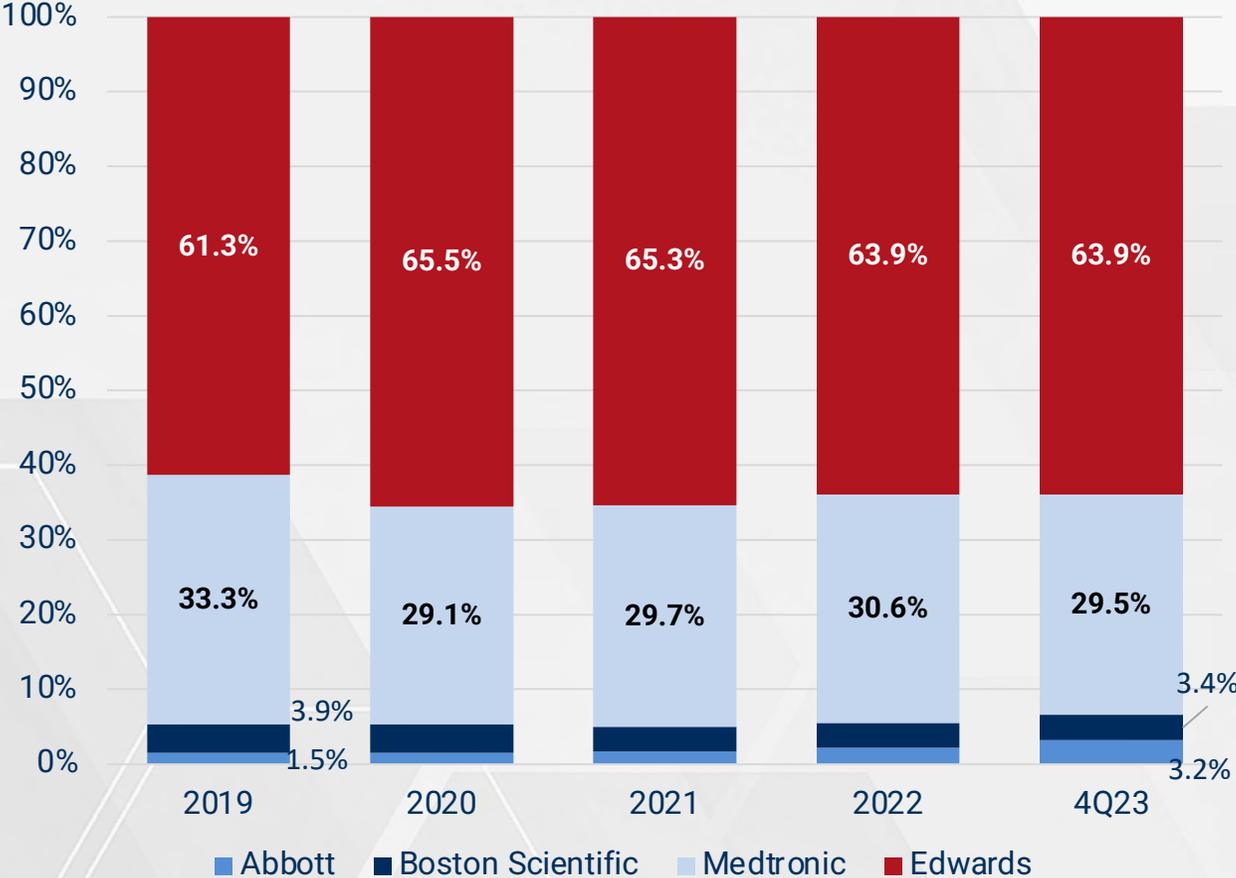


The volume of isolated surgical aortic valve replacement (SAVR), all forms of SAVR (SAVR + coronary artery bypass grafting, Bentall procedures, and SAVR plus other surgical procedures), and transcatheter aortic valve replacement (TAVR)

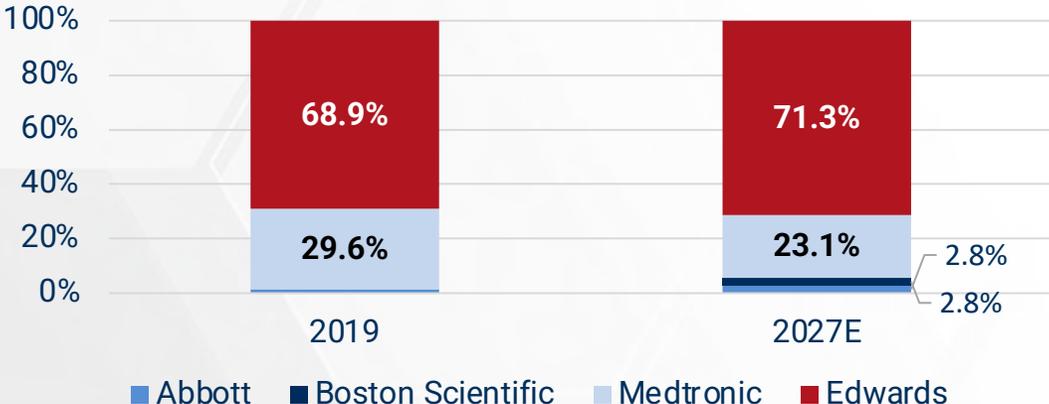


# Balloon Expandable Technologies have the Majority of Market Share

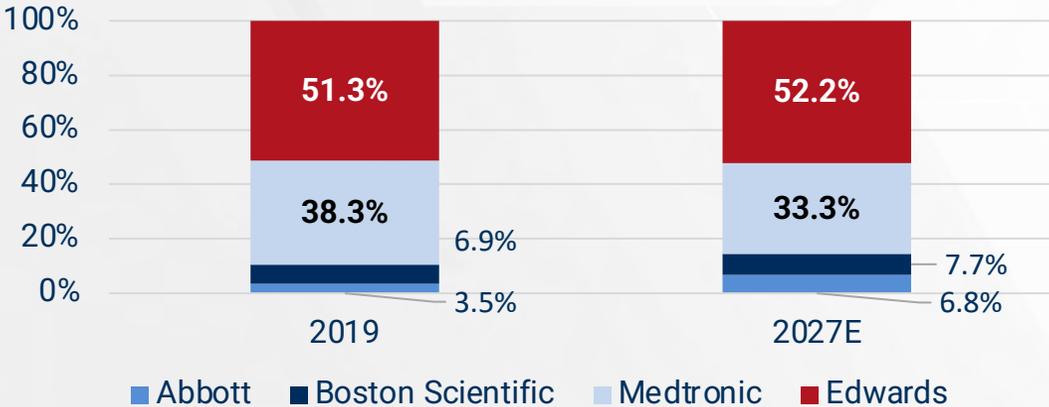
### WW TAVR \$ Market Share



### US TAVR \$ Market Share



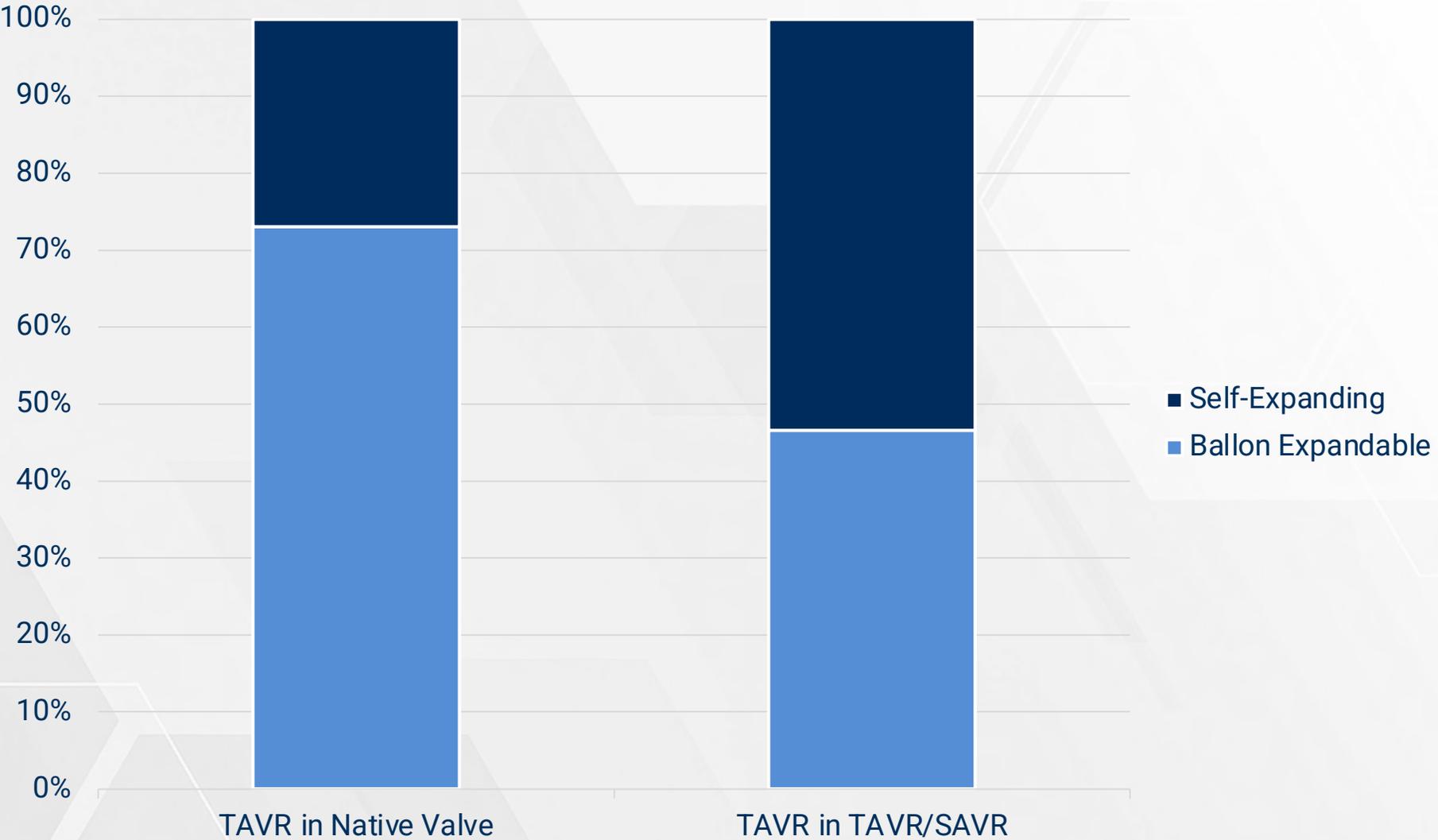
### OUS TAVR \$ Market Share



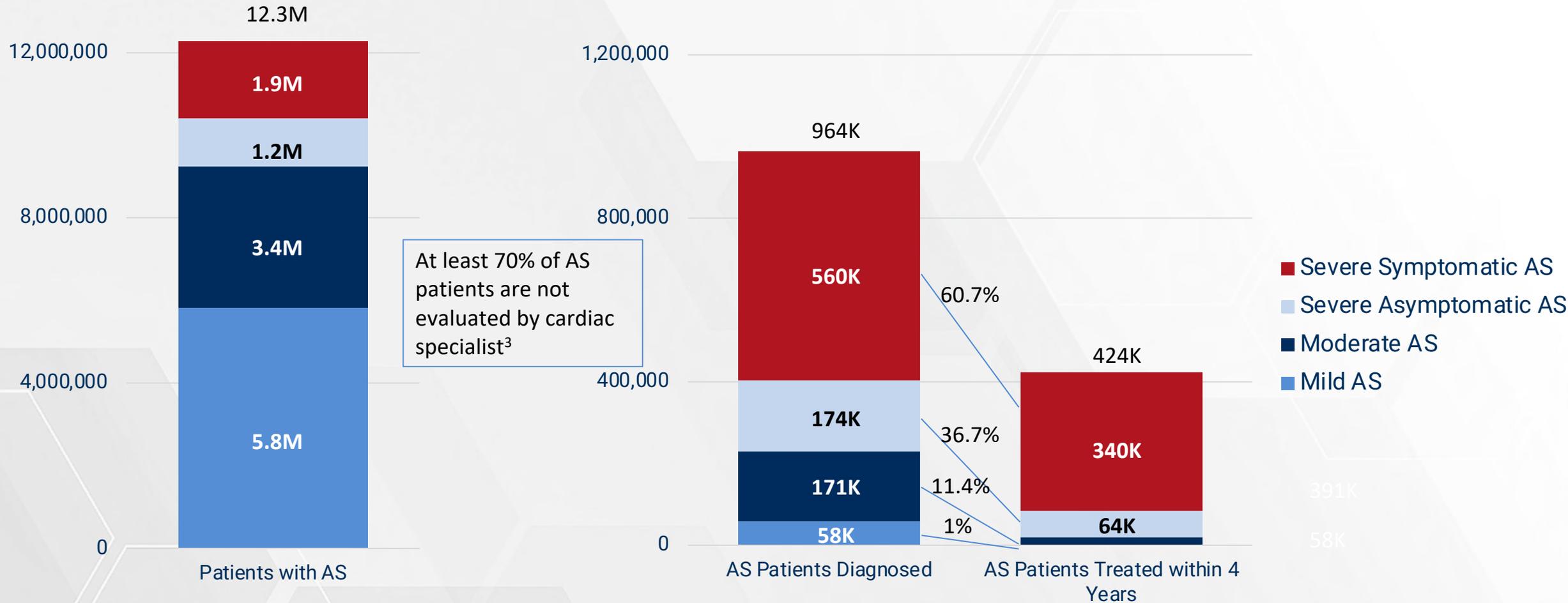
Source: UBS Estimates; Company Reports, Visible Alpha March 2024



# Balloon Expandable TAVRs are Favored in First Implantation, but Currently Valve-in-Valve are Seeing Greater Use of Self-Expanding



# There are over 12M Patients with Aortic Stenosis, but Diagnosis and Treatment Remains Underpenetrated



- <https://data.worldbank.org/indicator/SP.POP.65UP.TO?locations=EU-US-GB>
- Osnabrugge, R, Mylotte, D, Head, S. et al. Aortic Stenosis in the Elderly: Disease Prevalence and Number of Candidates for Transcatheter Aortic Valve Replacement: A Meta-Analysis and Modeling Study. J Am Coll Cardiol. 2013 Sep, 62 (11) 1002–1012. <https://doi.org/10.1016/j.jacc.2013.05.015>
- Bach DS, Siao D, Girard SE, Duvernoy C, McCallister BD Jr, Gualano SK. Evaluation of patients with severe symptomatic aortic stenosis who do not undergo aortic valve replacement: the potential role of subjectively overestimated operative risk. Circ Cardiovasc Qual Outcomes. 2009 Nov;2(6):533-9. doi: 10.1161/CIRCOUTCOMES.109.848259. Epub 2009 Oct 27. PMID: 20031890.
- Généreux P, et al. J Am Coll Cardiol. 2023;82(22):2101–2109.





Go to

**Market**

**Strategy**



# Product Launches and Market Share are Not a Function of Luck

- The **commercial plan** was written before the product existed and drove the product design
- The **Medical Advisory Board** was chosen for their experience, center volume, podium presence and influence, to facilitate the market adoption at launch
- The **Product was designed to fill a need in the market** – ie its not a “me too” but a highly differentiated first in class (Biomimetic) product
- The most important issues of **clinical benefit, ease of use, and normal flow have been achieved.**
- The **first physician designed TAVR** and delivery system
- Compact **step wise launch. 20-40 Centers** in the US
- **5-10 Centers in the EU**
- Proportional increase in resources as adoption increases.
- **Break even achievable within 6-9 months** post launch



# So What Drives Adoption?

- ✓ Clinical data – superiority
- ✓ Ease of use
- ✓ Advanced science
- ✓ Physician peer advocacy
- ✓ Hands on experience

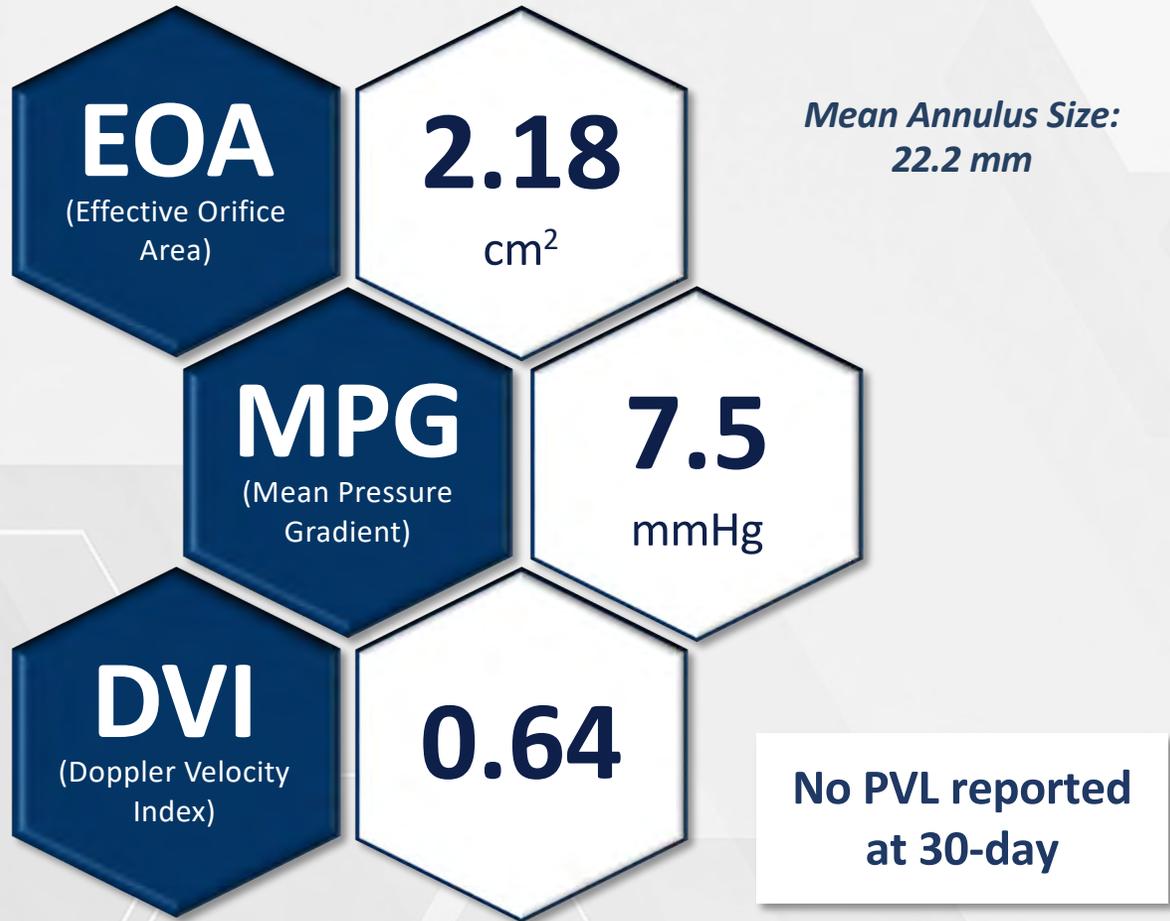




# Clinical Data

# DurAVR™ EFS: Excellent 30-Day Results

## Paradigm Shifting 30-Day Hemodynamic Results\*



\* Follow-up Echo Core Lab Analysis

## Excellent Safety Profile

30 Day Events	N = 15
<b>Primary Safety Endpoints</b>	
All-cause mortality or disabling stroke	0 (0)
<b>Secondary Safety Endpoints</b>	
All-cause mortality	0 (0)
Disabling Stroke	0 (0)
VARC-3 type 2-4 bleeding	0 (0)
Major vascular or structural heart complications	0 (0)
Acute Kidney Injury (AKI) Stage 3 or 4	0 (0)
Moderate or severe aortic regurgitation	0 (0)
New permanent pacemaker due to procedure-related conduction abnormalities (**)	1 (6.7)
Surgery or intervention related to the device, including aortic valve reintervention	0 (0)

Data presented as n (%)

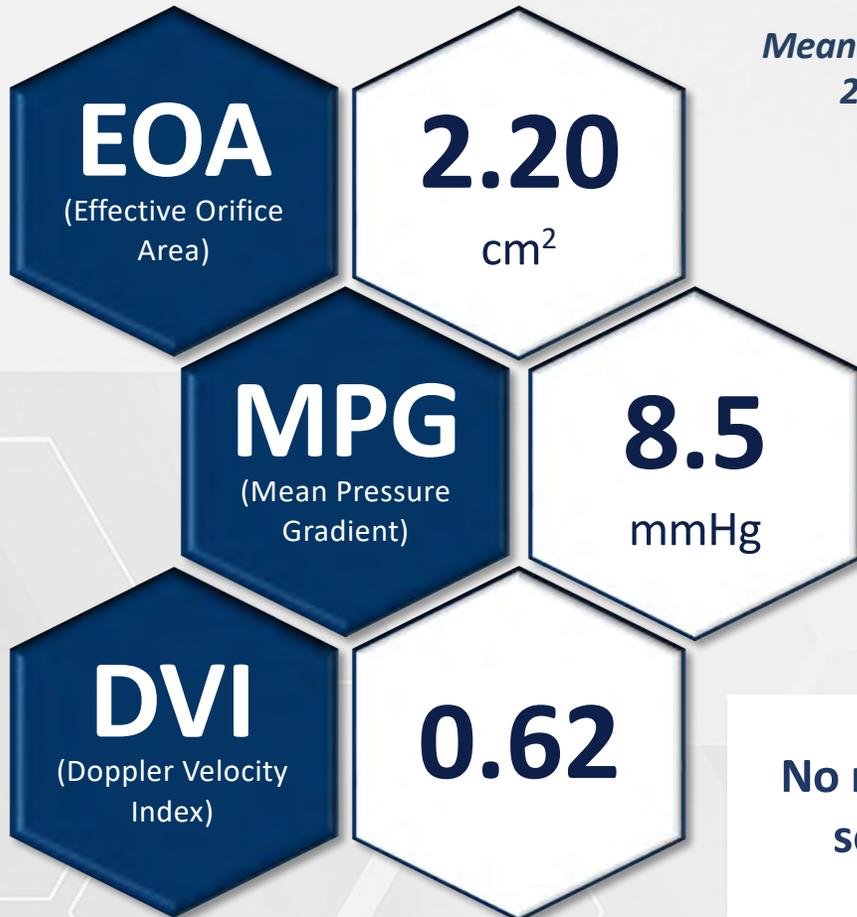
(\*\*) Subject with pre-existing significant conduction abnormalities with prolonged QRS



# DurAVR™ FIH: Consistent Hemodynamic Results through 1 Year

## Excellent Post-procedure Hemodynamic Results

(N=41)

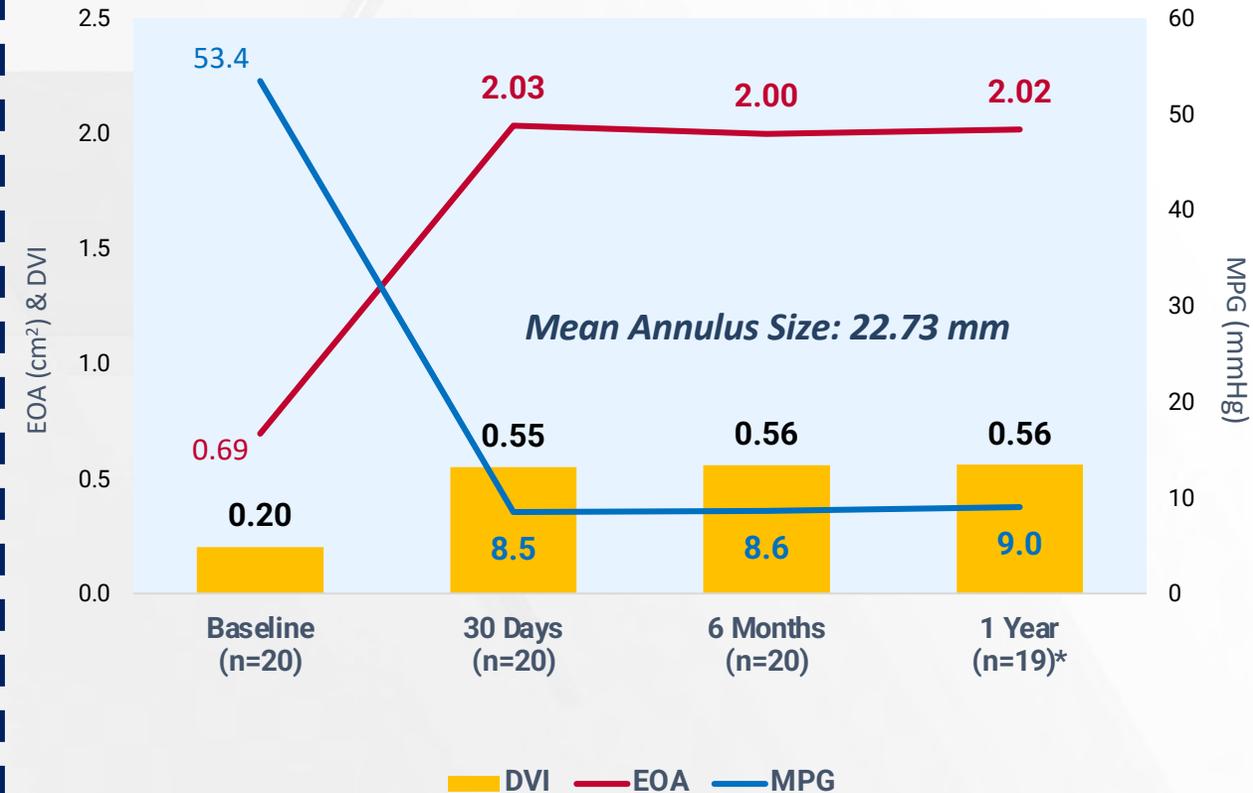


Mean Annulus Size:  
22.57 mm

No moderate or severe PVL

## Sustained Hemodynamics Through 1 Year

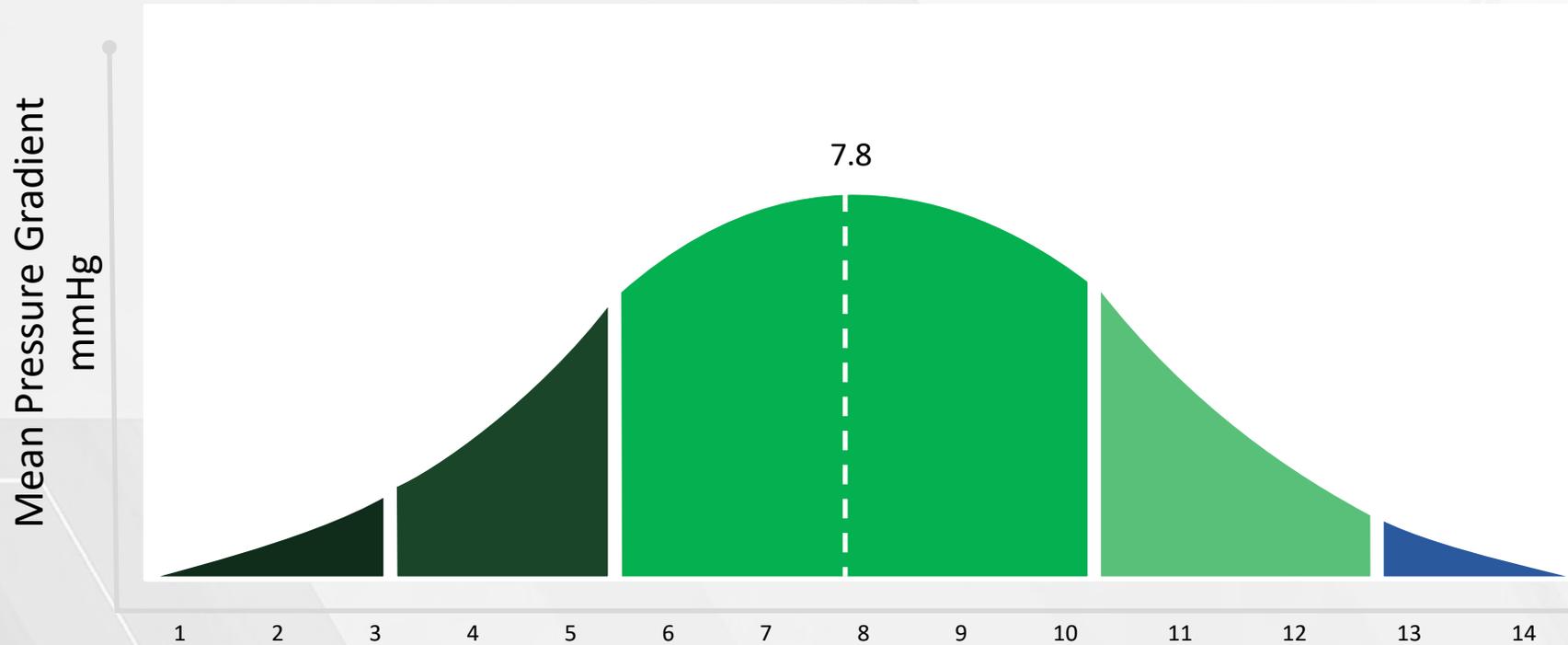
FIH 1 Year (to date)



\* One subject died before reaching the 1-year follow-up (non-cardiac death)



# DurAVR™ has Excellent Hemodynamics Patients at 30 Days



## 30 Day Follow Up

43 Patients

Mean Gradient 7.8 mmHg

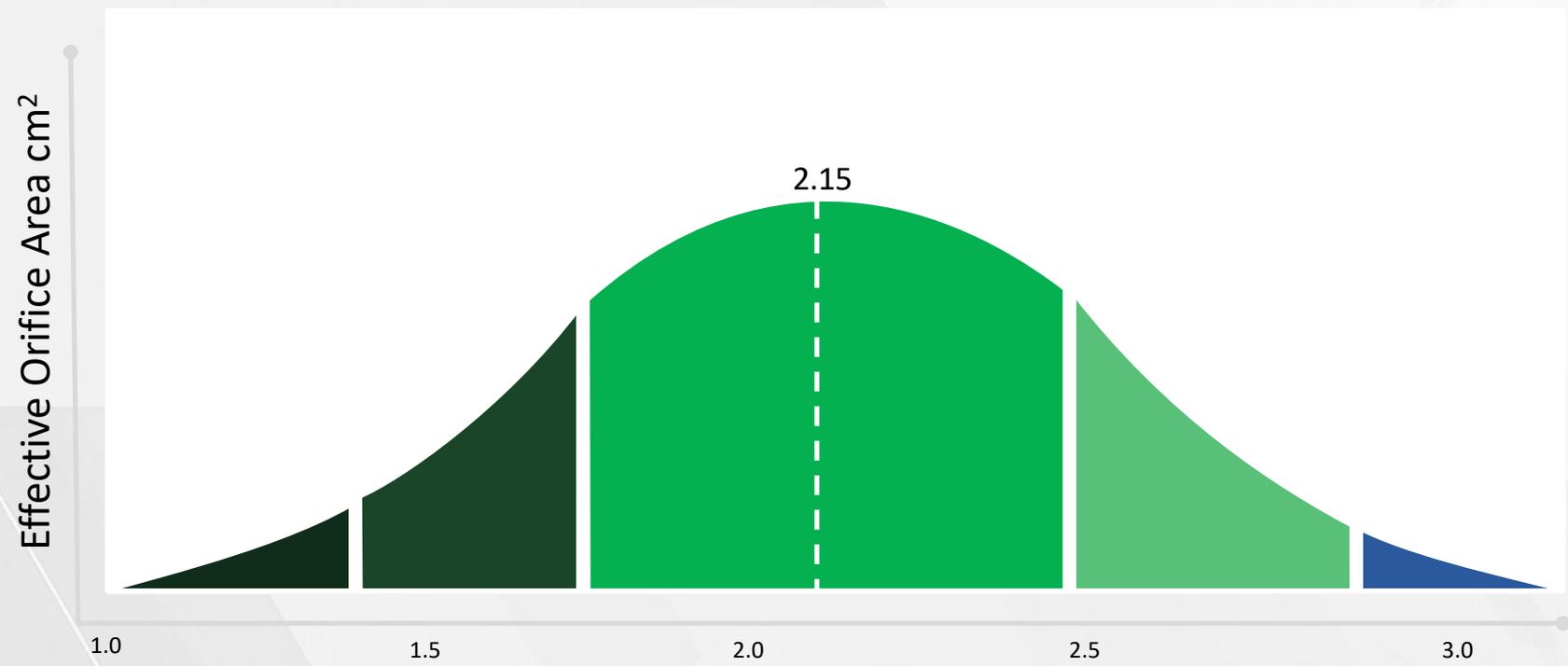
Mean Annulus 22.48 mm

← 68.2% →

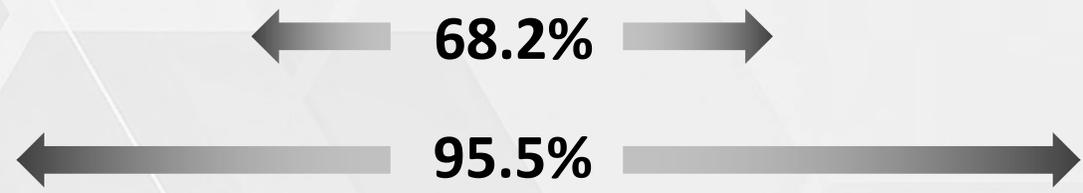
← 95.5% →



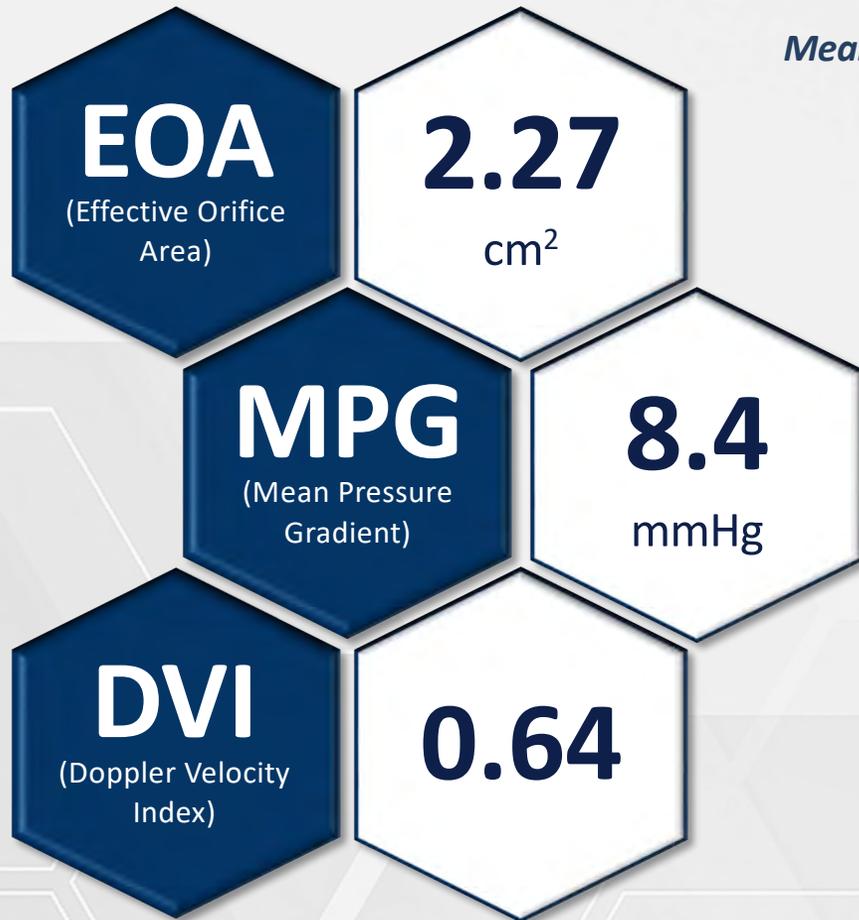
# Outstanding Effective Orifice Area in DurAVR™ Patients at 30 days in Small Annulus



**30 Day Follow Up**  
43 Patients  
EOA 2.15 cm<sup>2</sup>  
Mean Annulus 22.48 mm

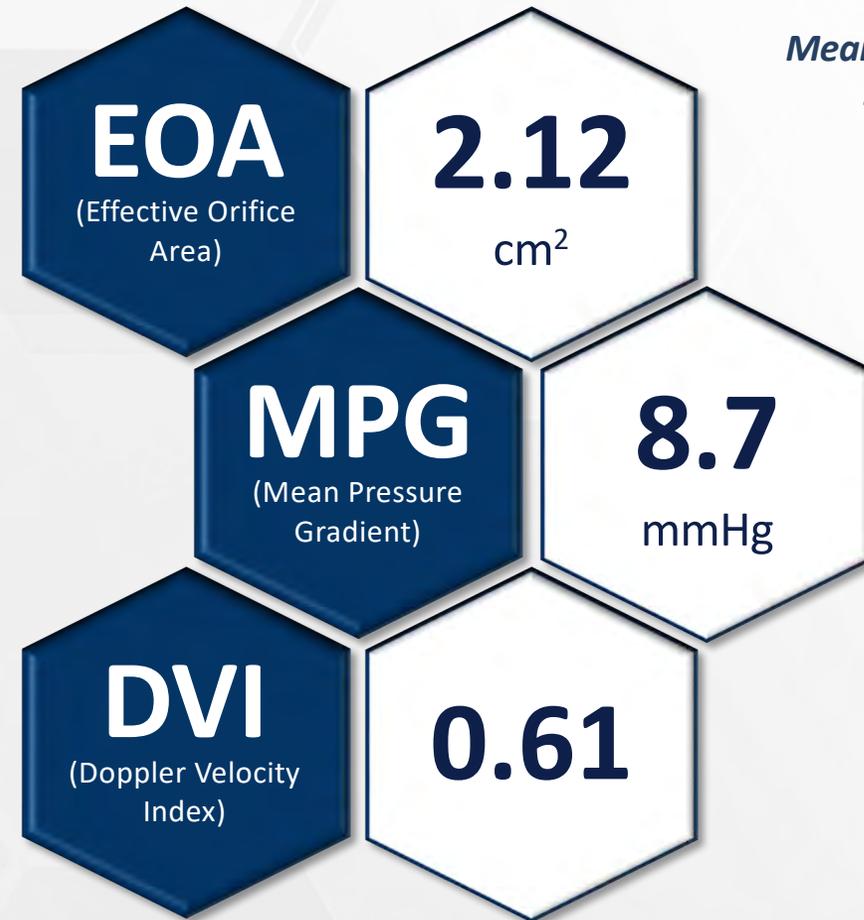


## Latest Cohorts (4-5) (N=21)



Mean Annulus Size:  
22.41 mm

## Initial Cohorts (1-3) (N=20)



Mean Annulus Size:  
22.73 mm



# DurAVR™ Outperforms Competitor Benchmark Hemodynamics\*

ASX:AVR  
ANTERISTECH.COM

Mean Annulus Size 22.2mm (Area 389.3)

DurAVR™ EOA

**2.36**

cm<sup>2</sup>

Sapien 3 EOA

**1.58**

49% LOWER

Evolut EOA

**1.82**

30% LOWER

DurAVR™ DVI

**0.71**

Sapien 3 DVI

**0.44**

61% LOWER

Evolut DVI

**0.61**

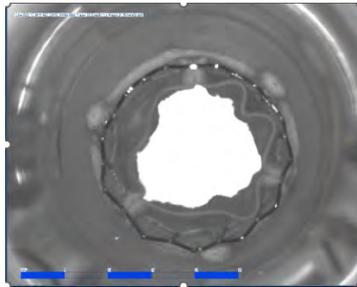
16% LOWER



## Current valves require compromises for Valve-in-Valve

- Balloon expandable (BE) TAVR have poor hemodynamics in small SAVR
- Self expanding (SE) TAVR have moderate hemodynamics, but higher rates of limited future coronary access
- Physicians most often trade off coronary access for hemodynamics

Sapien 23:  
Constricted leaflets  
Inhibit opening area



Poor Hemodynamics

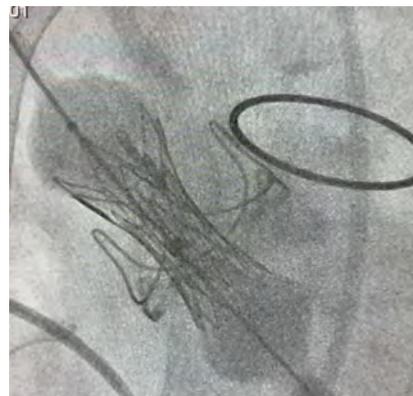
VS

Coronary Access Issues



Evolut 23:  
Tall frame prevents  
coronary access

6 DurAVR™ ViV cases now complete through compassionate use programs in Canada and Sweden



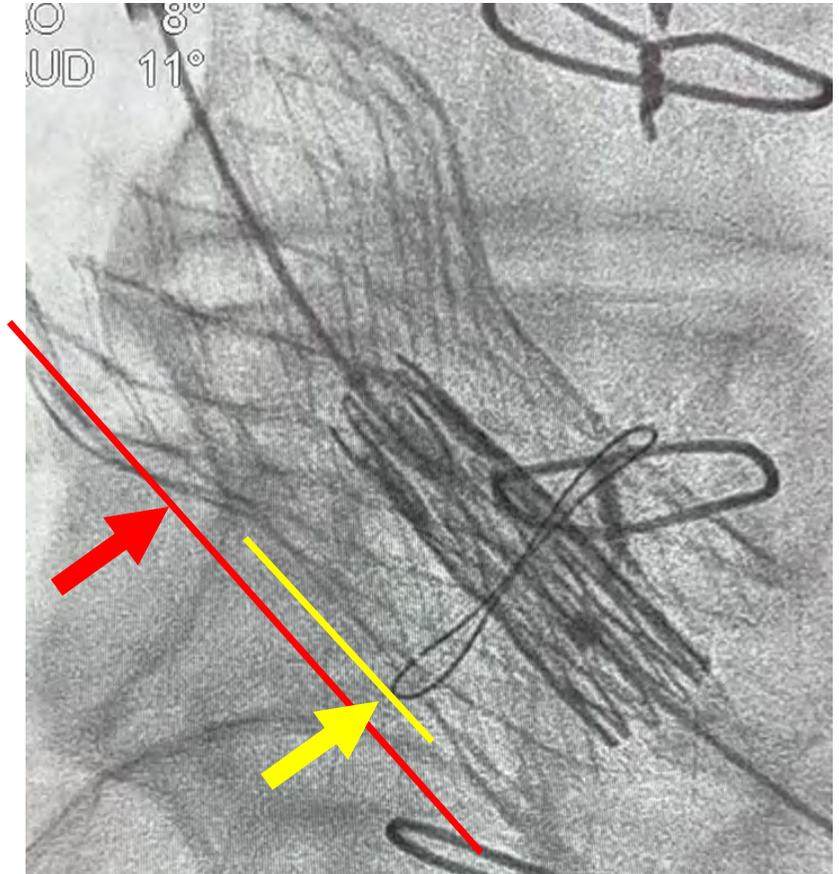
DurAVR™ restores hemodynamic performance at or better than first AVR with while preserving coronary access



# DurAVR™ Outperforms All Valves - Even When Inside Them!

- 77-year-old male, too high risk for repeat surgery with failure of his valve-in-valve.
- First surgical valve went in with mediocre hemodynamics and eventually failed.
- A self expanding TAVR was placed in it (currently believed to be best in class for ViV) and it also provided mediocre hemodynamics.
- Patient unsuitable for surgery and left with no reasonable alternatives. DurAVR™ proposed as compassionate use and only option for the patient. Swedish FDA agreed it was only option and approved its usage.

Date	Vmax Ao	Mean Gradient	DVI
2011 Surgical Valve	3.1	23	0.4
2018 Evolut in Surgical Valve	3.7	31	0.34
2024 max stress	4.0	41	0.15
Post DurAVR™	2.8	18	0.45



Failed  
Evolut



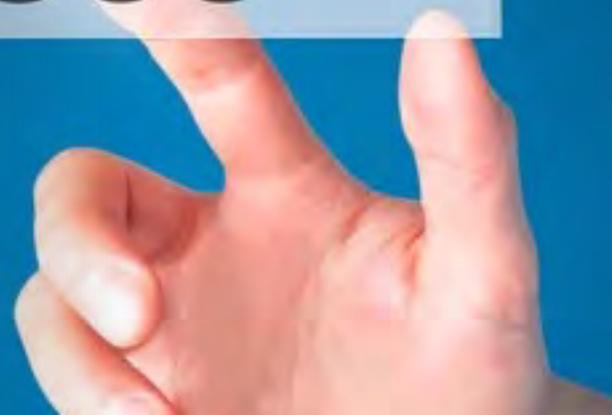
Surgical  
Valve

Successfully treated! Patient discharged home feeling great with best functioning valve since the one he was born with!





# Ease of Use



# Advanced Science



nature reviews cardiology

<https://doi.org/10.1038/s41569-023-00943-6>

Perspective

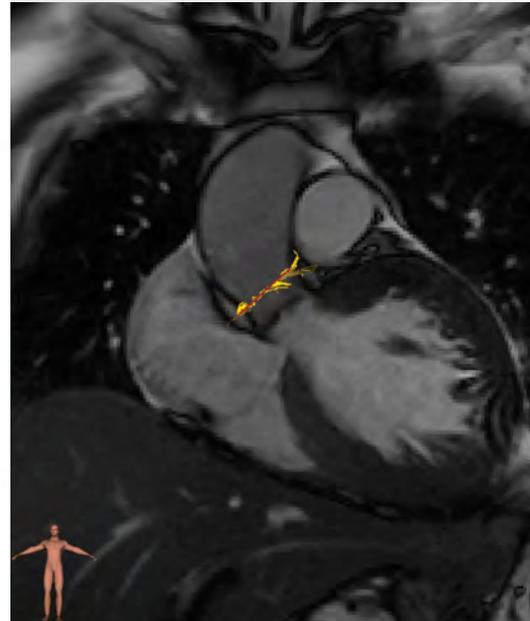
Check for updates

## Restoration of flow in the aorta: a novel therapeutic target in aortic valve intervention

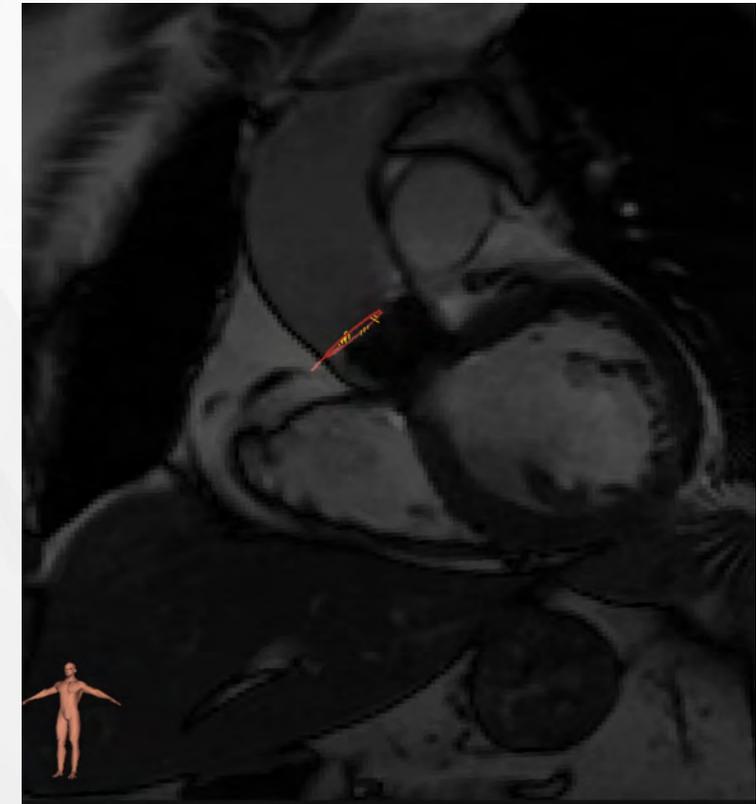
resistance. Pilot data are now emerging from first-in-human studies that assessed the DurAVR valve, which incorporates a large length-to-diameter ratio with a wide effective valve area and a 3D single-piece leaflet geometry<sup>79,80</sup>. Early data suggest that, after implantation of the DurAVR valve in patients with aortic valve disease, aortic flow patterns (in terms of flow eccentricity measured by SFD and vortical flow measured by sFRR) were restored to those seen in healthy control individuals. This improvement in haemodynamics has implications both for the longevity of the valve and for the prevention of aortic root dilatation owing to eccentric aberrant flow in the ascending aorta. The emergence of these novel transcatheter aortic valves provides a less invasive treatment option, which might even be suited to younger cohorts when their safety and longevity have been tested in medium-to-long-term outcome studies.

### 4D Flow Before and After DurAVR™

Pre



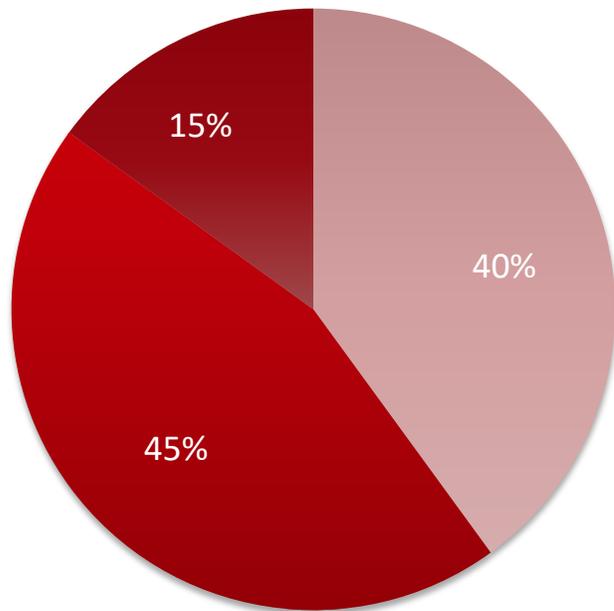
Post



## SMART is the first head-to-head randomized TAVR trial

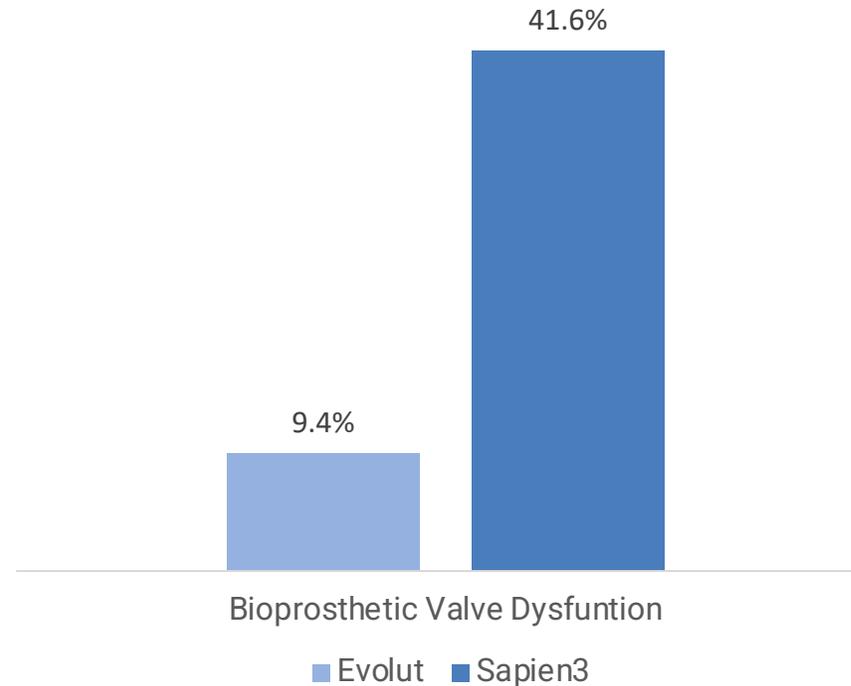
demonstrated statistically significant performance differences in *small annuli patients*

40% of global TAVR market is Small Annuli patients



■ Small ■ Medium ■ Large

Sapien3 demonstrated significantly worse BVD at 1 year



p<0.001 for superiority

BVD is defined as a composite of:

- mean gradient >20 mmHg
- severe PPM
- ≥ moderate aortic regurgitation (AR)
- Thrombosis
- Endocarditis
- Aortic valve re-operation/re-intervention



# Small Annuli Sapien3 Creates Poor Flow and Leaflet Function promotes high mean gradients and prosthesis patient mismatch – leading to BVD

## Bioprosthetic Valve

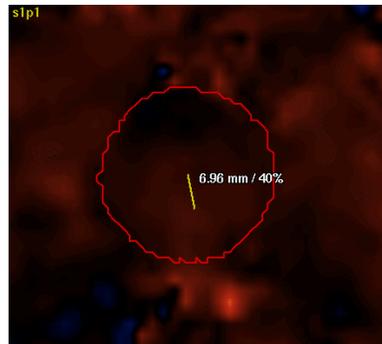
Competitor valves look like nature but have turbulent blood flow performance



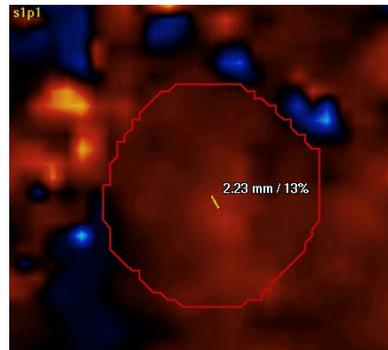
Sapien3



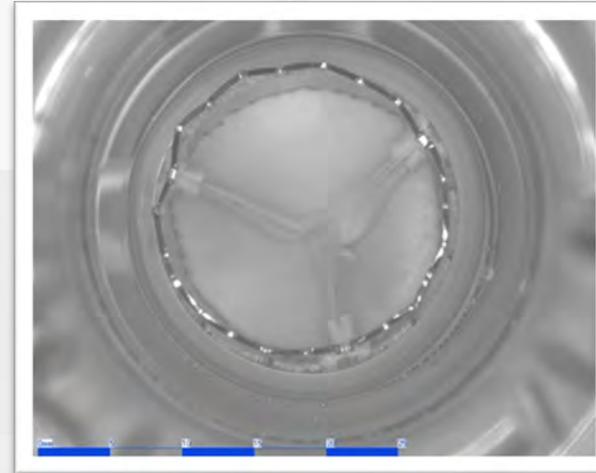
Evolut



48% Flow Displacement  
35% Flow Reversal Ratio

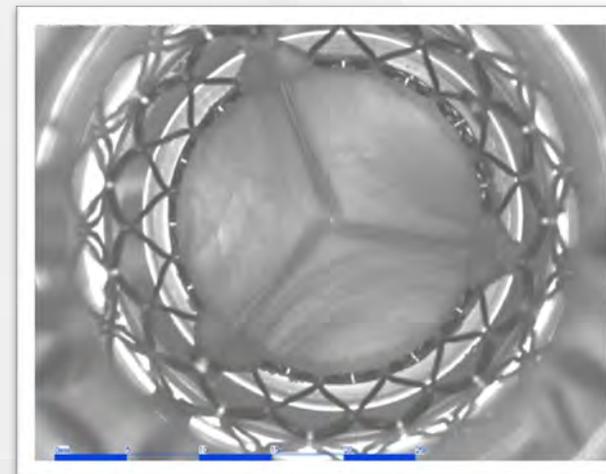


25% Flow Displacement  
4% Flow Reversal Ratio



## Sapien3

Excess tissue in small deployments



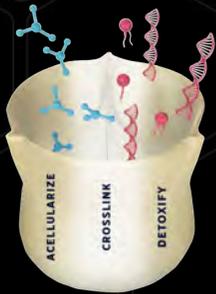
## Evolut

Higher leaflet coaptation avoid excess tissue... but still results in poor flow



## Three highly innovative technologies = clinical and commercial advantage

Anteris has addressed unmet medical needs with a new class of products for the treatment of aortic stenosis. This first-in-class biomimetic technology can be used for new patients, (USD 10 BN) and replace existing valves in patients(USD 3BN) (valve-in-valve ("ViV")).



### ADAPT

- Anti-calcification tissue technology
- Tissue processing
- Anteris' patented technology



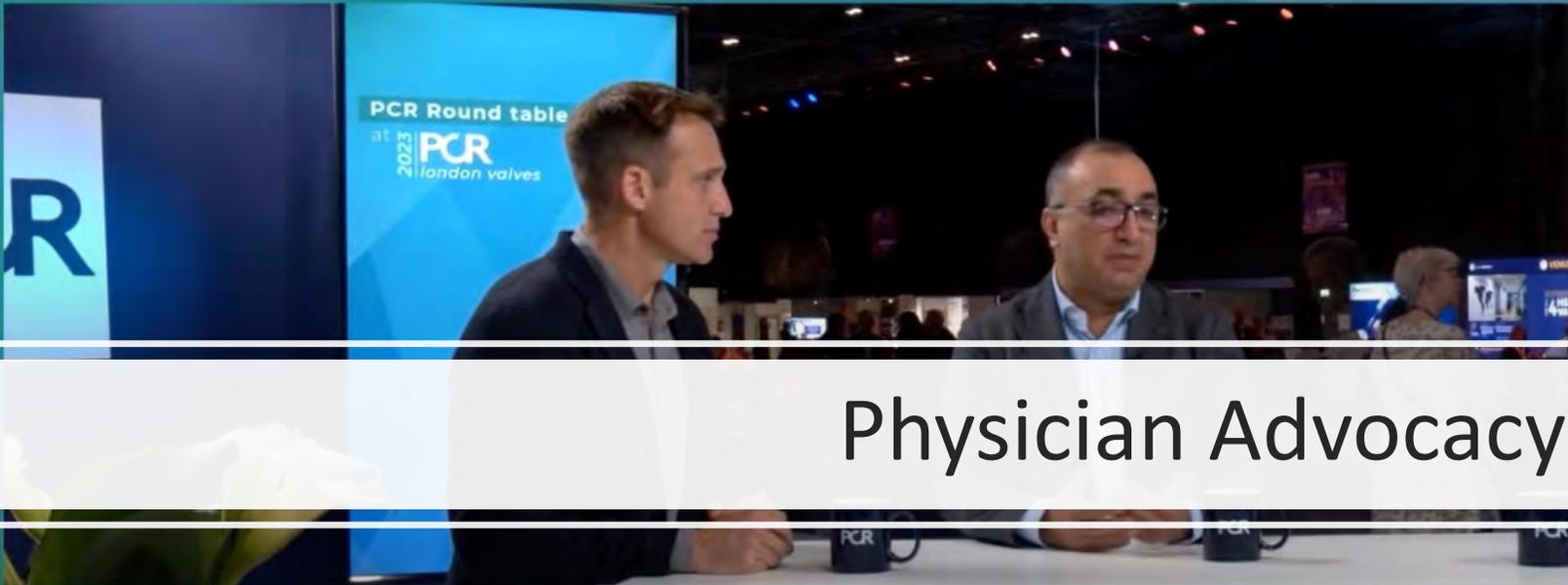
### DurAVR™ THV

- Novel biomimetic valve
  - Shaped to perform like a native aortic valve
- Single piece tissue
- Improved coronary access
- US patent protected design (11,648,107 and 11,622,853)



### ComASUR™ Delivery System

- Provides controlled deployment and accurate alignment of the DurAVR™ THV valve with the position of the native aortic valve
- Patent for the sterilised packaging system



# Physician Advocacy

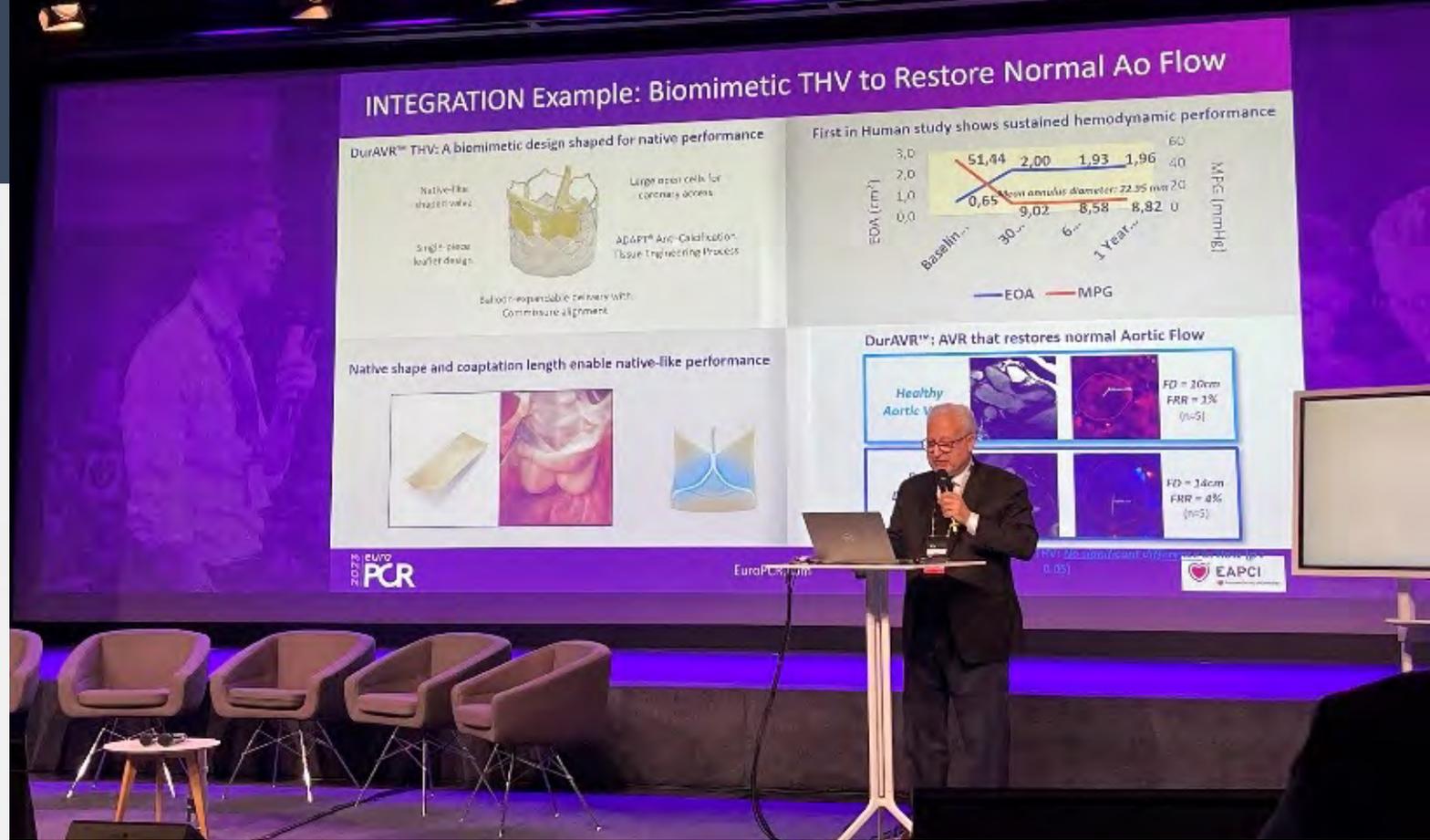


### DurAVR™: A First-in-class Biomimetic Transcatheter Aortic Valve

**DurAVR™ THV System**

- DurAVR™ THV Biomimetic valve:**
  - Native-like shaped valve
  - ADAPT™ Anti-Calcification Tissue Engineering Process
  - Single piece leaflet design
  - Balloon-expandable large cells
  - Commissure alignment
  - PVI skirt
- ComASUR™ TF Delivery System**

2023 PCR | EuroPCR.com | TF = Transcatheter THV = Transcatheter Heart Valve | EAPCI



### INTEGRATION Example: Biomimetic THV to Restore Normal Ao Flow

**DurAVR™ THV: A biomimetic design shaped for native performance**

- Native-like shaped valve
- Single-piece leaflet design
- Balloon-expandable delivery with commissure alignment
- Large inter cells for coronary access
- ADAPT™ Anti-Calcification Tissue Engineering Process

**First in Human study shows sustained hemodynamic performance**

Time Point	EOA (cm <sup>2</sup> )	MPG (mmHg)
Baseline	0.65	51.44
30 min	9.02	2.00
6 mo	8.58	1.93
1 Year	8.82	1.96

**DurAVR™: AVR that restores normal Aortic Flow**

Valve Type	Flow Diameter (FD)	Flow Reduction Ratio (FRR)
Healthy Aortic Valve	20cm	1% (n=5)
DurAVR™ THV	14cm	4% (n=5)

2023 PCR | EuroPCR.com | PVI: no significant difference between groups (p=0.05) | EAPCI



**ERATED TER LAB**

**The novel DurAVR™ balloon expandable transcatheter heart valve: a comparative hemodynamic study.**

**RESULTS**

Parameter	Value
EOA (cm <sup>2</sup> )	0.65
MPG (mmHg)	51.44

**Speakers:**

- Meduri
- Susheel Kodali (US)
- João Cavalcante (US)

**2023 PCR | 16-19 May, 2023 | Palais des congrès, Paris | euroPCR**

**ned rformance ar**

**VR™ TH al Study**

Parameter	n=5	Baseline
EOA (cm <sup>2</sup> )	0.65	0.5
MPG (mmHg)	58.0	51.44

Cardiologists globally are recognising the capabilities of DurAVR™, mentioning that the hemodynamics are amazing and that it has the potential to offer superior gradients for ViV patients.

## Professor Martin B. Leon, MD

*Professor of Cardiology at the Columbia University Irving Medical Center College of Physicians and Surgeons;  
Director of the Columbia Center for Interventional Care (CICC) at New York-Presbyterian Hospital/Columbia University Medical Center*



- “The **3D geometry of DurAVR™’s single leaflet design**, with far fewer sutures, will make an **important difference to durability**.”
- “You can’t help but be **impressed by the visible differences in DurAVR™’s** opening and closing pattern, and orifice area for similar size devices. At the same time, changing the leaflet tissue preservation and character will add to differences over time.”
- “If we can absolutely normalize the valve performances from the standpoint of hemodynamics and valve behaviour relative to a normal aortic valve, that would be such an **important advance in our field**.”
- “DurAVR™ is a new technology that we all think has **great promise to take transcatheter heart valve approaches to a new level**.”
- **“To think we can treat younger people with bioprosthetic valves, with the hope it might be the only valve they’ll ever need with hemodynamics that emulate a normal valve.... it’s pretty mind-boggling!”**

## Professor Rebecca Hahn

*Columbia University Irving Medical Center, Columbia Structural Heart & Valve Center;  
Director of Interventional Echocardiography New York*



- **“Normal healthy valves have laminar flow, and DurAVR™ mimics these good flow dynamics, with little turbulence or flutter which can stress leaflets like we see in other valves.** I think this will play a role in durability of DurAVR™ and how patients feel in all functional quality of life measures.”
- “The valve-in-valve aspect of DurAVR™ in small annuli and haemodynamic is pretty enticing. It is a **valve for everyone**, including patients that need repeat valve-in-valve.”
- “The **design of the leaflet is impressive** to me. During imaging, it opens and closes very smoothly with **no pin-wheeling or twisting is advantageous for durability**”.
- “We did a lot of females that tend to have smaller annuli. And we **continued to see these really, really optimal hemodynamics**”
- “Our goal is to perhaps limit that young patient (under 65) to only one surgical procedure. It is a **slam-dunk for older-patients**.”
- **“The hemodynamics of DurAVR™ are so fantastic, yet it has the ease, reliability and accuracy of the balloon expandable valve”**

## Professor Michael J. Reardon, MD

*Methodist DeBakey Heart & Vascular Center Houston Methodist, TX;  
Allison Family Distinguished Chair In Cardiovascular Research, Department of Cardiovascular Surgery,  
Professor of Cardiovascular Surgery, Academic Institute*



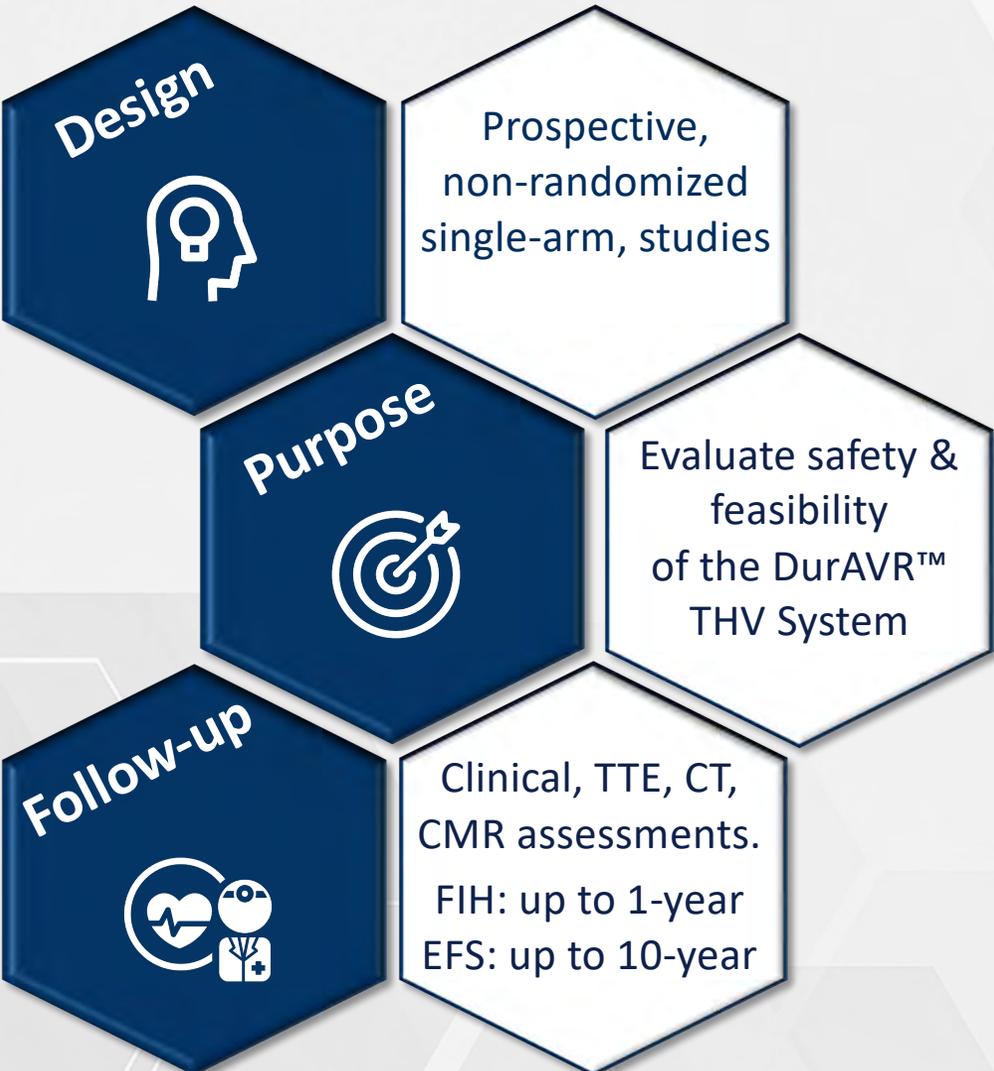
- “Our goal as interventionalists is to create a valve as close to the human valve as possible. With DurAVR™, we see consistent laminar flow throughout the valve and native like leaflet function. We’re seeing **excellent results and closer to what we expect from normal valves**. This will allow younger people to be physically active without substantially raising their gradients.
- **“The hemodynamics of DurAVR™ in the first in human study are absolutely stunning. The safety and implantability are absolutely stunning.”**





**Hands on Experience**

# DurAVR™ FIH and EFS Study Design and Baseline Characteristics



Study & Baseline Characteristics	FIH N = 41	EFS N = 15
Number of Centers	1 (Tbilisi, Georgia)	7 (United States)
Population	Severe symptomatic AS (Nov 2021 – May 2024)	Severe symptomatic AS (Aug – Oct 2023)
Age (years)	74 ± 6	81 ± 7
Gender (female)	31 (76)	10 (67)
STS Prom (%)	3.03 ± 1.99	5.8 ± 4.8
Area-derived annulus diameter (mm)	22.57 ± 1.17	22.2 ± 0.8
<b>NYHA class</b>		
II	21 (51.2)	8 (53)
III	19 (46.3)	7 (47)
IV	1 (2.5)	0 (0)
<b>Main Risk factors</b>		
CAD	34 (83)	8 (53)
Renal insufficiency	19 (46)	6 (40)
Conduction disturbances	18 (44)	7 (47)
Obesity	15 (37)	3 (20)
Diabetes type II	13 (32)	7 (47)
Prior PCI	20 (49)	2 (13)

Data presented as mean ± SD or n (%)

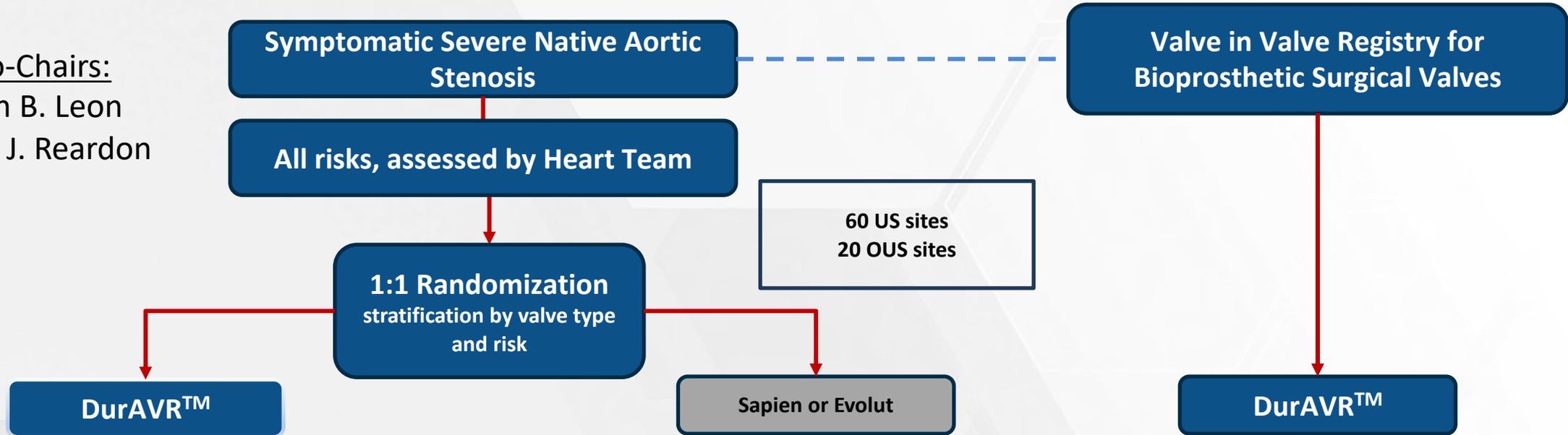


# Path to Commercial Approval



# DurAVR™ Pivotal Study is the First All Risk Head-to-Head TAVR Registration Trial

Study Co-Chairs:  
Dr. Martin B. Leon  
Dr. Michael J. Reardon



Proposed Sub-studies:

- Flow dynamics
  - Exercise Hemodynamics
- CT sub-study (HALT, RLM)
- Health Economics

Follow-Up annually through 10 years

Primary Endpoint: at 1 year:  
Non-Inferiority composite All-cause mortality, stroke, or hospitalization

Secondary Endpoint: Hemodynamic Superiority at 30 day/1 year

Primary Endpoint: at 1 year:  
Non-Inferiority composite All-cause mortality, stroke, or hospitalization against PG



Biomimetic outcomes are driving enthusiasm - Anteris will request continued access for DurAVR™ with FDA

### ENROLLMENT

Patients are screen for eligibility. If selected, they are randomized and treated

### FOLLOW UP

Patients return monthly for 12 months, then complete their 1yr follow up for the study end point – continue annually for 10 years.

### REVIEW

Company assembles the data into a submission package and sends to FDA seeking market approval.



#### Category B Revenue

- \$25k per device



#### Continued Access Revenue

- \$25k per device



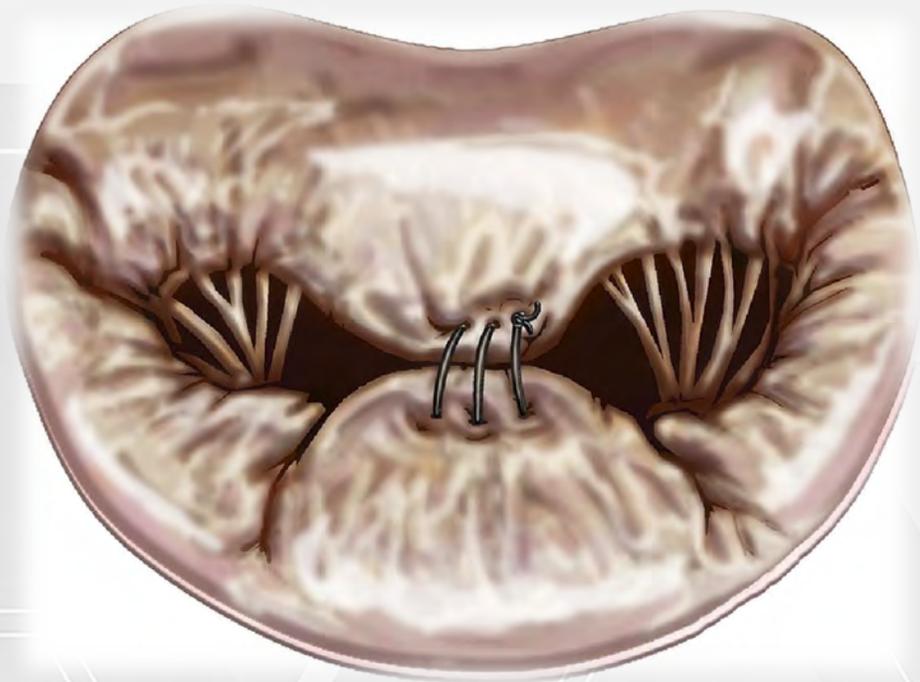
# Mitral Repair TEER Project



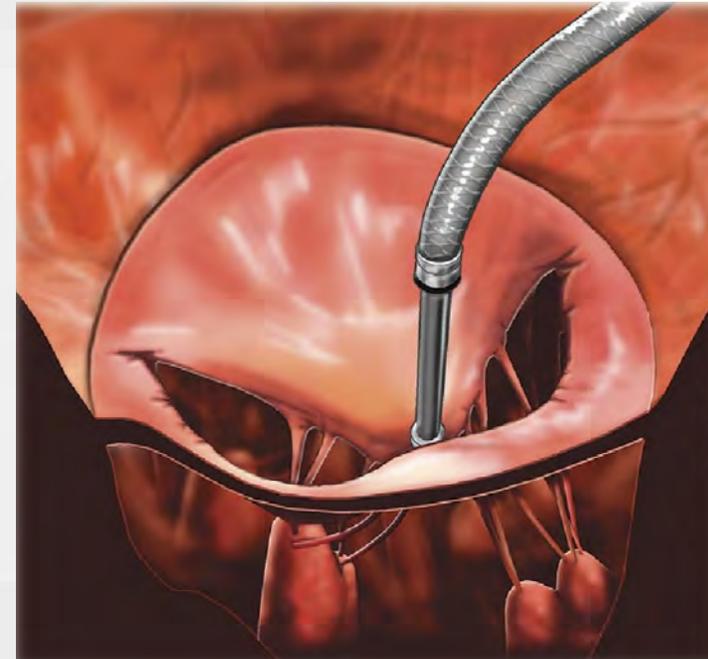
# TEER Procedure

Transcatheter Edge to Edge Repair (TEER) improves valve performance by approximating the edges of the Mitral or Tricuspid valve leaflets together to improve valve function and reduce regurgitation.

Edge to edge was proven as a surgical repair

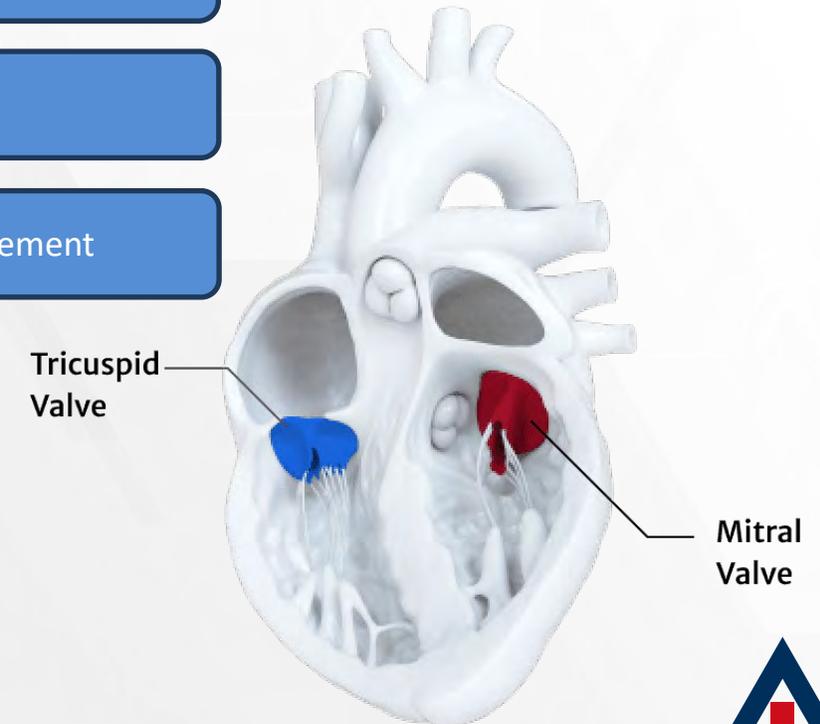
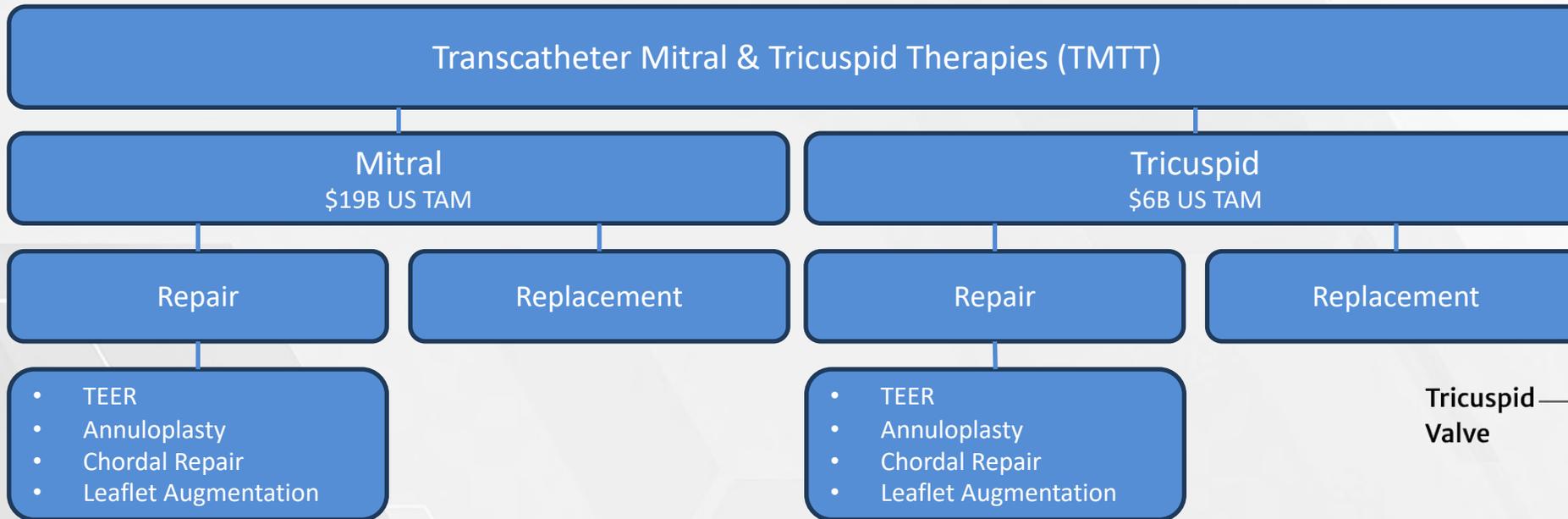


It has transitioned to a transcatheter procedure:  
less invasive, shorter hospital stay, faster recovery



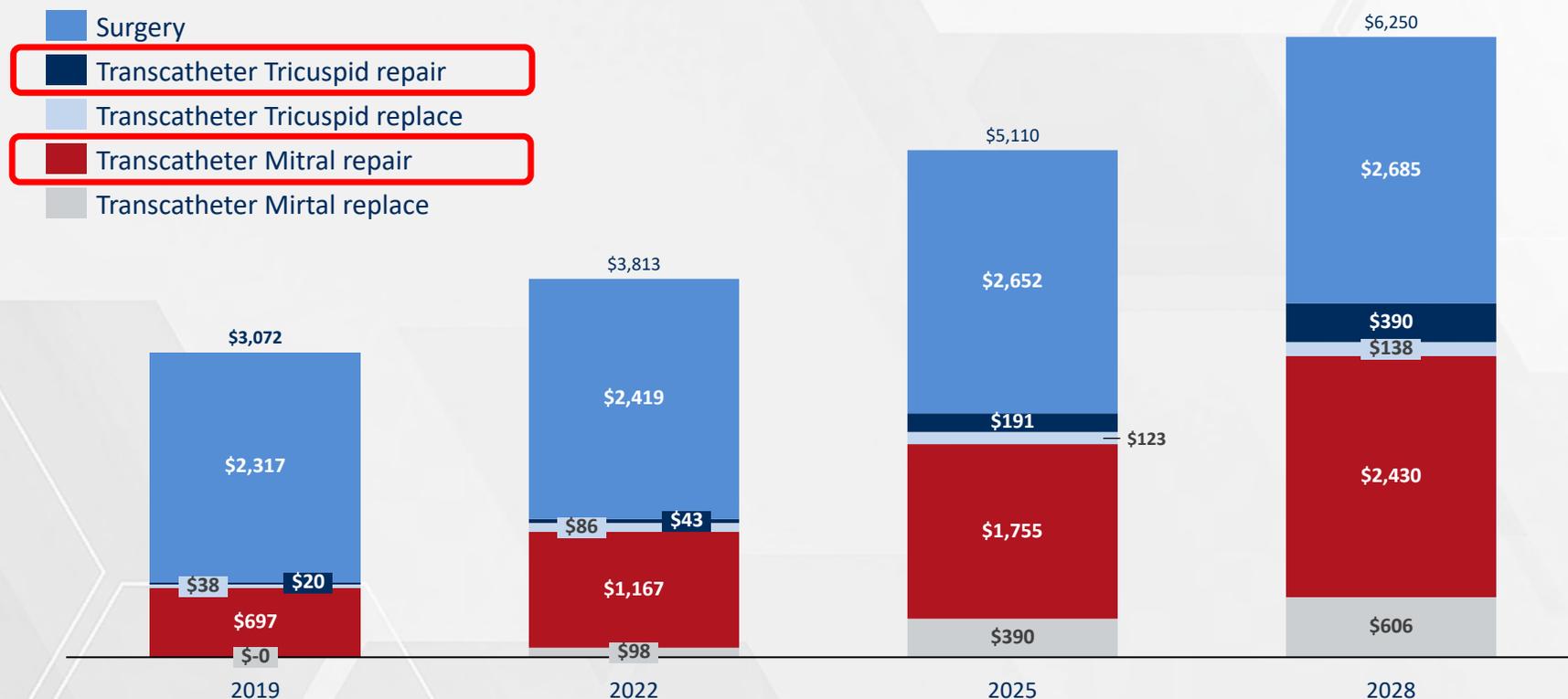
## Large & Underpenetrated Transcatheter Mitral & Tricuspid Therapies TAM

### US TMTT TAM Estimates & Market Segmentation



# TMTT Growing at 14% CAGR Resulting in 2028 Market of ~US\$2.8B

## TMTT Market Revenue (\$US M)



In 2022 Surgery is the Gold Standard Treatment for Mitral valve disease.

By 2028 Surgery is still the prevalent treatment for TMV and TTV Repair.

But TMV and TTV Repair with ASP of \$US 25k makes up 45% of revenue share.



## Currently Available Devices with FDA and CE Mark

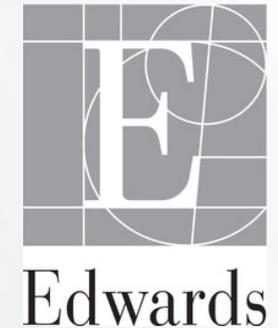
- Abbott's MitraClip received CE Mark 2009 & FDA approved in 2013 & since then >150,000 patients treated worldwide, ~\$US 3.5b
- The MitraClip™ remains the only device with commercial approval in the United States
- CMS reimbursement in 2020, driving market penetration

MitraClip



- Edwards PASCAL obtained CE Mark in 2019 with ~ 4,500 patients Treated, ~\$US 100m  
(Edwards Investor Conference Dec 2021/ JP Morgan Presentation Jan 2022)
- Tricuspid 1,500 patients treated  
(with EVOQUE, PASCAL & CardioBand)
- Pascal FDA approval for DMR Sept. 2022

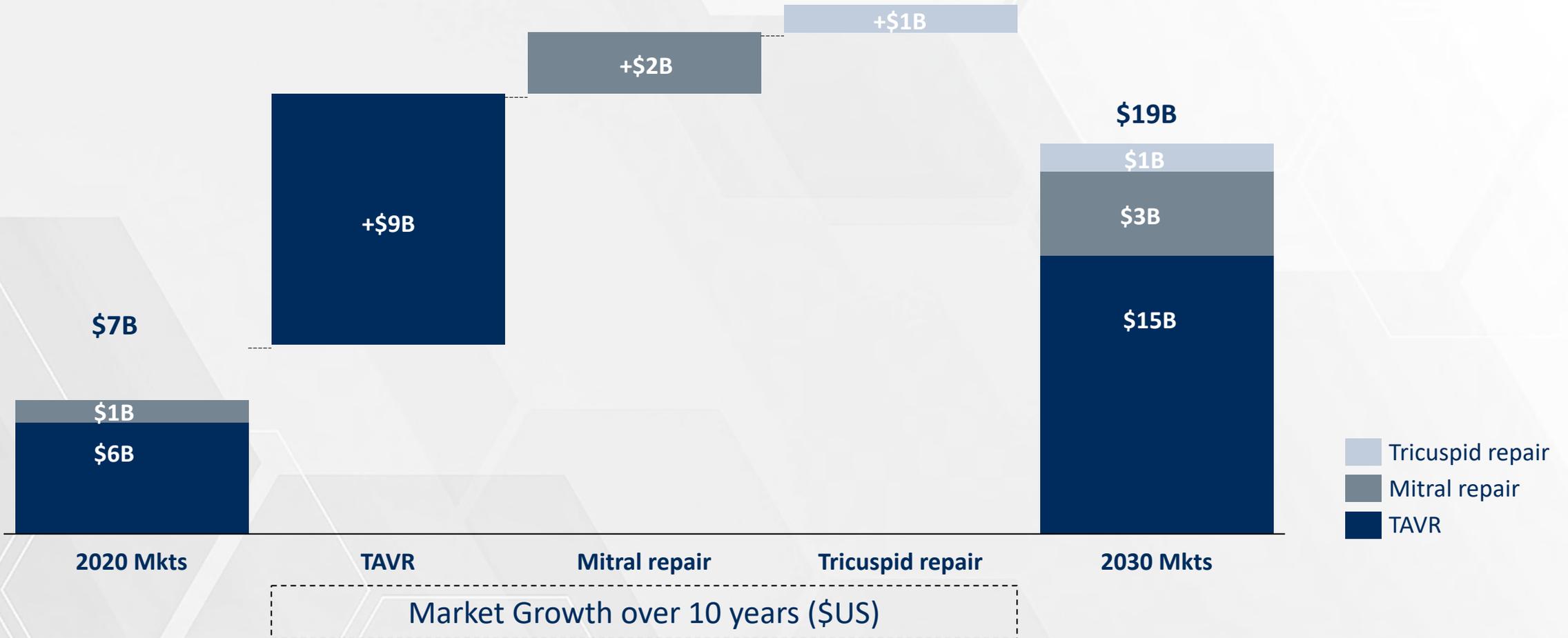
Pascal



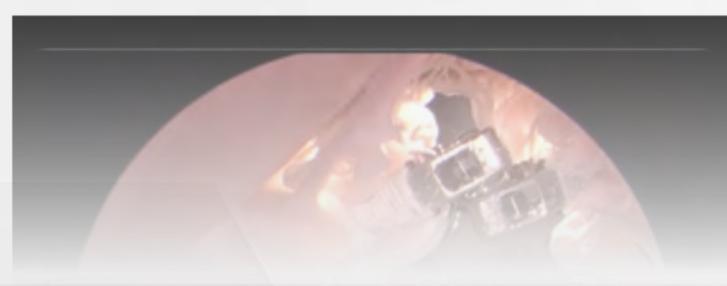
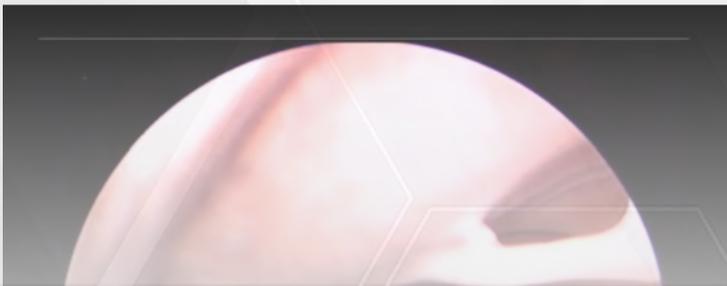
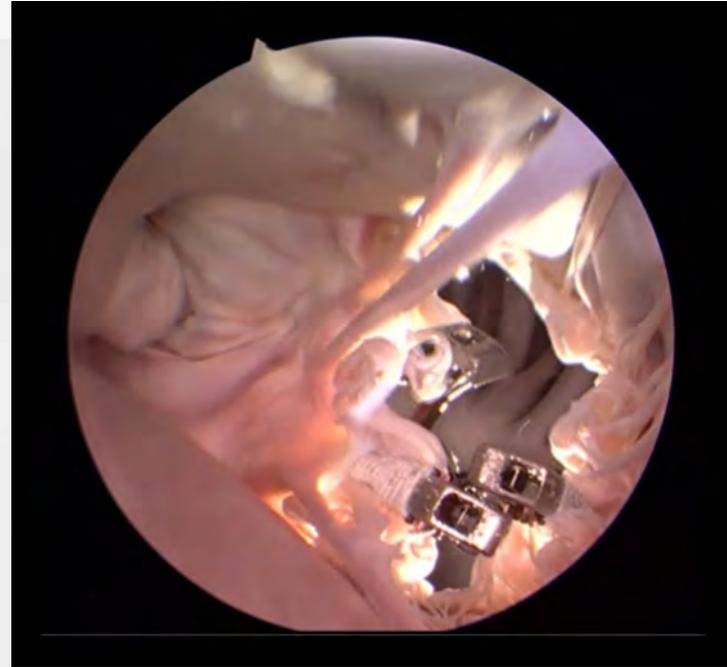
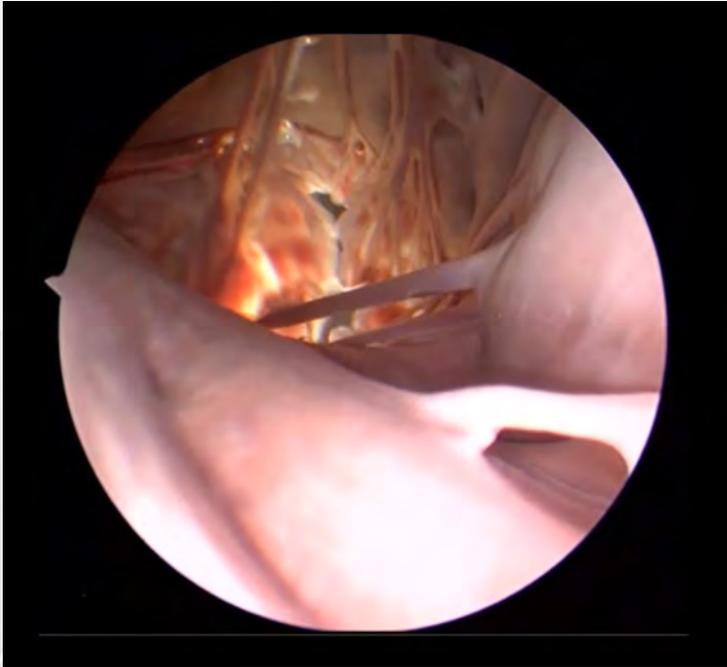
# Anteris will Establish a Leadership Foundation in High-Growth High-Value Markets

**1** Deliver DurAVR™ in growing TAVR market

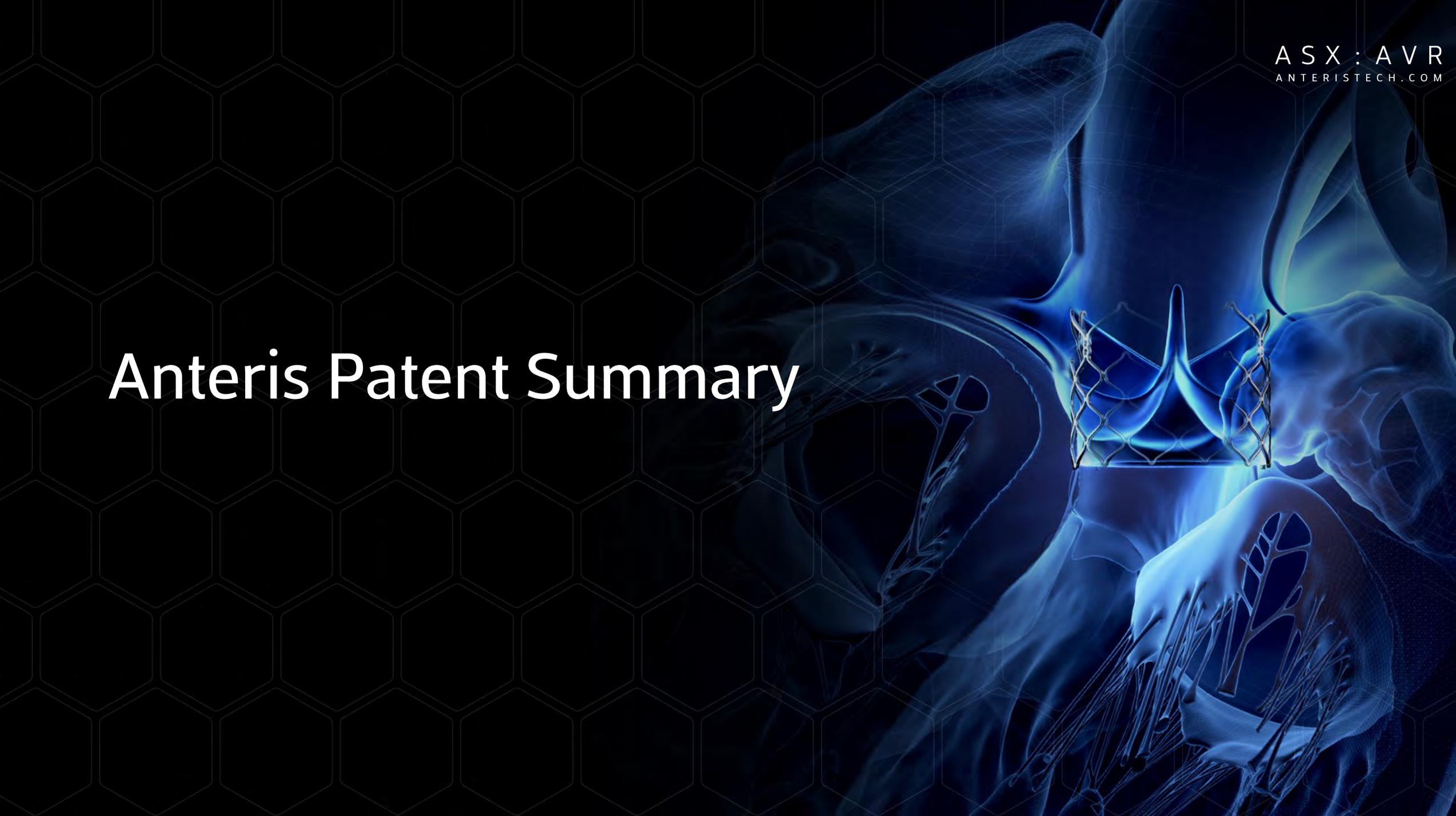
**2** Establish foothold in emerging high growth adjacent SH markets



# V2V in Action

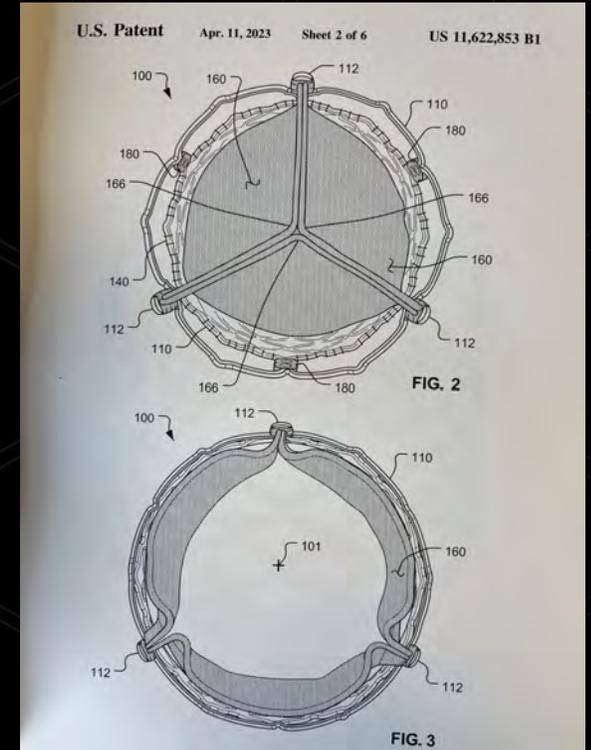
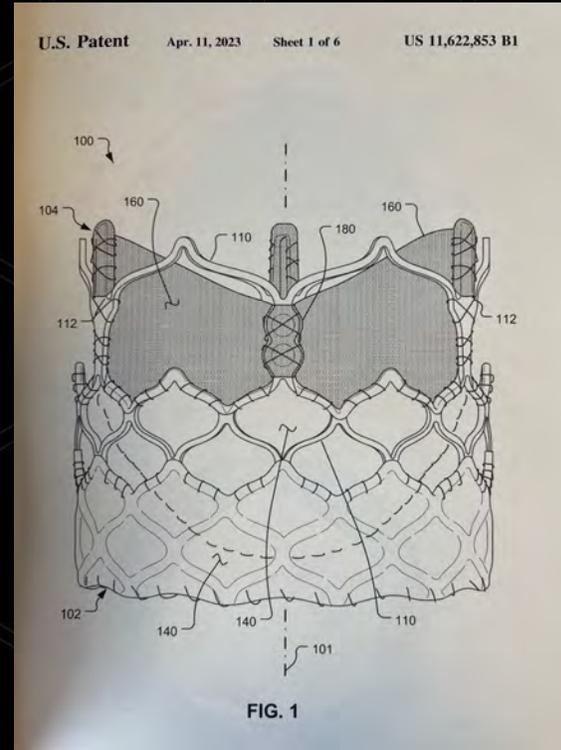
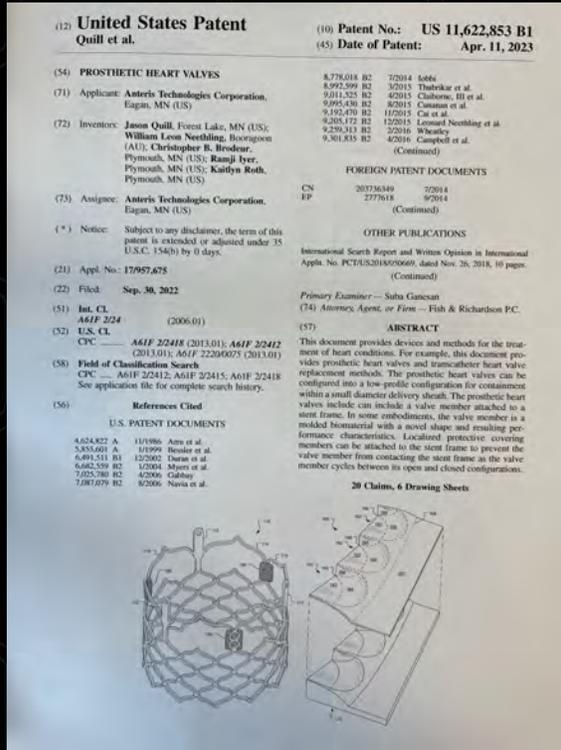
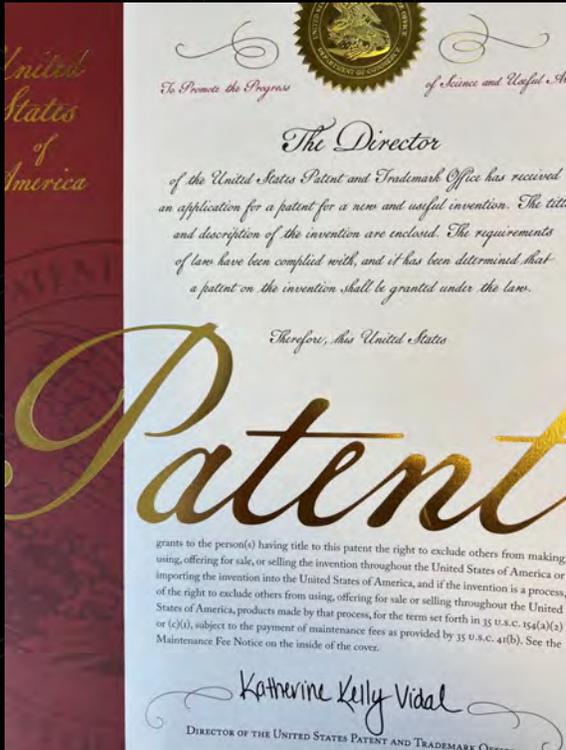


# Anteris Patent Summary



# IP Protection

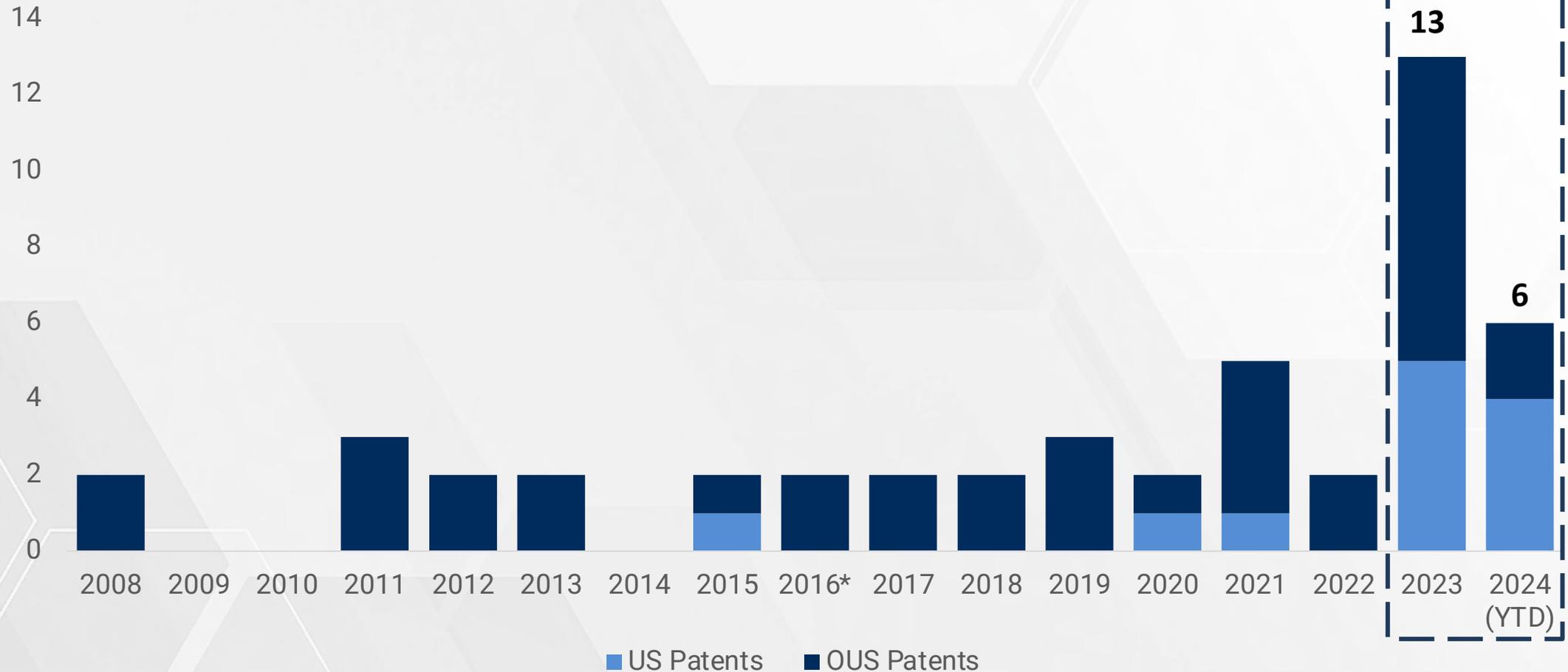
Anteris has been issued patents for its ground breaking biomimetic design, which has changed the landscape.



# Our Patent Portfolio has Grown Significantly Over the Past 18 Months

## 13 Patents Issues in 2023 and 6 Patents Issued Year-to-Date

### Granted Patents



\* Includes an EP patent that is validated in 13 European countries



## Examples:

- US 9,205,172
  - Covers the current ADAPT manufacturing process
  - Active patents in: US, AU, BR, CA, CH, CN, DE, FR, GB, IE, JP, MX, NL
- US 11,648,107
  - Covers the current TAVR valve design (focused on the molded valve)
  - Active patents in: US, AU, JP, KR
  - Pending applications in: US, AU, BR, CN (2), EP(2), HK, IL, IN, JP, MX
- US 11,877,927
  - Covers the current TAVR valve design (focused on the stent frame)
  - Active patents in: US, AU
  - Pending applications in: US, AU, BR, CA, CN, EP, HK, IL, IN, JP, KR, MX
- US 11,903,827 and US 11,622,853
  - Cover the current TAVR valve design (focused on the overall design)
  - Active patents in: US
  - Pending applications in: US, WIPO (national stage filings TBD)



## Summary of patent coverage strength of the DurAVR™ TAVR:

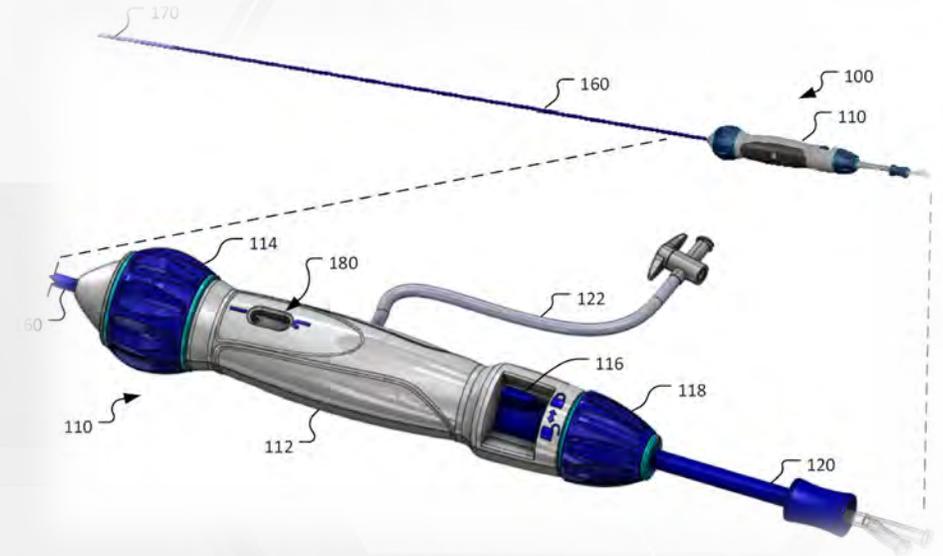
- Anteris' patents cover key design features that provide competitive advantages (e.g., reduced pinwheeling during valve closure, long coaptation length, large opening area in systole, coronary access due to large open cells and short frame, two-stage opening).
- Anteris' patents cover the DurAVR™ design from multiple angles. Difficult to 'slightly' design around all. Difficult to invalidate all.
- The cumulative coverage provides strong coverage.



# Delivery System

## Examples:

- US 11,883,286
  - Covers the current delivery system (focused on predictable commissural alignment)
  - Pending applications in: US, AU, CA, EP, JP
- US 63/469,121
  - Covers the current delivery system overall
  - Pending applications in: US, OUS (TBD)
- US 63/469,267
  - Covers the current delivery system (focused on the pleated balloon)
  - Pending applications in: US, OUS (TBD)
- US 63/554,666
  - Cover the current delivery system (focused on the braided hard stop)
  - Pending applications in: US, OUS (TBD)



## Summary of patent coverage strength of the delivery system:

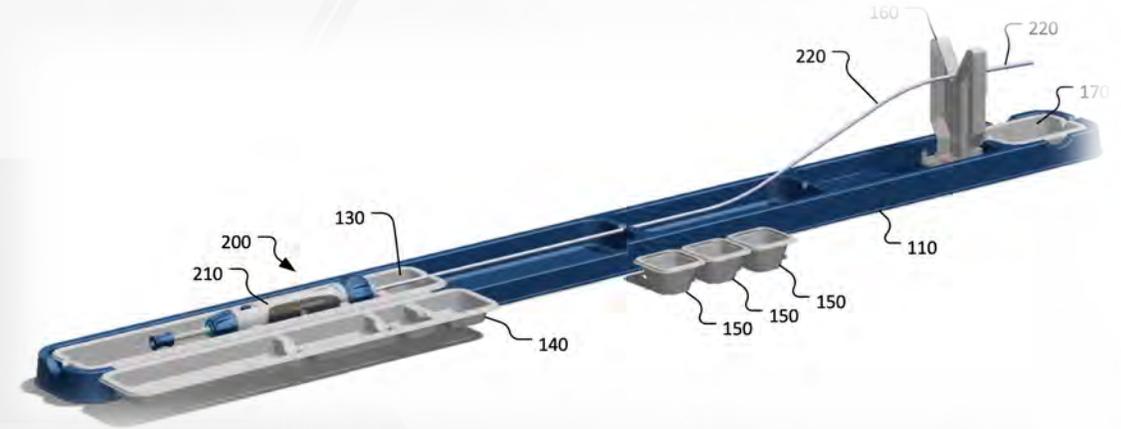
- Anteris' patents/applications cover key design features that provide competitive advantages (precise commissural alignment control, pleated balloon, braided hard stop).
- Anteris' patents/applications cover the delivery system design from multiple angles. Difficult to 'slightly' design around all. Difficult to invalidate all.
- The cumulative coverage provides strong coverage.



# Sterilization, Packaging, and Valve Preparation

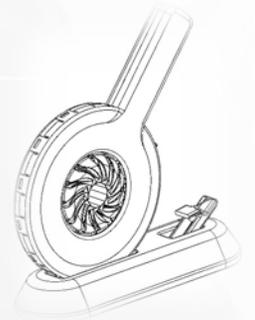
## Examples:

- US 10,758,642
  - Covers the current sterilization and storage of the tissue valve
  - Active patents in: US, AU, BR, JP, KR, MX, MY
  - Pending applications in: US, CN, IN
- US 63/504,383
  - Covers the current packaging and preparation system
  - Pending applications in: US, OUS (TBD)
- US 63/587,337
  - Covers the current single-use crimper
  - Pending applications in: US, OUS (TBD)



## Summary of patent coverage strength of the sterilization, packaging, and valve preparation systems:

- Anteris' patents/applications cover key design features that provide competitive advantages (novel packaging/preparation system, economical single-use crimper).





**NASDAQ**

# The TAVR Space is High Value and DurAVR™ is Competitive

## Edwards Lifesciences:

- 65% US TAVR market share
- Majority of revenue from TAVR
- Current market cap A\$79bn

Anteris  
Clinical results  
>30% better

Estimated  
market size post  
commercial:  
**A\$15bn+**

## Edwards Lifesciences (2023)\*

TAVR revenue	A\$5.7bn
Total revenue	A\$8.8bn
TAVR revenue %	65%
Current market cap	US\$52bn / A\$79bn
Revenue multiple	8.7x

## What if...?

Market share	Revenue	Revenue multiple	Market cap ?	Multiple to today's market cap
5%	A\$750m	8.7x	A\$6.5bn	16x
10%	A\$1.5bn	8.7x	A\$13bn	32x
XX%				??%

## Anteris current market cap

A\$400m

\* All USD figures translated at 31 Dec 2023 AUD/USD rate of 0.684.



# What Happens When a Medtech Lists on the Nasdaq?

Market Summary > Shockwave Medical Inc

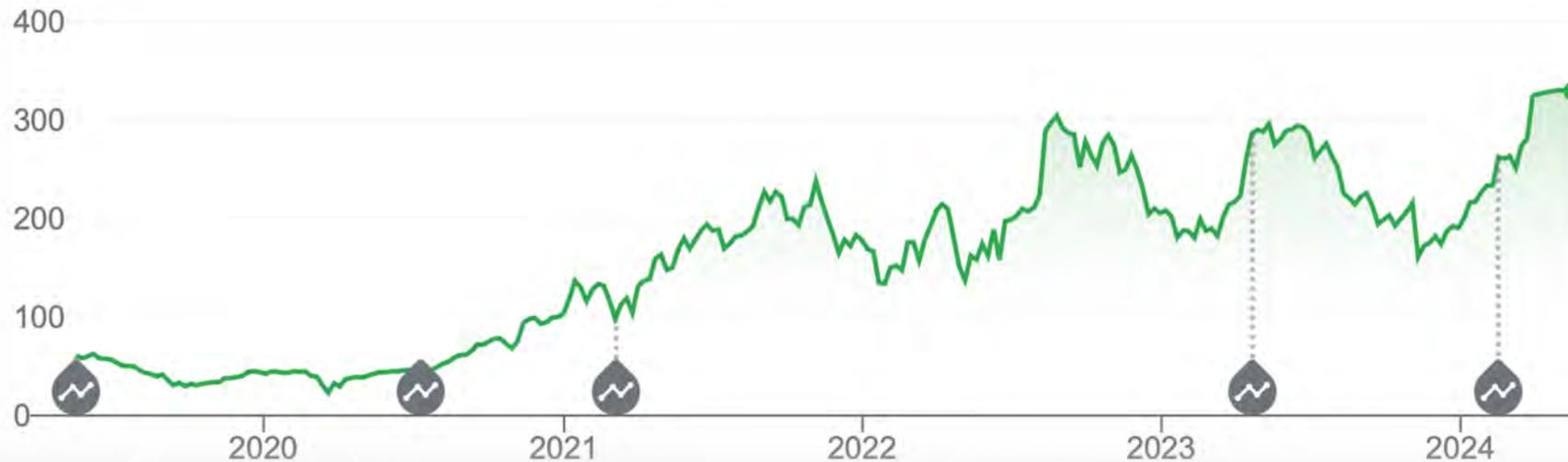
1000% increase since listing

**330.11** USD

+269.11 (441.16%) ↑ past 5 years

May 16, 12:16 PM EDT • Disclaimer

1D | 5D | 1M | 6M | YTD | 1Y | **5Y** | Max



- As previously reported, Anteris continues to evaluate a potential dual listing of its securities on Nasdaq and ASX and has undertaken preparatory work related to this.
- A Nasdaq listing would facilitate greater exposure to the US markets, with potential to access deeper sources of available funding.
- Remaining on the ASX will importantly retain our Australian heritage.
- Target listing in HY2 2024 – expected to be accompanied by a capital raising to provide funding for US DurAVR™ pivotal trials.
- Any potential dual listing would be subject to customary conditions, which may include market and other conditions, obtaining any necessary shareholder and court approval and obtaining any necessary approvals from regulatory authorities.
- There can be no assurance Anteris will complete a potential dual listing in a timely manner or at all.





WHAT'S  
NEXT?



# What to Expect from AVR over the Coming Period

- Company confirms DurAVR™ is clinically relevant and competitive, data continues to support the commercial thesis. Expect ongoing follow up data as cohorts reach significant milestones.
- FDA Approval for Pivotal study
- Commencement of study
- “Potential” Nasdaq listing
- V2V FIH
- Patient count to top 80
- More patent approvals further protecting our position
- First DurAVR™ revenues



Thank

you



# Board of Directors and Management Team

ASX:AVR  
ANTERISTECH.COM



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CHAIRMAN



**DR WENYI GU**  
NON-EXECUTIVE DIRECTOR



**STEPHEN DENARO**  
NON-EXECUTIVE DIRECTOR & COMPANY SECRETARY



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Melbourne



# Our Incredible and Visionary Shareholders



And of Course  
our Patients

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# Thank You