

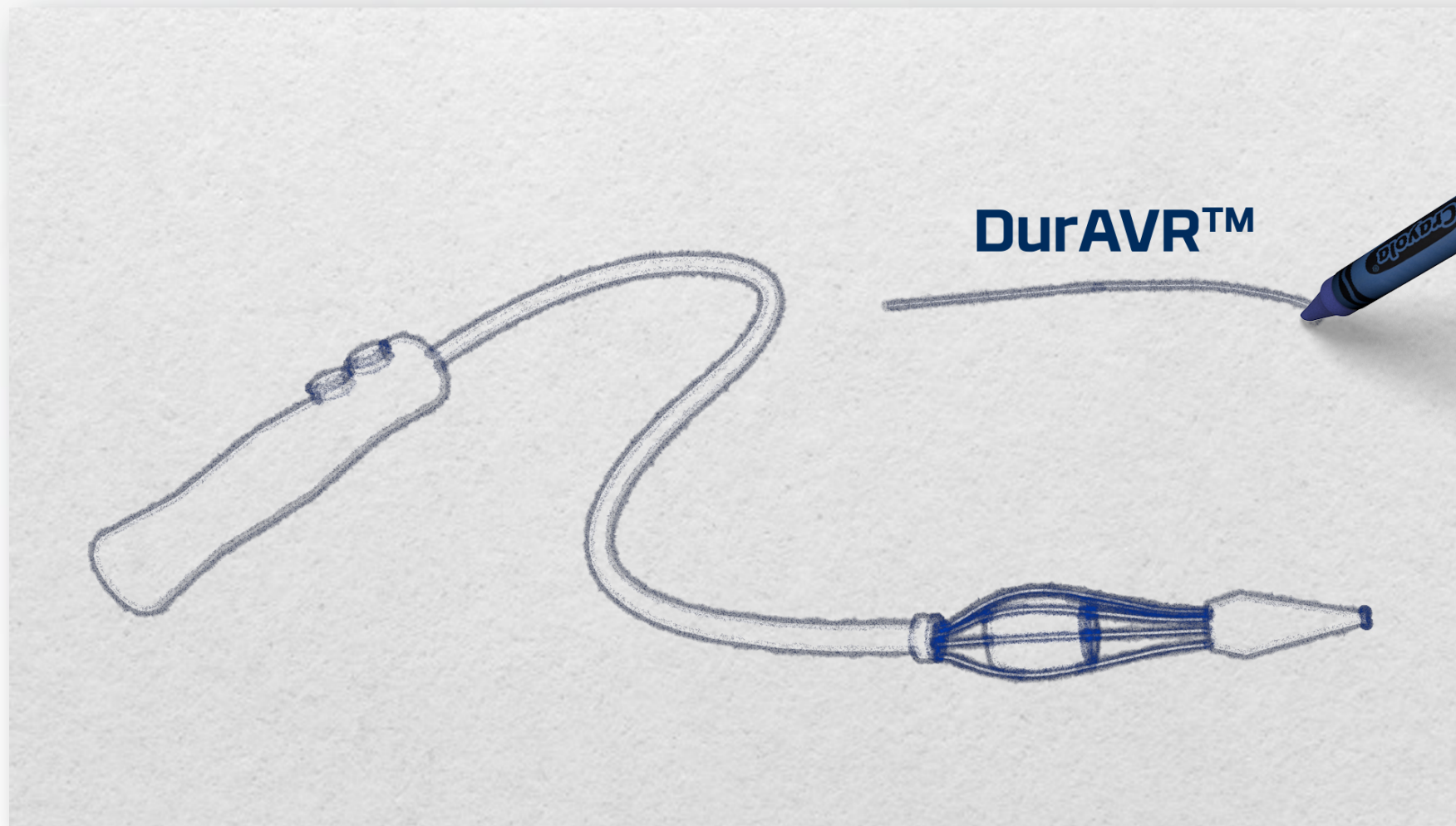


# Admedus Ltd AGM

May 2020



# Developing the world's most durable heart valve



# COVID-19 preparedness and response

- Group continues to expect the coronavirus impact to be minimal
- Alternate suppliers identified to source at-risk supplies and manufacturing inputs
- Restricted manufacturing site access to required personnel only. Production team split and staggered to reduce unnecessary interaction (Mid-Mar)
- Office staff in all sites working remotely
- Directors and Senior executives taken a 25% pay reduction effective May 2020.
- No significant impact on operations



# 2019 – A year of transactions



# 2019 – Restructuring for the future

Divestments enabled company to focus on high potential opportunity for DurAVR™

## Infusion division

- Low margin business sold for AUD \$6.3 million
- Company headcount reduced by 18

## Immunotherapies

- Admedus ceased funding in 2017 due to low probability of success and high funding requirements
- Division was put into administration in 2019

## CardioCel division

- Highly competitive market requiring scale and high cost base
- Sold for AUD \$20.3 million up front
- Company headcount reduced by 23

# Shifting to high potential opportunities with single focus

- 2019 saw multiple transactions and divestitures which enabled the company to exit lower margin lower potential businesses
- Transactions raised non – dilutive capital for investment into significantly higher potential opportunities.
- Transformed the company from a low revenue company to a full scale Med Tech development company
- Company can leverage the considerable benefits of its ADAPT® technology and DurAVR™ 3D single-piece valve.
- Company now has access to a potential \*USD \$4.7 billion dollar market.



# Financial highlights 2019/20

**\$17.1M**

**Sales Revenue**

**\$24.9M**

**Profit on Sale  
of divestments**

**75%**

**Improvement in Result  
compared to prior year**

**\$16.1M**

**Cash**  
(including term deposits)  
compared to  
\$12.0M in prior year

**42.1**

**Total Full Time  
Equivalent Staff**  
decreased from 82.5 in the prior period  
driven by two divestments

# CY19 Financials

\$ millions	CY2019	CY2018
<b>Group revenue</b>	<b>17.1</b>	<b>25.6</b>
Cost of sales	(8.8)	(13.2)
<b>Gross profit</b>	<b>8.3</b>	<b>12.4</b>
<b>Other income</b>	<b>25.5</b>	<b>0.1</b>
Selling, general and administrative costs	(32.4)	(34.3)
Impairment	(4.5)	-
Other	(3.1)	(2.9)
<b>NLAT</b>	<b>(6.2)</b>	<b>(24.7)</b>

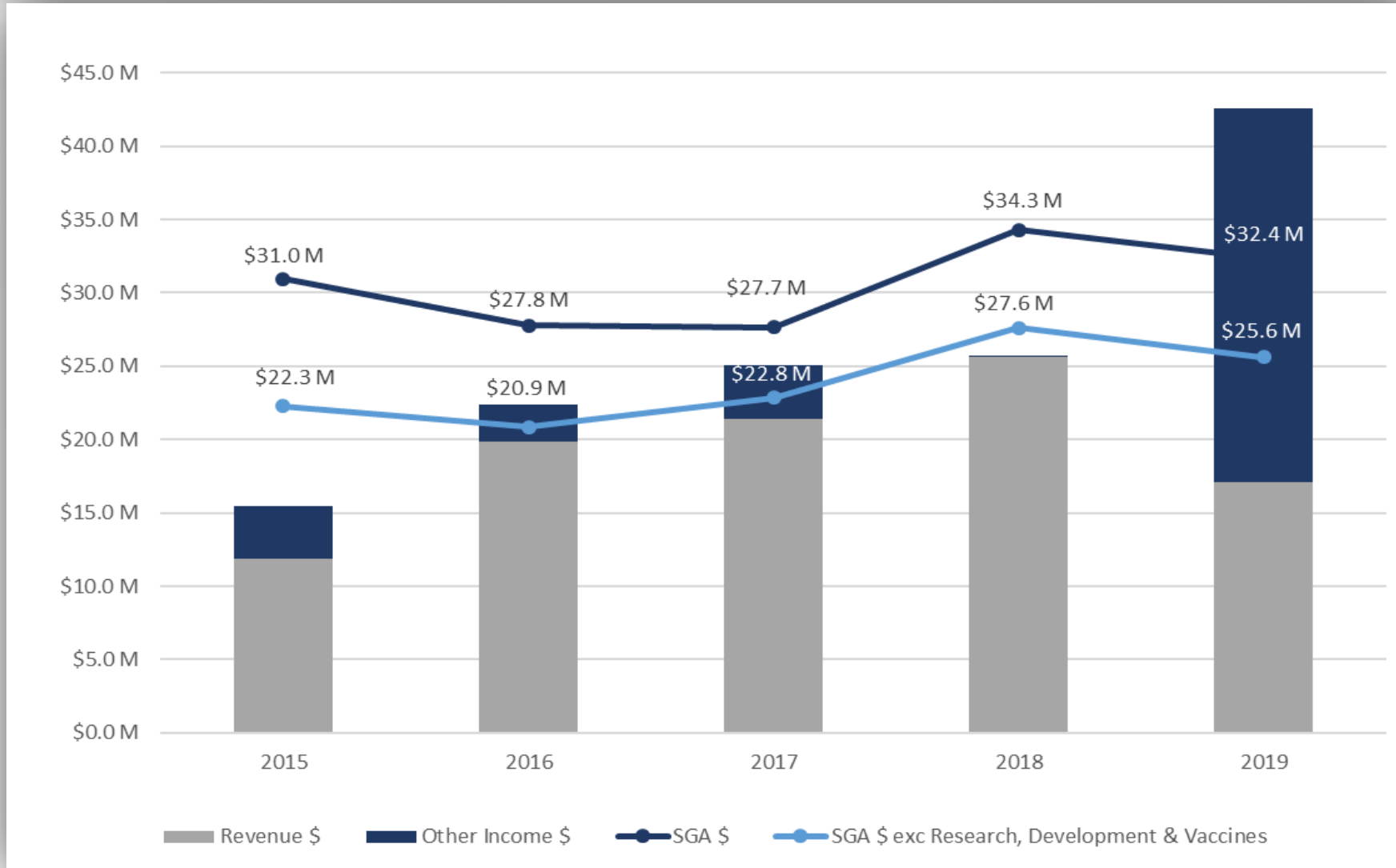
- Group revenue of \$17.1M
  - ADAPT® revenue: \$10.2M
  - Infusion revenue: \$6.9M
- Gross profit margin 49% (2018: 49%)
- Other income includes transaction gains
- Impairments linked to Vaccines and residual PPE

\* All values are in Australian dollars (AUD)



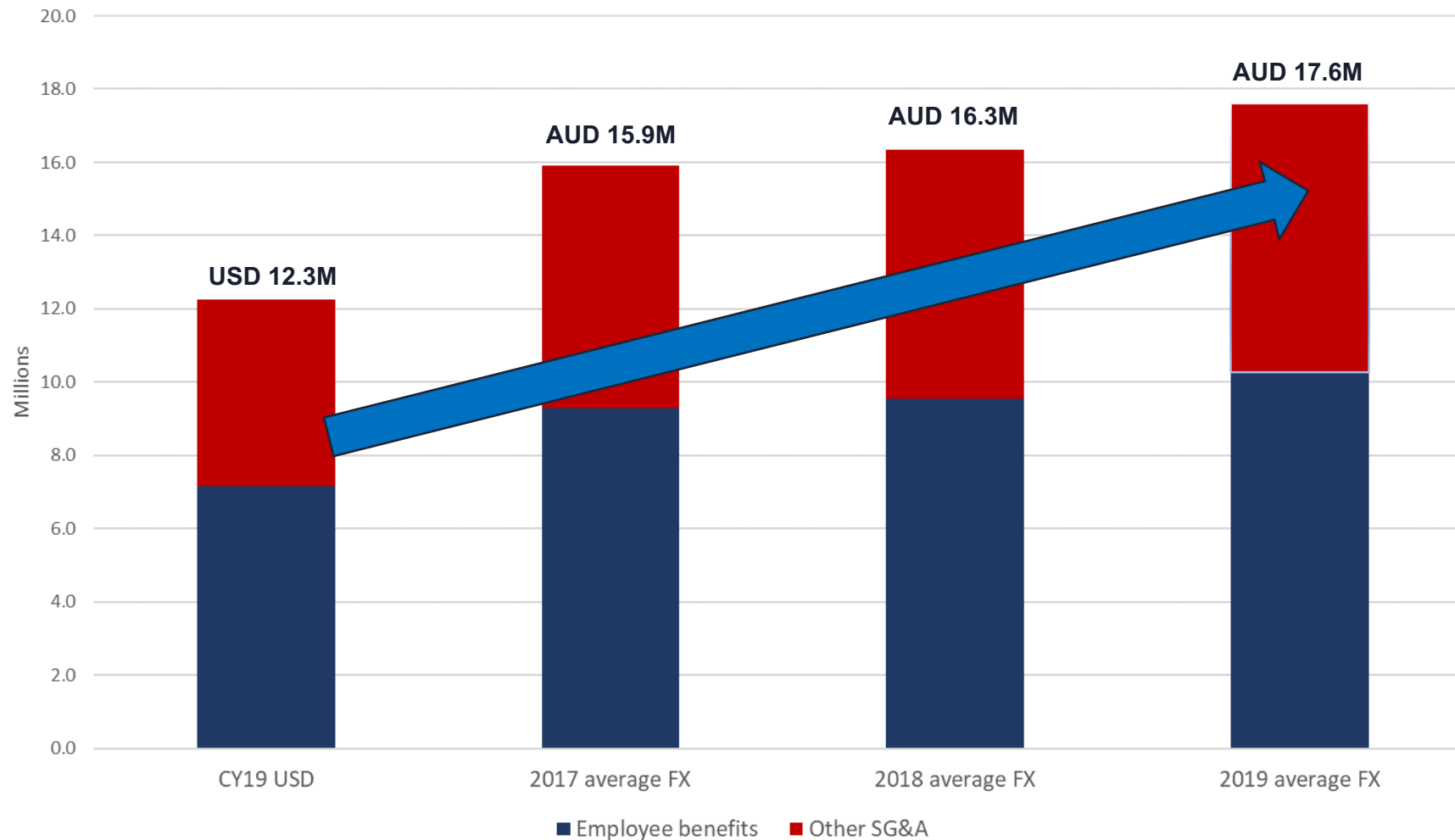


# Investments drive results



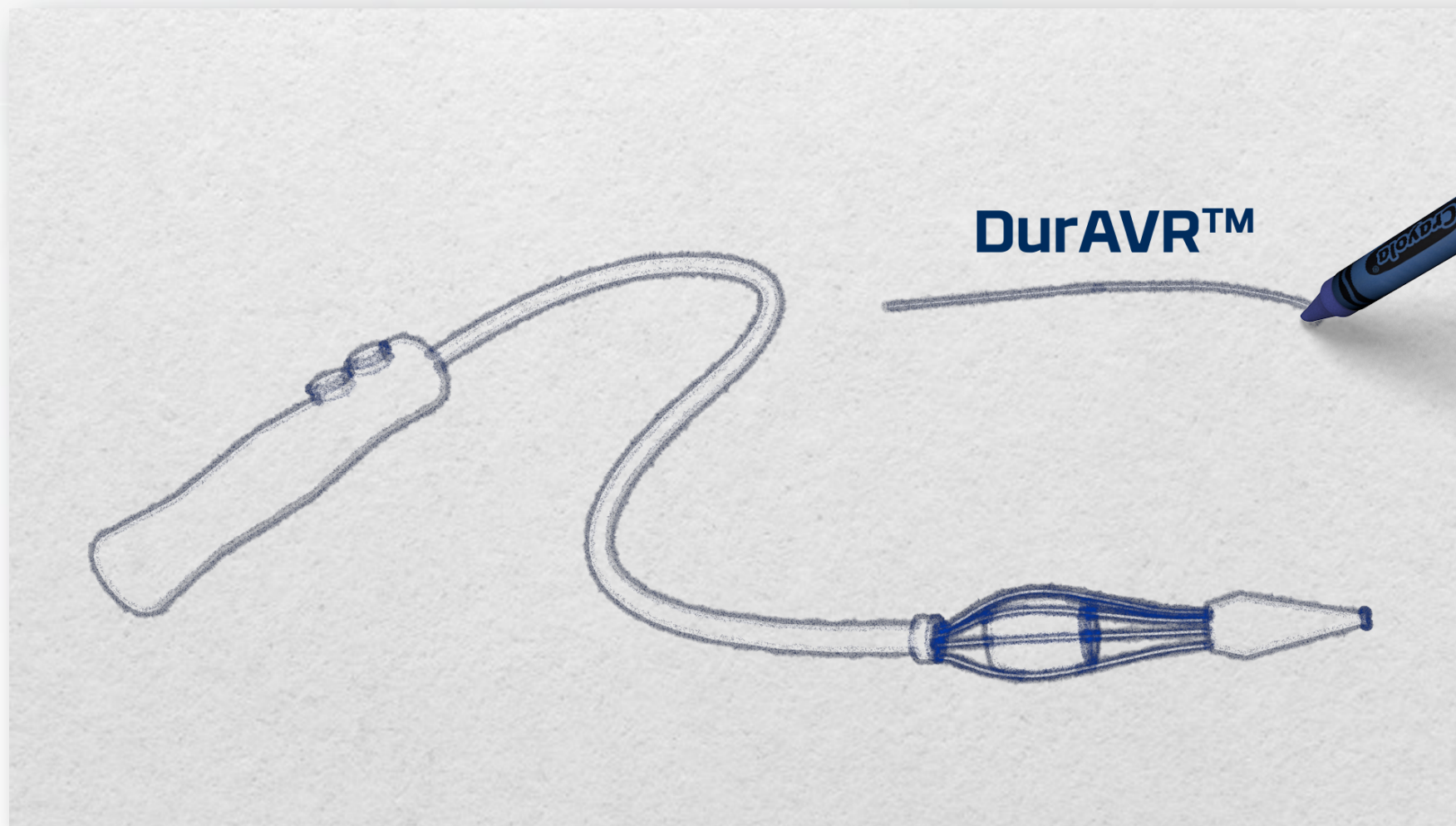
- Group continues to invest in Research & Development to accelerate its product development pipeline
- Benefits of divestments flowing through

# Exchange rate driving AUD reported costs



- USD \$12.3M of expenses incurred in 2019 converting into \$A17.6M
- The same USD \$12.3M in 2017 converted into \$A15.9M

# Developing the world's most durable heart valve



# Capitalizing on the multi-billion dollar TAVR opportunity

Market Potential of AVR as Treatment of SAS

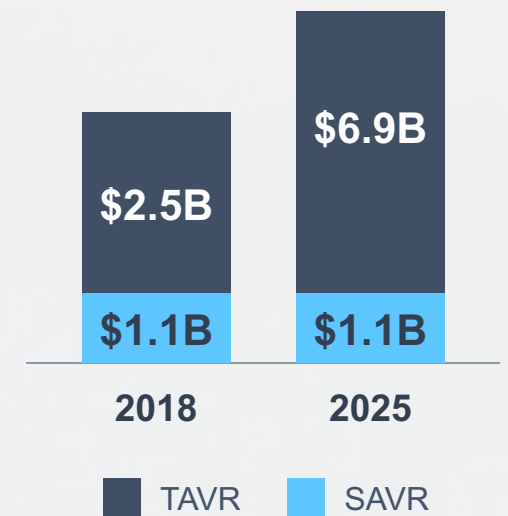


By 2025, Global Aortic Valve Replacement to reach

**\$8B USD\***

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

TAVR CAGR **15.6%**

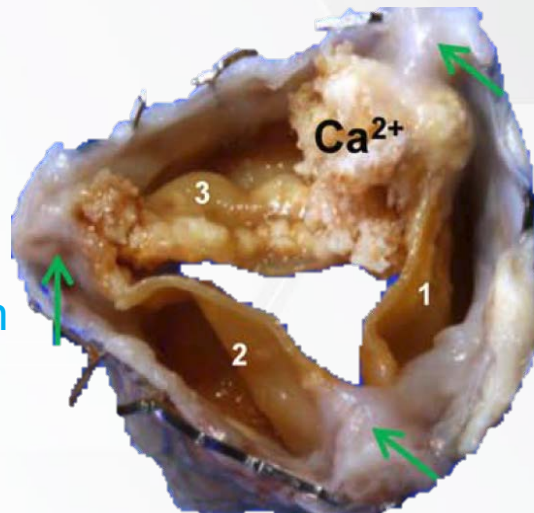


\* Includes Tier 1 markets (US,EU) and China; data on file

# 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

FDA

- 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

FDA

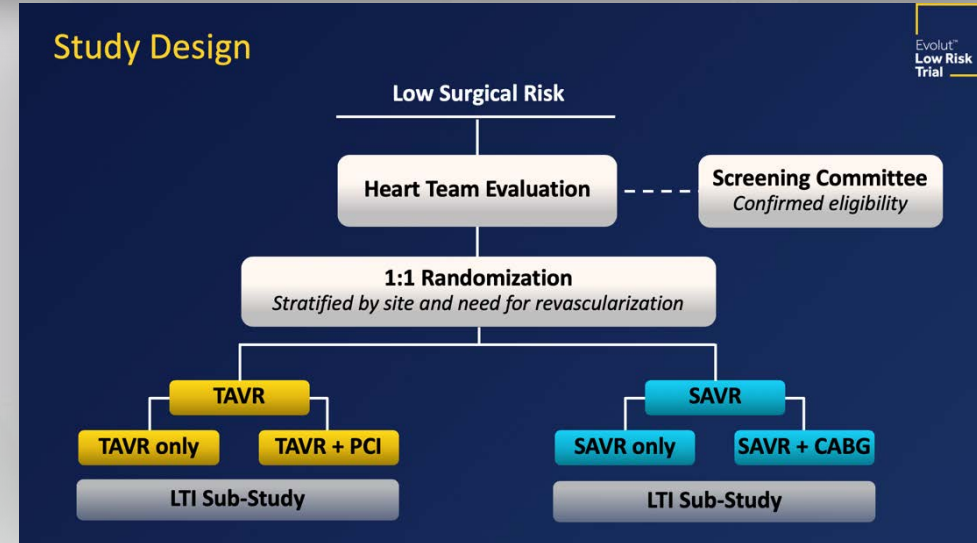
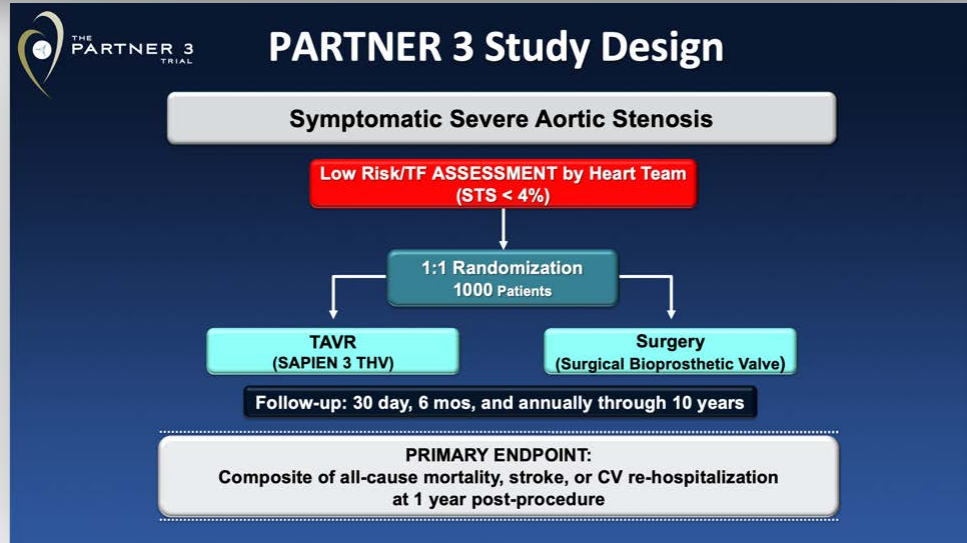
- The question of long-term durability is not feasible to address premarket
  - Durability is largely a function of structural valve deterioration, and biological responses cannot be accurately modeled in non-clinical testing
  - A premarket requirement for clinical studies to evaluate long-term durability 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)

	Continued follow-up of pivotal trial subjects	TVTR/CMS-linked surveillance 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

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# Major studies of TAVR “vs” SAVR in low risk\* (younger patients) are underway



ORIGINAL ARTICLE

**Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients**

M.J. Mack, M.B. Leon, V.H. Thourani, R. Makkar, S.K. Kodali, M. Russo, S.R. Kapadia, S.C. Malaisrie, D.J. Cohen, P. Pibarot, J. Leipsic, R.T. Hahn, P. Blanke, M.R. Williams, J.M. McCabe, D.L. Brown, V. Babaliaros, S. Goldman, W.Y. Szeto, P. Genereux, A. Pershad, S.J. Pocock, M.C. Alu, J.G. Webb, and C.R. Smith, for the PARTNER 3 Investigators\*

ORIGINAL ARTICLE

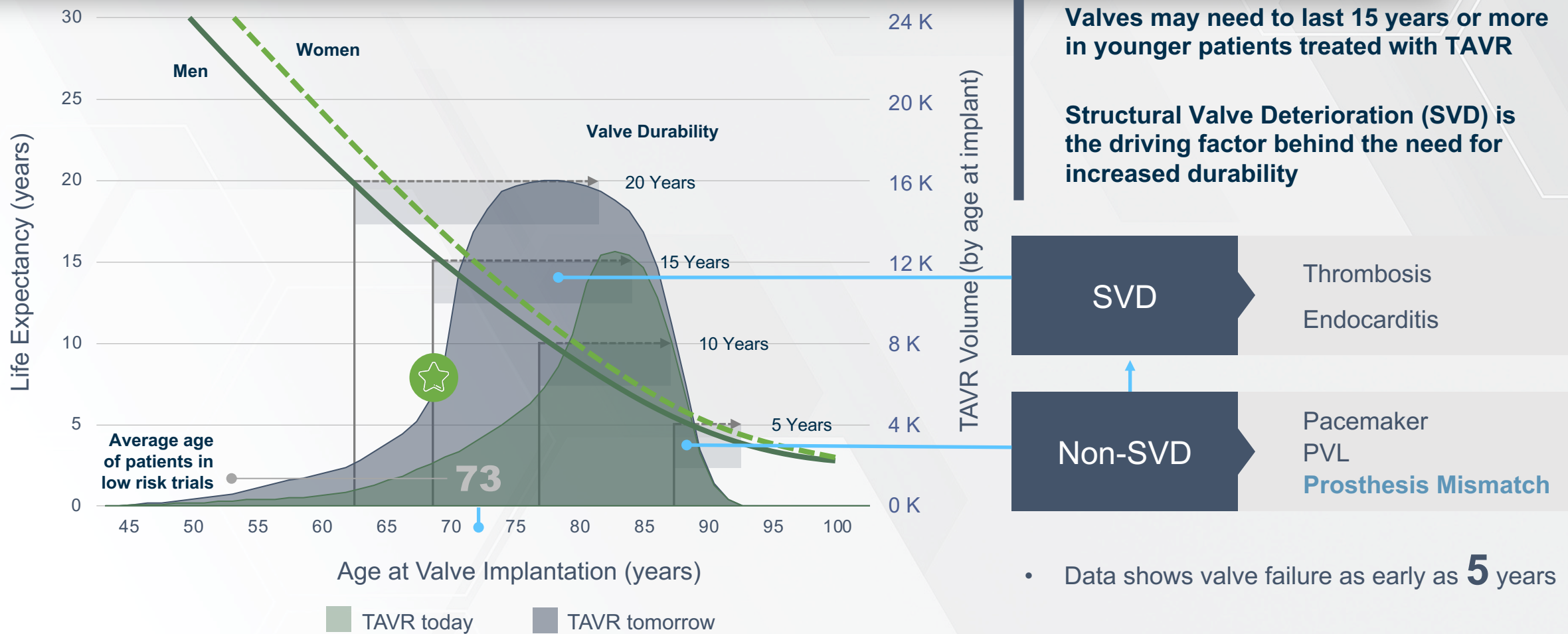
**Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients**

Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O’Hair, M.D., Tanvir Bajwa, M.D., John C. Heiser, M.D., William Merhi, D.O., Neal S. Kleiman, M.D., Judah Askew, M.D., Paul Sorajja, M.D., Joshua Rovin, M.D., Stanley J. Chetcuti, M.D., David H. Adams, M.D., Paul S. Teirstein, M.D., George L. Zorn, III, M.D., John K. Forrest, M.D., Didier Tchétché, M.D., Jon Resar, M.D., Antony Walton, M.D., Nicolo Piazza, M.D., Ph.D., Basel Ramlawi, M.D., Newell Robinson, M.D., George Petrossian, M.D., Thomas G. Gleason, M.D., Jae K. Oh, M.D., Michael J. Boulware, Ph.D., Hongyan Qiao, Ph.D., Andrew S. Mugglin, Ph.D., and Michael J. Reardon, M.D., for the Evolut Low Risk Trial Investigators\*

\* trials to be conducted over 10 years to assess differences between surgical replacement valves (SAVR) and transcatheter valves (TAVR) in low risk patients



# FDA has approved TAVR in low risk (younger patients)



Valves may need to last 15 years or more in younger patients treated with TAVR

Structural Valve Deterioration (SVD) is the driving factor behind the need for increased durability

- Data shows valve failure as early as **5** years

Lancalotti et al;  
 Courtesy of Windecker S. TCT 2019  
 Barbanti et al; J AM HeartAssoc 2018

\*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



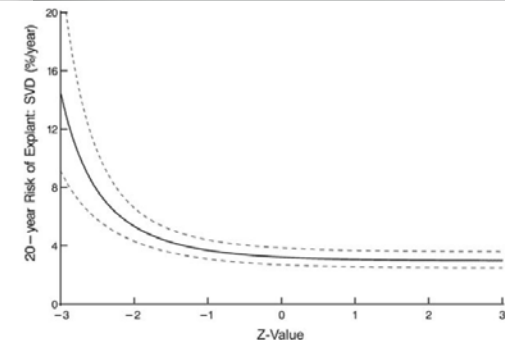
# Replacement valve deterioration is a key area of research

*Ann Thorac Surg.* 2015 April ; 99(4): 1239–1247. doi:10.1016/j.athoracsur.2014.10.070.

## Long-Term Durability of Bioprosthetic Aortic Valves: Implications From 12,569 Implants

Douglas R. Johnston, MD, Edward G. Soltesz, MD, Nakul Vakil, MD, Jeevanantham Rajeswaran, PhD, Eric E. Roselli, MD, Joseph F. Sabik III, MD, Nicholas G. Smedira, MD, Lars G. Svensson, MD, PhD, Bruce W. Lytle, MD, and Eugene H. Blackstone, MD  
Department of Thoracic and Cardiovascular Surgery, Heart and Vascular Institute, and Department of Quantitative Health Sciences, Research Institute, Cleveland Clinic, Cleveland, Ohio

We found that gradients increased slowly with time for the whole patient group, consistent with previous studies [22]. Of particular importance, however, is that for patients with the highest initial gradients early after AVR, risk of explant for SVD rose exponentially faster.



**Fig 4.** Structural valve deterioration (SVD) at 20 years and prosthesis–patient mismatch, represented by the number of standard deviations the geometric size of the aortic prosthesis deviates from normal. Nomogram is based on preoperative variables alone.



# DurAVR™ addresses the key areas that lead to valve deterioration

Ca<sup>2+</sup>



Only DurAVR™ is made from ADAPT® treated tissue with superior anti calcification properties

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

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



Other valves are constructed of three separate pieces of tissue resulting in greater stress and sub-optimal coaptation



DurAVR™ has no residual glutaraldehyde



DurAVR™ has 20-30 sutures = lower manufacturing costs



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

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

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

# DurAVR™ Durability experiments continue to be positive

## ACCELERATED WEAR TESTING

Admedus Valve shows no wear at **400 million cycles**

**Day 1**



**200 million**



**400 million**

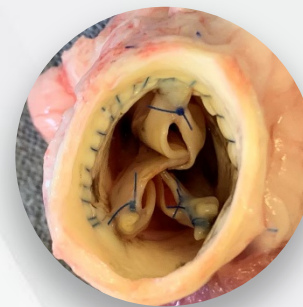


Competitor Valves demonstrate wear and may breakdown at 250 million cycles

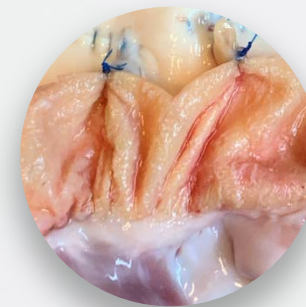
## SHEEP CALCIFICATION MODEL

A hostile environment for valves

**Well Anchored Sutures**



**Supple Cusps**



**Clean Margins (Annulus)**



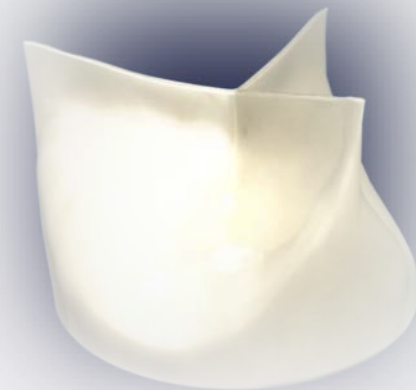
Valves implanted in juvenile sheep and assessed at 6 months:

- ADAPT® aortic valves show no calcification

# DurAVR™ is addressing the key issues impacting valve durability



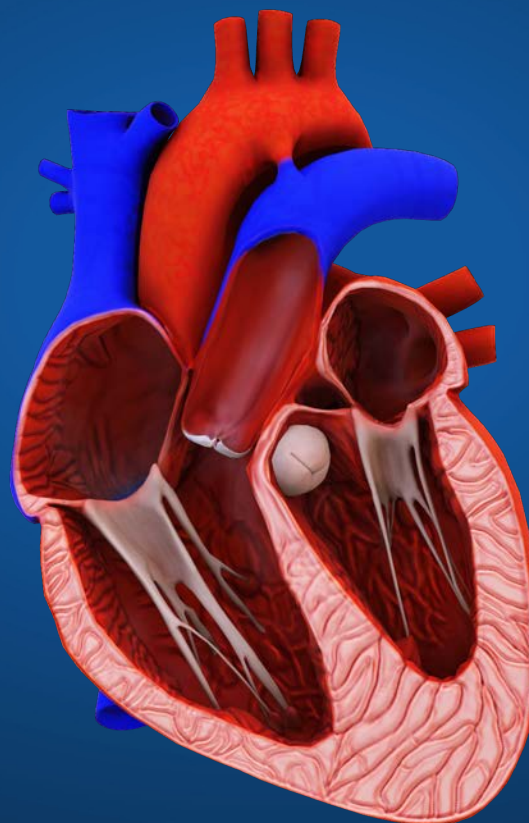
1. We have a unique tissue science (ADAPT®) which has zero DNA and proven not to calcify over 10 years in humans
2. 3D single-piece Aortic Valve (DurAVR™) which has shown no signs of wear over 450 million cycles (approx. 10 years )
3. DurAVR™ is now being studied in humans with excellent early results
4. Evidence is building that indicates superior hemodynamics\*
5. DurAVR™ 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 - Executing on the vision



# Key Clinical and Preclinical Programs

## 2020 Milestones

### First in Human DurAVR™ SAVR Feasibility Clinical Study



Confirm safety and clinical performance of 3D single-piece valve

ClinicalTrials.gov Identifier: NCT0417821

Ethics Committee Approval (Feb 2020)

Belgium Competent Authority Approval (Mar 2020)

First Patient Enrolled and Successfully Discharged (Apr 2020)

### DurAVR™ THV Preclinical Animal Studies



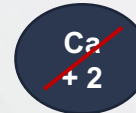
Successful transcatheter access, deployment and delivery of single-piece 3D valve

Acute and Chronic implants

Assess optimal valve function and improved hemodynamics

Data (along with FIH) could bolster our position with regulatory bodies

### Anti-Calcification Comparison Study



Confirm ADAPT® Technology's superior resistance to calcification vs. a commercially available anti-calcification technology tissue commonly used in surgical and TAVR valves.

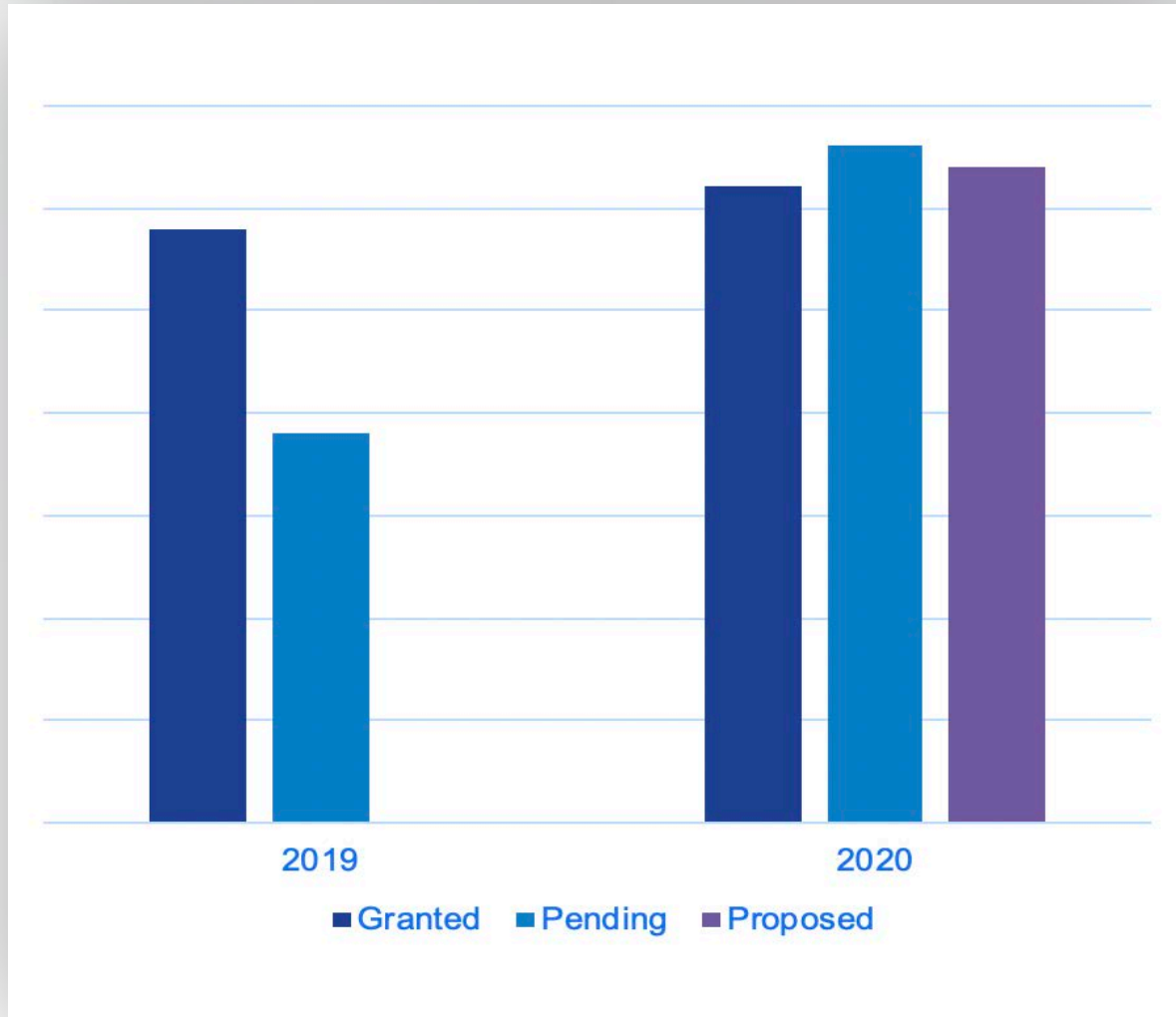
### Conduit Proof of Concept Animal Study



Proof of Concept Study of ADAPT® Technology processed conduit

Potential Carotid and Coronary Bypass Graft

# ADAPT® 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® portfolio will be **2X** their 2019 levels.

# Key Opinion Leader Advocacy supports the science



## ADAPT® PRESENTED AT MAJOR CONGRESSES

- **Dr. Paul Sorajja** (Abbott Northwestern, Minneapolis)
  - World renowned interventional cardiologist
  - First podium presentation of our TAVR at 2019 Cardiovascular Innovations Conference (07/19)
- **Dr. Alan Zajarias** (Washington University, St. Louis)
  - Advancements in tissue technology in TAVR specifically with ADAPT® at the Cardiovascular Innovations Conference (07/19)
- **Dr. Kiran Bhirangi** (Admedus, CMO)
  - Next generation ADAPT® treated BioScaffold at TCT Meeting during Innovation Session (09/19 )
- **EACTS Symposium** (Prof Meuris, Belgium)
  - Over 110 cardiac surgeons in attendance, the benefits of the Next Generation ADAPT® BioScaffold in Aortic Valve Repair to Replacement (10/19)
- **Dr. Vinayak Bapat** (New York Presbyterian / Columbia University)
  - Presented Admedus Innovative TAVR Device at PCR London Valve innovation session (11/19)



# DurAVR™ First in Human study patient #1

	<b>Patients with other surgical valves* (N&gt;1400)</b>	<b>DurAVR Patient 1</b>
Peak Gradient	23	11
Mean Gradient	11	5
EOA	1.9	2.9



\* Average of 1400 patients implanted with commercially available surgical valves at Leuven University Hospitals





# Anteris™ – A new name for a new direction



A new name to reflect the Company's new positioning

Anteris is associated with wasps

- Wasps are:
  - Industrious
  - Team focused
  - Great engineers
  - Undaunted by larger foes
  - Aggressive



# Developing the world's most durable heart valve



## The right science

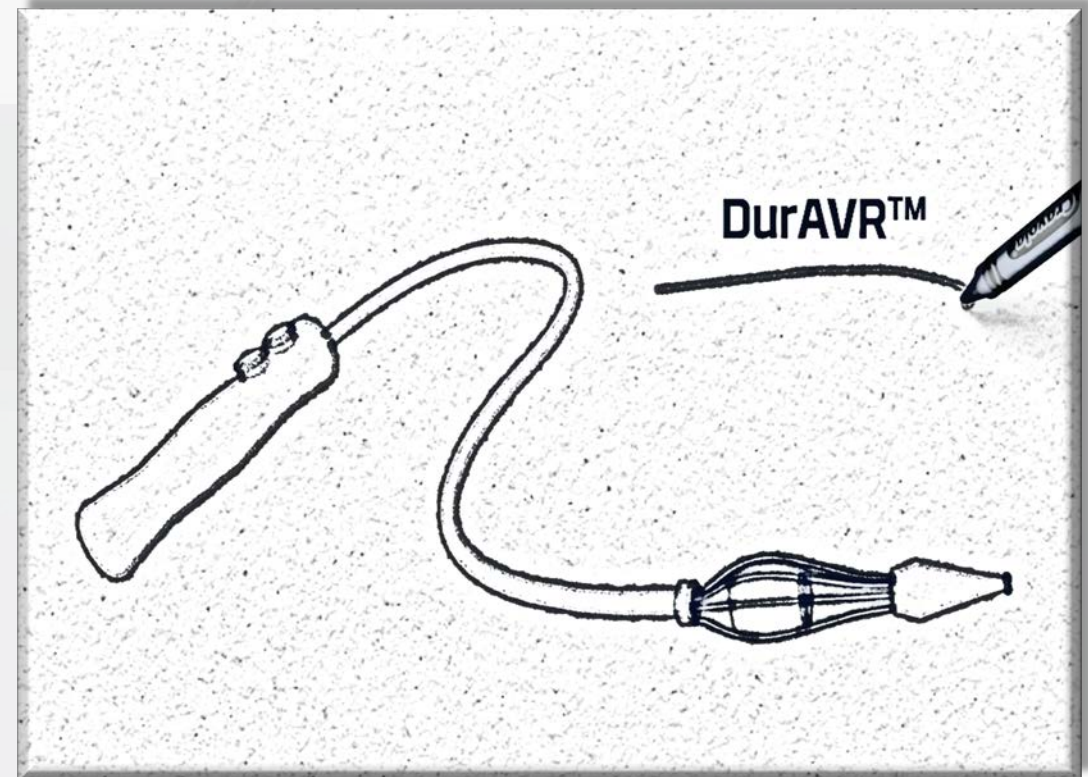
- ADAPT® anti-calcification treatment is proven over 10 years in humans, with zero calcification in published studies

## The right design

- The DurAVR™ 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.



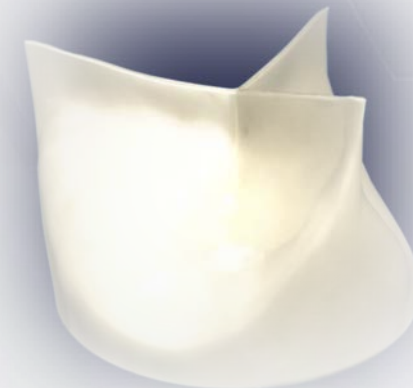
# Capitalizing on the assets



Discussions are ongoing with several of the large MedTech companies

Potential partnership deals could include:

- Licensing of ADAPT® technology to existing in-market TAVR and SAVR products
- Supply of ADAPT® treated material for current in-market products
- Co development of DurAVR™
- Co Commercialisation of DurAVR™



# World class TAVR specific advisory board



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



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



Samir Kapadia, MD  
Cleveland Clinic  
Cleveland, OH



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



Christopher Meduri, MD  
Piedmont Heart Institute  
Atlanta, GA



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



Jeffery Popma, MD  
Harvard Medical  
Boston, MA



Paul Sorajja, MD  
Abbott Northwestern Hospital  
Minneapolis, MN



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



# OPPORTUNITY SUMMARY

Total Aortic valve replacement market expected to be \$7B USD or more by 2025

## THE RIGHT TIME

FDA has approved TAVR in younger, lower risk patients creates need for ultra-durable valve

## THE RIGHT TECHNOLOGY

DurAVR™ 3D single-piece aortic valve with ADAPT® tissue technology

- ▶ Superior resistance to calcification
- ▶ Scientific evidence of superior durability and hemodynamics

## THE RIGHT OPPORTUNITY

TAVR in younger, lower risk patients creates need for ultra-durable valve

- ▶ ADAPT® advantages support business development opportunities
- ▶ Path forward for partnering or independent TAVR development in select markets

## More to come - parallel early-stage R&D:

- ▶ large potential markets for other structural heart indications, as well as non-structural heart indications, with potential to be best-in-class using ADAPT®