ANTERIS TECHNOLOGIES

Building Value with Better Bioprosthetic Valve

Initiation of coverage

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Next-Generation Heart Valves

Anteris Technologies is developing the DurAVR™ valve, an off-the-shelf heart valve made from tissue produced using its proprietary ADAPT® tissue-engineering process. Results to date suggest a functional cure could be achieved in patients suffering from aortic stenosis, the most common form of valvular heart disease requiring intervention in the developed world, using the DurAVR™ valve. DurAVR™ has the potential to become the new standard for bioprosthetic aortic valves implanted via catheter given its durability and hemodynamic profile. Notwithstanding the impact of COVID-19, trials now underway could see clinical validation of the DurAVR™ valve by 2H CY2021. If successful, it could gain a significant market share of the burgeoning transcatheter aortic valve replacement (TAVR) market, valued at US$4b.

Leveraging Unique ADAPT® Tissue Technology

ADAPT® technology confers two important advantages for bioprosthetic heart valves:

- virtually no inflammation or calcification (10 years of clinical data showing anti-calcification with no degradation in 20,000 patients globally)
- better durability and blood flow as the tissue can be moulded into a 3D structure, for better positioning as well as less (and better distribution of) valve leaflet stress.

Two Key Clinical Trials: Watch This Space

Given the unique characteristics of the ADAPT® tissue and clinical interest in the development program to date, Anteris is well positioned to improve significantly on the current industry standard for aortic valves, and we expect its products (subject to clinical validation) could be rapidly adopted when they come on the market. We foresee meaningful news flow over the next 12 months from:

- SAVR (surgical aortic valve replacement): human trials have recently commenced
- TAVR animal study: the company commenced implanting the DurAVR™ valve into nine animals to inform development of proprietary catheter for use in human trials in CY2021.

Anteris is an Australian structural heart med tech company focused on developing medical products and technologies with improved clinical outcomes and durability using its proprietary engineered bovine tissue platform ADAPT. The first-in-human SAVR clinical trial, currently underway, is assessing the performance of the company's proprietary DurAVR™ valve, an ADAPT single-piece 3D aortic valve, in patients undergoing surgical aortic valve replacement for the treatment of aortic stenosis. Anteris recently implanted the DurAVR™ valve into the first three of nine animals via catheter as part of a TAVR feasibility study ahead of an FDA submission for use in a human clinical trial in 2021.

Stock	AVR
Price	A$3.92
Market cap	A$23.4m

Company data	
Net cash	A$5.6m (30 June 2020)
Shares on issue	5.9m

Next steps	
Near term catalyst	SAVR trial completion

AVR Share Price (AS)

FDA Approval Expands TAVR Market

The indications for TAVR have been expanded from the high and intermediate surgical risk patients to include low surgical risk patients, effectively doubling the addressable market and highlighting the need for more durable leaflet tissue to be used, such as ADAPT® treated tissue.

Multiple ADAPT® Opportunities Beyond Cardiovascular

Beyond TAVR, Anteris intends to leverage its ADAPT® tissue technology into other high-value areas of surgical repair, including coronary artery bypass grafts, hernia and dura repair.

Valuation

We value Anteris Technologies at ~A$133m, or ~A$23 per share (undiluted), using a risk-adjusted net present value (rNPV) method to discount future cash flows through to FY2030.

Investment Summary: Moving Up the Med Tech Value Chain

Company Description: Structural Heart Pure Play with Unique Technology Platform

Anteris Technologies (formerly Admedus) is a clinical phase med tech company developing differentiated cardiovascular tissue products for the structural heart market using proprietary ADAPT® tissue technology, notable for its durability and zero calcification properties. The ADAPT® technology has already been validated with several cardiovascular tissue repair products released successfully on the market (see Exhibit 1). Over time, the company's strategy has evolved with increased emphasis on more complex tissue constructs further up the value chain, expanding R&D efforts beyond soft tissue repair and towards more complex soft tissue replacement (see Exhibit 1).

Exhibit 1 – ADAPT® technology validated with products in market (ADAPT® sales in FY18~ A$11m)

Product	Application	Description	Launched	Distribution Rights Sold
CardioCel	repair and treatment of paediatric heart deformities	cardiovascular patch	2014	2019
VascuCel	vascular surgical procedures	collagen bioscaffold	2015	2019
CardioCel 3D	neonatal arch and pulmonary artery repair	contoured cardiovascular patch	2017	2019

Source: Anteris.

Corporate History: Narrowing the Focus to Value-Creating Opportunities

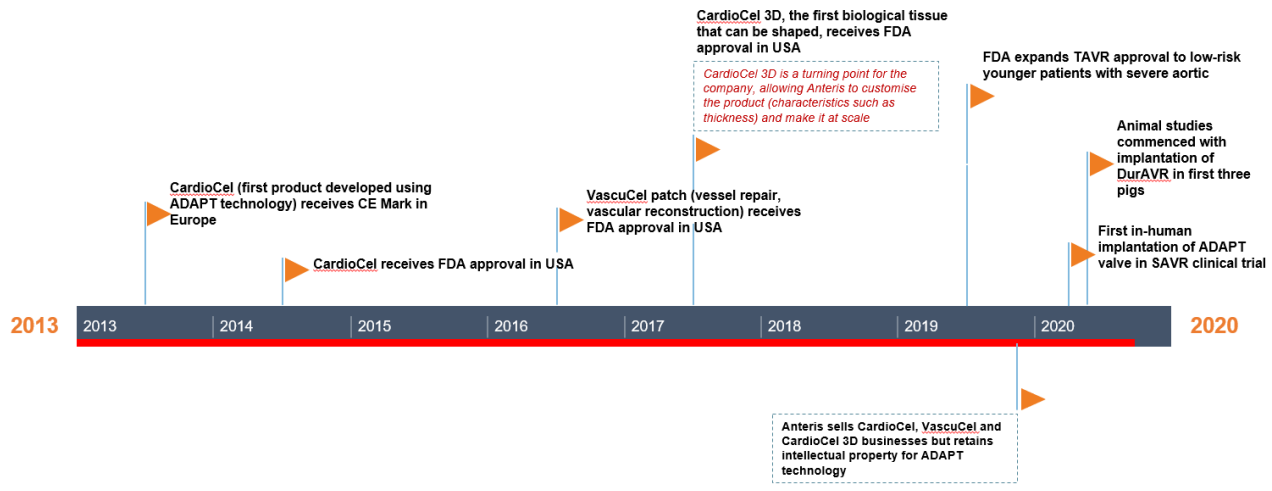
The most recent stage of the company's history began in 2011 when the merger of Allied Medical Ltd and bioMD Ltd (ASX: BOD) created Admedus, a diversified specialist healthcare company comprising three divisions:

- the 'infusion division': a medical device distribution business
- the 'vaccine division': DNA vaccine assets developed by Professor Ian Frazer, the investor of the Gardasil cervical cancer vaccine
- a tissue engineering division based around the proprietary ADAPT® tissue engineering process brought in with bioMD and containing the lead CardioCel program, which was then in phase II clinical trials.

In 2019, the company streamlined its operations by divesting the infusion division for A$6.3m and deconsolidating the vaccine division. Additionally, it sold the rights to the commercially successful ADAPT®-derived CardioCel® and VascuCel® patch portfolio of products to US-based LeMaitre Vascular (NASDAQ: LMAT) for A$36.2m but retained the rights to its patented ADAPT® process.

The subsequent change of name to Anteris Technologies in May 2020 marked the final stage in the transition from diversified specialist healthcare company to structural heart pure play with a unique biomaterial platform.

Exhibit 2 – A history of innovation: new products and technologies moving Anteris steadily up the value chain



Source: Anteris.

Strategy – Leveraging Unique Tissue Technology with Innovative Heart Valve Design

Anteris's long-term strategic objective of realising the potential value of its ADAPT® tissue technology reached a major milestone in March 2020 with the start of the first-in-human surgical aortic valve replacement (SAVR) trial of its single-piece 3D bioprosthetic aortic valve, the DurAVR™ valve, at Belgium's Leuven University Hospital. The 15-patient trial follows an earlier favourable sheep trial and aims to evaluate safety and performance in adults requiring replacement of the aortic valve. Interim results are expected in 1Q–3Q CY2021. The trial has successfully treated 5 patients to date.

The company's DurAVR™ valve leverages the proprietary ADAPT® bio-scaffold material using an innovative single-piece valve design, thereby combining the attributes of tissue durability and zero calcification, both major shortcomings of conventional bioprosthetic valves, with the superior hemodynamic profile of the suture-less design.

With the DurAVR™ valve, Anteris is targeting the rapidly growing area of transcatheter aortic valve replacement therapy (TAVR), a minimally invasive approach to treating patients with aortic stenosis (AS), the most common and serious of valvular heart diseases requiring intervention in the developed world. TAVR uses a catheter-mounted valve introduced through a blood vessel in the patient's leg or small incision in the chest for access to the heart to replace a stenotic native aortic valve. Once the new valve is in place, the catheter is removed. TAVR has become an alternative to SAVR (open-heart surgery) in high- and intermediate-risk patients with AS, with the global market valued at around US$4b. In 2019, the FDA approved the use of TAVR in low-risk patients, effectively doubling the addressable market. According to market leader Edwards Lifesciences, the global TAVR market will reach US$7b by 2024 (CAGR ~12%).

Exhibit 3 – SAVR versus TAVR: TAVR is a less invasive, longer-lasting, safer process

Surgical Aortic Valve Replacement (SAVR)	Transcatheter Aortic Valve Replacement (TAVR)
Established in 1952	Established in 2002
General anesthesia	Conscious sedation
Requires open-heart surgery	Minimally invasive
For mechanical and biosprosthetic valves	For bioprosthetic valves
For mechanical require lifelong anti-coagulants	Long term anticoagulants not required
7 day hospital stay post procedure	3 day hospital stay post procedure
Rehospitalization for heart failure at 1 yr ~ 3.6%	Rehospitalization for heart failure at 1 yr ~ 1.4%

Source: MST Access.

Based on results rendered in the Belgian SAVR trial and animal studies of the DurAVR™ valve implanted using TAVR, subject to FDA approval, the first-in-human TAVR trial of the device could launch by end-CY2021. Results delivered in bench, animal and human studies to date indicate it could be a fully functional, more durable cure for severe AS.

Potential Near-Term Catalysts

- SAVR trial completion of recruitment and update on performance findings of patients implanted to date
- Rat study findings for signs of calcification in head-to-head comparison with commercial valve in market
- TAVR animal trial program progress and the development of TAVR catheter delivery system
- Early Feasibility Study (EFS) submission to FDA for commencement of human TAVR trial
- FDA approval for the go ahead and commencement of first-in-human TAVR trial of the DurAVR™ valve

Valuation: Risk-Adjusted NPV Method

We value Anteris Technologies at ~A$133m, or ~A$23 per share (undiluted), using a risk-adjusted net present value (rNPV) method to discount future cash flows through to FY2030 (see valuation section for details).

Risks: Validated Technology with Over 10 Years of Clinical Data Follow-up

Notwithstanding the company's proven technology and compelling clinical data history to date, Anteris' near-term investment case relies heavily on the commercialisation of the DurAVR™ valve in the TAVR setting. As such, key sensitivities include: the rate of clinical progress in both its SAVR (as the first step towards validation of the valve) and TAVR trials, regulatory risk related to timing of FDA approvals, funding risk given capital requirements to support ongoing development, reimbursement risk, and adoption by end users of the product, essentially interventional cardiologists.

Company Outlook: Unique Tissue Technology Platform

Anteris Technologies (formerly Admedus) has a validated tissue platform and proven track record of developing and commercialising niche cardiovascular products for the structural heart disease market, which have been adopted by interventional cardiologists in more than 135 global centres. The treatment of structural heart disease as a sub-segment of cardiology has grown significantly over the past 20 years driven by advances in surgical techniques, the growing incidence of heart valve disease given the ageing population, and advances in tissue engineering technologies and valve design innovation. Tissue engineering strategies have been a key driver of new product development for a multitude of applications and remain fertile ground for innovative new entrants.

The Investment Story: Moving Steadily Up the Value Chain

Anteris' investment story is built on the merits of its proprietary ADAPT® tissue engineering technology, used to develop regenerative medical devices for the heart with high growth potential. In 2005, ASX-listed bioMD, which later merged with Allied Healthcare to form Admedus, acquired a 50% stake in Celxcel, bringing in the tissue engineering technology developed by Professor Leon Neethling. Professor Neethling had brought the concept back from South Africa where he founded the first human heart valve bank in 1984. An early R&D collaboration with Anteris leveraging the technology for cardiovascular soft tissue repair applications culminated in the development of the company's first three commercial ADAPT® soft tissue repair products: CardioCel, VascuCel and CardioCel 3D (see Exhibit 2).

2017 pivot to TAVR

In 2017 the company shifted its strategic focus towards the rapidly growing area of transcatheter aortic valve replacements (TAVR), as the next commercial opportunity for its ADAPT® tissue technology, evolving into the DurAVR™ valve program now in mid-stage development. The TAVR market was valued at ~US$4b globally in 2019 and according to market leader Edwards Lifesciences is expected to reach US$7b by 2024, representing CAGR of ~12%.

A Short History of Tissue Engineering – ADAPT® Is a Shining New Landmark on a Long Road

Tissue engineering (TE) is the generation of new tissue from cells with the support of biomaterials and growth factors. TE is a branch of regenerative medicine, using biological scaffolds, cells, and biologically active molecules in clinical practice to construct functional matrices that allow the body's own cells to restore, maintain, or improve damaged tissue and organs.

TE has held promise for a variety of clinical applications, in the repair of diseased or damaged vital organs (e.g., liver, kidney, pancreas, spinal cord) and more structural tissues (e.g., skin, cardiac tissue, blood vessels, muscle). Despite the excitement and early approvals of tissue engineered products (see Exhibit 4), progress across all targeted indications has been uneven[1].

The most successful clinical applications of TE to date have been in the therapeutic areas involving structural tissue such as skin (acute and chronic wound care – notably, Apligraf and Dermagraft), musculoskeletal indications (orthopaedics), and cardiovascular (heart valves, vascular).

Engineered tissue constructs with properties resembling human native cardiac tissue have been of special clinical interest in congenital cardiac surgery given the shortage of viable donor tissues and the potential to avoid repeated interventions and/or surgery, particularly in paediatric patients. Initial applications of cardiac TE involved the creation of blood vessel substitutes using synthetic polymer scaffolds seeded with autologous (patient's own) endothelial cells and cultured in a bioreactor. This has been expanded upon to include novel methods of de-cellularisation[2] of natural materials (porcine and bovine) and production of 'off-the-shelf' tissue-engineered products capable of in situ[3] host cell repopulation or ingrowth.[4] Nonetheless, tissues with all the desired qualities for surgical repair of congenital heart disease remain elusive. Ideal qualities include resisting calcification, immunogenic response activation, infection, and thrombosis in addition to supporting tissue remodelling, cost effectiveness, ready availability, and easy handling.

[1] Tissue Engineering: The Hope, the Hype, and the Future: R.Nerem

[2] Decellularisation refers to the removal of cells from a tissue or organ while maintaining the underlying extracellular matrix (ECM)

[3] In position post implant

[4] State of the Art: Tissue Engineering in Congenital Heart Surgery: R.Boyd, F.Parisi, D.Kalfa

Exhibit 4 – Select tissue engineered medical products approved by the FDA

Product	Sponsor	Use	Approval
Skin Applications			
Apligraf (Viable Allogeneic Fibroblasts/ Keratinocytes On Type-1 Bovine Collagen)	Organogenesis Inc.	Standard therapeutic compression for treatment of non-infected partial and full-thickness skin ulcers	1998-Device (PMA)
Dermagraft (Cryopreserved Dermal Substitute; Allogeneic Fibroblasts, Extracellular Matrix, Bioabsorbable Scaffold)	Advanced Tissue Sciences, Inc.	Treatment of full-thickness diabetic foot ulcers	2001-Device (PMA)
Composite Cultured Skin (Viable Allogeneic Fibroblasts/Keratinocytes On Collagen Matrix)	Ortec International Inc.	Adjunct to stndard autograft procedures for covering wounds and donor site after surgical release of hand contractions in Recessive Dystrophic Epidermolysis Bullosa patients	2001-Device (HDE)
Dermagraft (Cryopreserved Dermal Substitute; Allogeneic Fibroblasts, Extracellular Matrix, Bioabsorbable Scaffold)	Smith and Nephew Wound Management	Treatment of wounds related to Recessive Dystrophic Epidermolysis Bullosa	2003-Device (HDE)
Musculoskeletal Applications			
Carticel (Autologous Cultured Chondrocytes)	Genzyme Corporation	Repair of femoral condyle casude by acute or repetitive fracture	1997-Biologic (BLA)
OP-1 Implant (Recombinant Human Osteogenic Protein (rh OP-1), Type-1 Bovine Bone Collagen Matrix)	Stryker Biotech	Alternative to autograft in recalcitrant long bone nonunions	2002-Device (PMA)
InFUSE Bone Graft/ LT-Cage Lumbar Tapered Fusion Device (Recombinant Human Bone Morphogenetic Protein-2, Type-1 Bovine Bone Collagen, Titanium Alloy Cage)	Medtronic	Spinal fusion for degenerative disc disease	2002-Device (PMA)
Cardiovascular Applications			
CardioCel (Collagen scaffold bio-engineered using ADAPT® engineered tissue technology)	Admedus (Anteris)	Cardiovascular patch repair of paediatric heart deformities	2014-510(k) clearance
VascuCel (Collagen scaffold bio-engineered using ADAPT® engineered tissue technology)	Admedus (Anteris)	Vascular patch surgical procedures used for repair	2016-510(k) clearance
CardioCel 3D (Collagen scaffold bio-engineered using ADAPT® engineered tissue technology)	Admedus (Anteris)	Pre-shaped (contoured) patch for repair of complex heart defects with non-antigenic response and calcification resistance	2017-510(k) clearance

Source: Topics in Tissue Engineering, Vol. 4. Eds. N Ashammakhi, R Reis, & F Chiellini/Anteris.

ADAPT® Tissue Technology: The Heart of the Matter

The ADAPT® technology is used to process animal-derived tissues to produce implantable tissue prosthetic devices that are compatible with the human body. This technology has been shown to produce reliable, biocompatible, and versatile regenerative prosthetic devices capable of being used in place of synthetic products currently used in many soft tissue repair applications. Enhanced crosslinking and effective anti-calcification produce a biomaterial with advanced in-vivo tissue-engineering properties.

ADAPT® tissue technology uses bovine (cow) pericardium which is certified as free of BSE (bovine spongiform encephalopathy, commonly known as mad cow disease) to create a tissue scaffold, or bio-scaffold, that once implanted is repopulated with the host's native cells during the healing process. Although bio-scaffolds derived from xenogeneic[5] extracellular matrix (ECM) have been used in numerous tissue engineering applications (see Appendix 3), matrix preparation remains controversial due to incomplete cell removal, inflammatory responses, reabsorption, and thrombocyte activation. As such, processing methods play a critical role in determining the type of host response[6].

The ADAPT® treated tissue manufacturing process outlined in Exhibit 5 consists of six tissue engineering steps, many of which are novel, proprietary and/or patented. Several of these steps confer significant points of differentiation in structural heart applications. Overall, this process ensures that:

- the valve has strong anti-calcification properties
- all substances that could cause an immune response from the patient are removed (phospholipids, cells, cell remnants, nucleic acids such as DNA and RNA, α-Gal epitopes)
- the valve is strengthened for durability.

Exhibit 5 – ADAPT® tissue engineering process – steps in manufacturing protocol

Step 1 **Delipidation ***	Bovine pericardium sourced in WA and stored in alcoholic solution at low temperature for up to 18 months
Step 2 (novel) **Decellularisation**	Removal of cells and cell remnants out of collagen followed by rinsing procedure
Step 3 **Nuclease treatment**	Removal of alpha gal epitope Removal of DNA + RNA using a nuclease treatment process
Step 4 (novel) **Cross-linking**	Stabilisation of collagen matrix with monomeric aldehyde (ultra-low concentration with precise pH and temperature)
Step 5 **Detoxification ***	Treatment of tissue with proprietary process that allows binding of residual aldehyde and enhances ingrowth of native cells
Step 6 (novel) **Sterilisation**	Sterilisation using propylene oxide which converts to propylene glycol (non-toxic) that allows tissue to be used directly without rinsing

* Note: Steps 1 and 5 in combination are patented and known as the ADAPT® process. Step 2, which ensures no antigenic response in the patient, is novel as a result of its unique chemical combination. Step 4, which increases the valve's durability, is novel and proprietary but not patented (in-house secret). The process for Step 6 is also novel and patented in various jurisdictions.
Source: Anteris.

Clinical evidence of durability with zero calcification compelling; 10 years and mounting

Importantly, ADAPT® tissue science has over 10 years of clinical evidence, from over 20,0000 implant procedures, demonstrating resistance to calcification. According to the company, ADAPT® technology is the first and only next-generation bio-scaffold that completely re-engineers xenograft tissue into a pure collagen scaffold with optimised strength and pliability, superior biocompatibility, and unparalleled durability. Exhibit 6 summarises key clinical studies leading up to the current SAVR trial.

[5] different species from the recipient

[6] Processing methods play a critical role in determining the type of host response (Valentin et al., 2009; Faulk et al., 2014 a,b).

Exhibit 6 – Select studies in development of ADAPT®

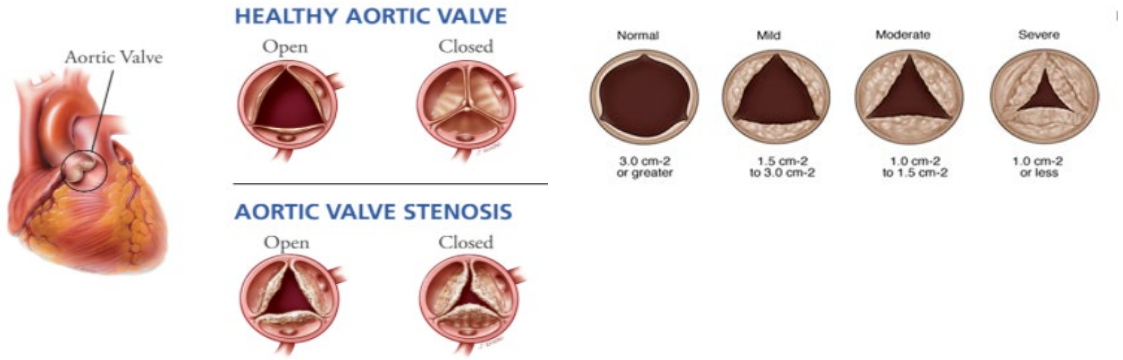
Dates	Study	Stage	Purpose	Notes
2004	Comparative study of ADAPT treated porcine valve tissue in rats	Pre-clinical	Compared crosslink stability and calcification behavior of ADAPT treated porcine tissue versus Medtronic Freestyle and Prima Plus	Crosslink stability and calcification behaviour found to be comparable to those of Freestyle and Prima Plus. (J Heart Valve Disease 2004;13:689-696)
2006	Rat implant study	Pre-clinical	Assessed level of fibrosis and suppleness of both kangaroo and bovine perciardial patches treated with ADAPT implanted in rats over 120 days.	Showed enhanced tissue regeneration characteristics with high resistance to calcification.
2006	Sheep implant study (independent 3rd party)	Pre-clinical	Assessed ADAPT treated kangaroo and bovine pericardium tissue patches implanted in sheep jugular vein for 150 days.	Both kangaroo and bovine patches found to be durable, functional and biocompatable.
2007	Sheep implant study	Pre-clinical	Assessed biostability and biocompatibility of ADAPT treated bovine pericardium patches implanted in jugular vein of juvenile sheep for 200 days.	ADAPT treated matrices proved to be: stable; with low immunoreactivity; host cell infiltration; optimal cross linking; almost zero calcification levels. (J Heart Valve Disease 2008 Jul;17(4):456-63)
2007	Comparative ADAPT treated bovine patch study in rats	Pre-clinical	Compared ADAPT treated bovine pericardial patches versus two other commerically available biomaterial patches for durability.	ADAPT treated pericardial patches showed superior long term (12 month) integrity and flexibility with signs of remodelling at the edge of the matrix.
2010	Comparison study in rats	n/a	Examined tissue characteristics (cytotoxicity, calcification potential, biocompatibility) of ADAPT treated bovine pericardium following prolonged implantation in a subcutaneous rat model	Showed reduced antigenicity, optimized crosslinking and efficient antimineralization of the acellular bovine pericardium tissue scaffold with favourable long-term tissue engineering properties following extended implantation times. (J Heart Valve Disease 2010;19:778-785)
April 2008 - September 2009	First in Human trials of CardioCel (the Bloemfontein Study)	Phase II	A 30 patient phase II trial evaluating the performance (morbidity and calcification) of the tissue-engineered ADAPT® bovine pericardial scaffold (CardioCel) in pediatric patients with congenital cardiac defects	CardioCel demonstrated excellent medium to long-term performance (up to 10 years) when used as a scaffold for repair of congenital cardiac defects in children. Durability, acellularity, biostability and non-calcifying potential of CardioCel® makes it a very attractive tissue for congenital
September 2015-November 2018	CardioCel Tri-leaflet Repair Study (CTRS)	n/a	Safety and efficacy of the CardioCel for the repair of aortic valve stenosis and/or insufficiency. Study quantified the safety and efficacy of the CardioCel implant in tri-leaflet repair. 80 patients in up to 7 sites in Europe and the US treated with the CardioCel implant.	Clinicaltrials.gov ID : NCT02629328
February 2016-September 2017	Vascular Post Market Review	n/a	Post market. Confrimatory study that properties of CardioCel provided operative benefit to surgeons when compared to Dacron, CorMatrix, and all other bovine pericardium not treated with proprietary ADAPT engineering.	Clinicaltrials.gov ID : NCT02681341
June 2020-March 2024	CardioCel 3D Registry	n/a	Post-market, prospective, multi-centre, open-label, registry designed to collect prospective safety and performance data on the use of CardioCel in patients with cardiovascular disorders and in accordance with local standard of care	Clinicaltrials.gov ID : NCT04175327
March 2020-January 2022	First in Human Feasibility Study With ADAPT 3D - ALR for Aortic Leaflet Repair	Phase I	This study will evaluate the safety and performance of the ADAPT 3D - ALR in adult patients requiring replacement of aortic valve. 15 patients in one site in Belgium will all be treated with ADAPT 3D - ALR.	Clinical trials.gov ID NCT04178213. Trial has commenced with 4 patients now implanted as at August 2020.

Source: Anteris.

Aortic Valve Stenosis: An Emerging Epidemic Driven by an Ageing Population

Aortic valve stenosis or aortic stenosis (AS) is a slow progressive disease characterised by narrowing of the aortic valve, making it difficult for the heart to pump blood from the left chamber (the left ventricle) into the aorta. This can cause the left ventricle to thicken and enlarge, reducing cardiac efficiency and weakening heart function overall. AS is the most common and serious of valve diseases with prevalence estimated at around 3% of the population aged between 60 to 74 years, increasing to around 13% for those over 75 years or around 1 in 8 people. Although AS can be caused by rheumatic fever or congenital heart defects, the most common cause is the build-up of calcium deposits over time, and therefore the disease is highly correlated with ageing.

Exhibit 7 – Aortic valve stenosis and the progressive narrowing of the aortic valve over time

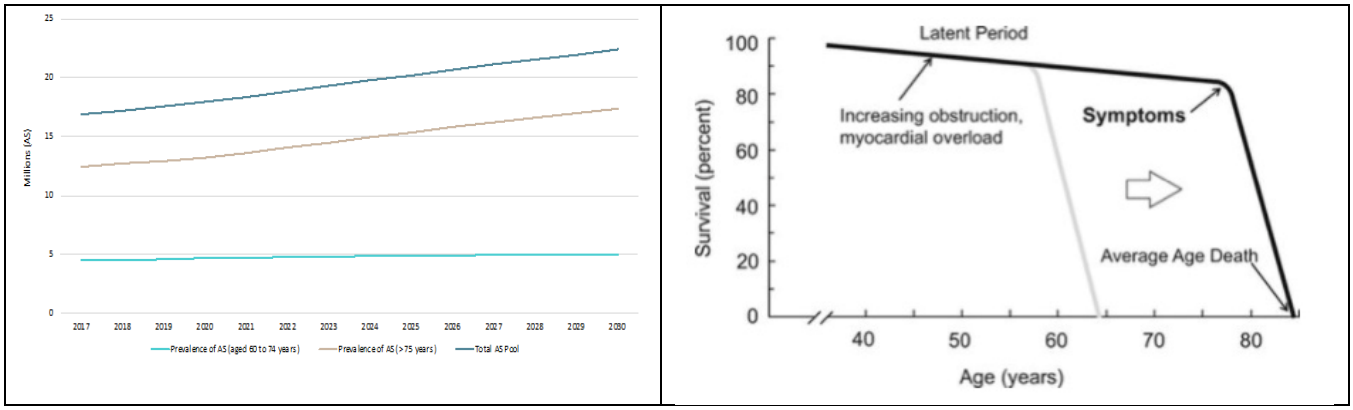


Source: https://intermountainhealthcare.org/services/heart-care/conditions/aortic-valve-stenosis.

Progressive narrowing of the aortic valve from calcification of the valve leaflets (see Exhibit 7) leads to inadequate cardiac output, decreased exercise capacity, heart failure and death from cardiovascular causes. Given its slow progression, AS patients can be asymptomatic for decades. In fact, many people are unaware they have the condition or may be told they have a heart murmur during a routine check-up. Notwithstanding sudden death syndrome (1% of asymptomatic patients), mortality is not increased when AS is asymptomatic. However, mortality is more than 60% at 2 years once patients develop symptoms (dyspnoea on exertion, angina, syncope). For more information about AS, including risk factors, symptoms, diagnosis and treatment, see Appendix 1.

We estimate total prevalence of AS for people aged over 60 will reach 22m by 2027, with the condition increasing particularly quickly among those over the age of 75 (Exhibit 8, left). Importantly, medical intervention is an urgent priority for patients once they have become symptomatic, as the typical time between symptoms presenting and death for this condition is alarmingly short (Exhibit 8, right). This shows the importance of the TAVR procedure for patients who start to show symptoms and may not be eligible for surgery due to their age or other conditions.

Exhibit 8 – AS is growing in developed nations (USA, EU, UK, Japan), especially among older people (left); left untreated, symptomatic AS is often quickly fatal (right)



Source: United Nations Population Forecasts and MST Access estimates (left); American Heart Association (right).

TAVR: A New Era in the Treatment of Aortic Valve Stenosis

Surgical aortic valve replacement (SAVR), first performed in the late 1960s, was until the past decade the standard of care for the treatment of AS. However, the landmark 2011 PARTNER (Placement of Aortic Transcatheter Valve) trial sponsored by Edwards Lifesciences established transcatheter aortic valve replacement (TAVR) as an alternative, less invasive procedure for the sickest AS patients. These patients deemed high risk for traditional open-heart surgery typically presented with comorbidities or anatomical complications and were considered too frail to undergo SAVR.

Extending TAVR to a New Cohort of Patients

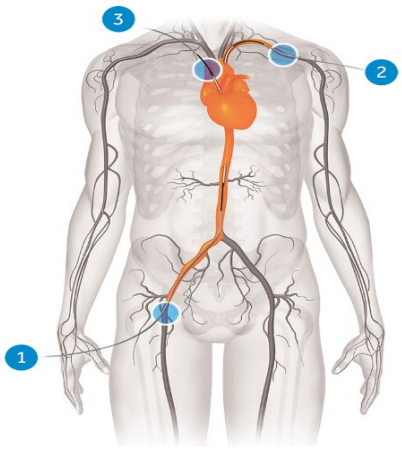
Based on findings from clinical trials[7] conducted in the past 5 years comparing SAVR and TAVR in patients with AS, approval for TAVR has been extended to patients with intermediate and low surgical risk. This extension of the procedure's availability to the low-risk cohort now covers all patients with AS, essentially doubling TAVR's addressable patient population and shifting the mean age of eligible TAVR patient lower to the mid-60s. TAVR is now considered a viable, less invasive alternative treatment for AS patients who:

- have low, intermediate or high risk of complications from a SAVR procedure
- are unable to undergo open-heart surgery due to advanced age or the presence of cardiovascular risk factors
- have other comorbid conditions, or prior history of stroke, chest radiation, open-heart surgery, COPD, frailty, renal insufficiency, or other conditions.

How TAVR Works: Minimally Invasive, Without Open-Heart Surgery

TAVR uses a catheter-mounted valve to replace the aortic valve percutaneously (see Exhibit 9). Using imaging and a delivery system, the physician threads the compressed bioprosthetic heart valve through the catheter and positions it within the diseased valve. After positioning the bioprosthetic valve, the physician begins deploying the valve. When deployment is complete, the bioprosthetic valve is fully expanded within the diseased native valve.

Exhibit 9 – TAVR: A minimally invasive procedure for severe aortic stenosis (top); aortic valve replacement (bottom)

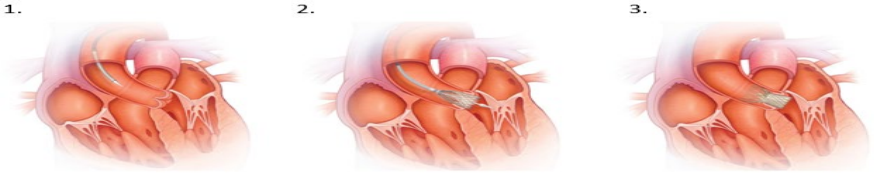


TAVR does not require open-heart surgery.

TAVR accesses the heart via an artery.

There are three access options:

1. Transfemoral
2. Subclavian
3. Direct aortic



Source: https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/cardiovascular/transcatheter-aortic-valve-replacement/tavr/about-the-therapy.html.

[7] The PARTNER 3 trial (The Safety and Effectiveness of the SAPIEN 3 Transcatheter Heart Valve in Low Risk Patients with Aortic Stenosis) that evaluated the Sapien 3 valve (Edwards Lifesciences LLC). The Evolut Low Risk trial (Medtronic Evolut Transcatheter Aortic Valve Replacement in Low Risk Patients that evaluated the Evolut valve (Medtronic Inc)).

Safe and Effective, but Some Risks Associated with TAVR

TAVR has been found to be safe and effective. Nonetheless, the procedure still carries some risk:

- **Valve leaks** if the replacement is not big enough.
- **Pacemakers** sometimes required because new valves press on the heart's electrical system.
- **Kidney damage:** The contrast dye used for imaging can damage kidneys, but the problem is usually reversible.
- **Vessel damage:** Passing catheters through arteries can sometimes damage them.
- **Stroke:** A small percentage of people undergoing TAVR can develop a stroke.

TAVR Procedure Numbers and Market Share Expected to Grow

We expect the shift towards TAVR approaches to continue and thereby increase the market opportunity for innovation in bioprosthetic valves (see Exhibit 10).

Doctors are getting on board

The FDA's approval of TAVR in both intermediate- and low-risk patients combined with mounting clinical evidence of non-inferiority to surgery is driving acceptance from doctors and putting the procedure on equal footing with SAVR in first line settings.

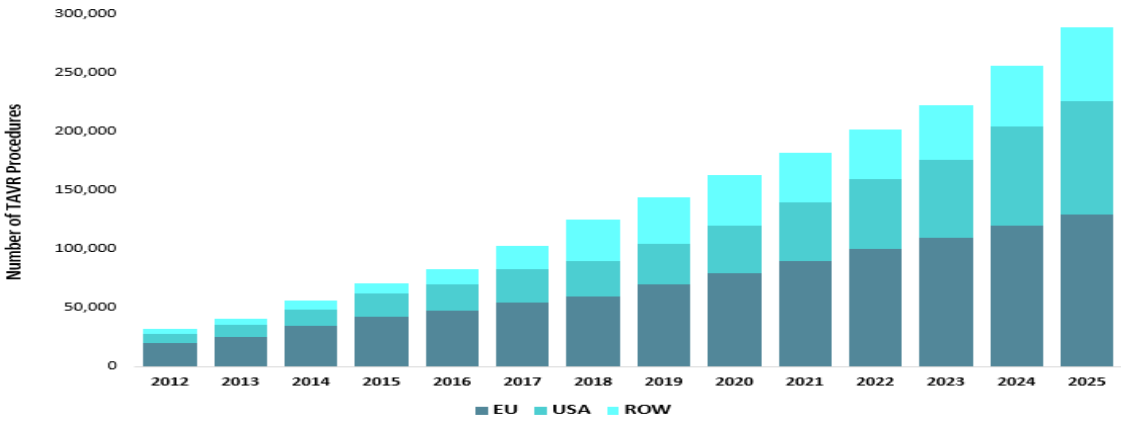
Procedure appears to boost long-term survival rates for some patients

There is also growing evidence in the scientific literature that earlier use of AVR in asymptomatic severe AS patients improves long-term survival rates when compared with similar cohorts of patients initially recommended to watchfully wait[8].

TAVR reduces costs to hospitals

Adoption of the TAVR procedure has been supported by the development and popularisation of techniques that enable its implantation in hybrid operating rooms[9] and catheterisation labs without the use of extra-corporeal circulation (such as a heart-lung bypass machine used with SAVR procedures), improved stent designs and smaller and more efficient delivery systems. With most procedures performed under local sedation with faster recovery times, TAVR also reduces hospital overheads when compared with open-heart surgery with less time in ICU.

Exhibit 10 – TAVR momentum set to continue



Source: Rapid adoption of transcatheter aortic valve replacement in intermediate- and high-risk patients to treat severe aortic valve stenosis (Cesna et al, 2017).

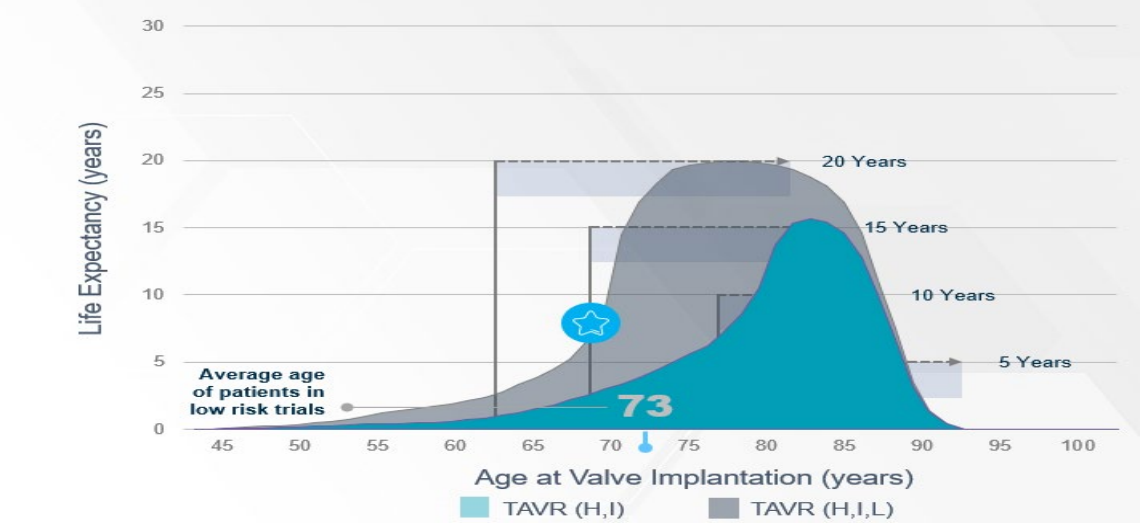
[8] Prognosis of Severe Asymptomatic Aortic Stenosis with and without Surgery (Campo et al, 2019)

[9] A Hybrid Operating Room is an advanced procedural space that combines a traditional operating room with an image guided interventional suite allowing cardiac surgeons and interventional cardiologists to work together more efficiently.

TAVR Market Expansion to Drive Bioprosthetic Valve Innovation

Continued growth of the TAVR market will test the shortcomings of current generation bioprosthetic valves and enhance the opportunity for innovative new entrants such as Anteris. We expect the approval of TAVR for low-risk patients combined with the growing demand for replacement of first generation bioprosthetic valves will focus clinical attention on durability of current generation valves – an area of strength for the DurAVR™ valve.

Exhibit 11 – TAVR market doubles following FDA approval of low-risk patients in 2019



Source: Anteris (AS patient risk classification approved for TAVR: H=High, I=Intermediate, L=Low).

Current bioprosthetic aortic valve technology still evolving – plenty of room for improvement

Surgical aortic valve surgery has evolved over six decades and remains the benchmark for reliable, reproducible, durable and readily available surgery using either mechanical, tissue or autologous valve technology.[10] Despite the rapid rise of minimally invasive TAVR procedures to first line settings, innovation has been largely focused around delivery systems[11] (frames and stents) and less on the valve technology per se. As such, we think this represents a significant opportunity for new entrants to compete with differentiated technology that can improve on current valve offerings along the following dimensions/parameters:

- durability
- shear stress
- EOA
- GOA
- mean peak gradients.

Durability is key according to KOLs

According to structural heart KOL, Dr Paul Sorajja[12], durability of transcatheter aortic valves (TAVs) is key, given tissue leaflets vulnerability to structural degeneration from calcification and thrombosis, and essential for extending penetration and adoption into younger and lower-risk patients. Other attributes cited for a 'perfect' TAVR prosthesis included:

- EOA of 3-4 cm
- a human-like design
- easily deliverable, accurate, precise and cost effective.

10 Technology for new surgical aortic valve replacement: current evidence and future directions (J. Shuhaiber, 2018)

11 For example, balloon-expandable devices (SAPIEN-XT and SAPIEN 3 by Edwards Lifesciences) versus self-expanding devices (Corevalve by Medtronic).

12 Roger L. and Lynn C. Headrick Family Chair at the Valve Science Centre at the Minneapolis Heart Institute Foundation

DurAVR™ Valve – Innovative Valve Design Using ADAPT® Technology

Anteris's transcatheter aortic DurAVR™ valve has been in development since 2017 and represents the company's first major new product since the CardioCel 3D patch. As a replacement rather than repair device, the valve is more complex and of a higher value than the patch. Based on Anteris' bench tests and animal study findings to date, combined with the highly differentiated anti-calcification properties of all products generated using the ADAPT® technology, there is potential for the DurAVR™ valve combined with TAVR to be a breakthrough for AS patients.

The DurAVR™ valve combines a novel single-piece 3D design with proprietary ADAPT® tissue-engineered bovine pericardium scaffold (tissue/biomaterial scaffold made using the company's proprietary ADAPT® technology). This combination of characteristics results in a superior hemodynamic valve that is more durable and better suited than current commercial valves for use in TAVR procedures in younger patients with severe AS.

Exhibit 12 – DurAVR™ valve – Leveraging ADAPT® tissue science

Better Science - ADAPT Tissue technology

- *Zero residual DNA*
- *No evidence of calcification*
- *Long term durability*

Better Design - First 3D single piece design

- *Anatomically correct*
- *Wider valve opening and better blood flow*
- *Easy to implant, requiring fewer stitches*

Source: Anteris.

Potential for Best in Class and the First Functional Cure for Aortic Stenosis

Head-to-head comparisons with commercially available products are impressive and are raising hopes of a functional cure (return to pre-disease hemodynamics) with the DurAVR™ valve when measured by two key parameters: changes in mean gradient (ΔP (mmHg)) and EOA (effective orifice area).

Exhibit 13 – Direct comparisons with commercially available TAVR valves raises hopes of a functional cure using the DurAVR™ valve, which obtains results very similar to a healthy patient

	ΔP (mmHg)	EOA (cm^2)
Normal	4.0-5.0	3.5-4.00
DurAVR	3.86-5.34	3.04-3.28
Corevalve (4)	7.76-10.27	1.44-1.66
Sapien (5)	11.66	1.35

Source: Anteris.

Exhibit 14 – Superior hemodynamic performance across the board (ΔP mean ≤ 6mmHg EOA ≥ 2.9cm^2)

Design Option	Inner Diameter of Annulus or Surgical Valve (mm)	ΔP mean (mmHg)	EOA (cm^2)
 DurAVR™ (25MM)	23	4.89	3.07
	21	5.17	3.04
 DurAVR™ (25MM)	23	5.34	3.26
	21	3.86	3.28
COREVALVE* (26mm)	21	7.76 ± 0.14	1.66 ± 0.05
COREVALVE* (23mm)	(True ID of 23mm Perimount)	10.27 ± 0.18	1.44 ± 0.05
SAPIEN* (23MM)		11.66 ± 0.22	1.35 ± 0.02

Source: Anteris.

Anteris commenced its first-in-human SAVR trial[13] of the DurAVR™ valve in May 2020 at the Leuven University Hospital in Belgium. The 15-patient trial follows an earlier favourable sheep trial of the valve and aims to evaluate the safety and performance of the ADAPT® valve in adult patients requiring replacement of the aortic valve, with results expected between 1Q CY2021 and 3Q CY2021. The SAVR trial has successfully treated 4 patients to date.

On 9 October 2020, the lead surgeon in the SAVR trial, Professor Bart Meuris MD, PhD, presented early findings at the European Association for Cardio-Thoracic Surgery (EACTS) Annual Conference stating early results support the clinical hypothesis that the DurAVR™ valve, given its anatomically correct design and superior anti-calcification treatment of ADAPT®, has 'the potential to offer patients a functional cure'.

Exhibit 15 – Encouraging results from first in-human SAVR trial (15 patients) on key valve parameters (see glossary)

	Patients with other surgical valves* (N>1400)	DurAVR™ Patient 1
Peak Gradient mm Hg	87 mmHg	11 mHg
Mean Gradient mm Hg	55 mmHg	5 mmHg
EOA cm^2	1.9	2.9

Source: Anteris.

The SAVR trial is assessing the hemodynamic performance of the DurAVR™ valve with the completion date set for the end of CY2020. Patients will be monitored for 6 months with interim results expected in 1Q CY2021. Early findings, albeit from the first of four patients implanted with the device, are encouraging.

Exhibit 16 – SAVR trial (clinicaltrials.gov ID NCT04178213)

Primary endpoints	
Performance	Hemodynamic performance assessment (Mean Gradient,EOA) at 6months following implantation
Safety	Objective performace critera for flexible heart valve events assessment at 6 months following implantation
Secondary endpoints	
	Onset atrial fibrillation 6 months post procedure
	ICU duration of stay (30 days post procedure)
	NYHA improvement assessment (6 months after implantation)
	Length of stay in hospital (30 days post procedure)
	Hemolysis screen (6 months post procedure)

Source: Clinicaltrials.gov.

In May 2020, the company also commenced animal studies to compare anti-calcification properties with commercially available valves in rats.

Delivery system in development

In September 2020, the company commenced animal studies for the development of its proprietary delivery system. The study will inform the design of the catheter used in the transport of its DurAVR™ valve from the femoral artery to the site of the patient's aortic valve with readout expected December 2020. Anteris has completed development of its proprietary frame device with supra annular balloon expander.

Manufacturing in place

All manufacturing is based in Malaga, near Perth in Western Australia. The facility has ISO13485 certification and manufactures the DurAVR™ valve for trials underway. It also manufactures CardioCel and VascuCel product lines for LeMaitre under its transition service agreement following the sale of distribution rights in 2019.

Early feasibility study submission in 2Q FY2021

Anteris plans to use findings from both the current SAVR trial and concurrent animal studies to file an EFS (early feasibility study) submission to the FDA in 2Q CY2021 for approval and optimisation of the planned TAVR trial anticipated to commence by 3Q FY2021.

Regulatory approval

The company plans to file for Pre-Market Approval (PMA) in the US and CE Mark in the EU for the DurAVR™ valve concurrently in CY2021.

[13] clinicaltrials.gov/ct2/show/NCT04178213

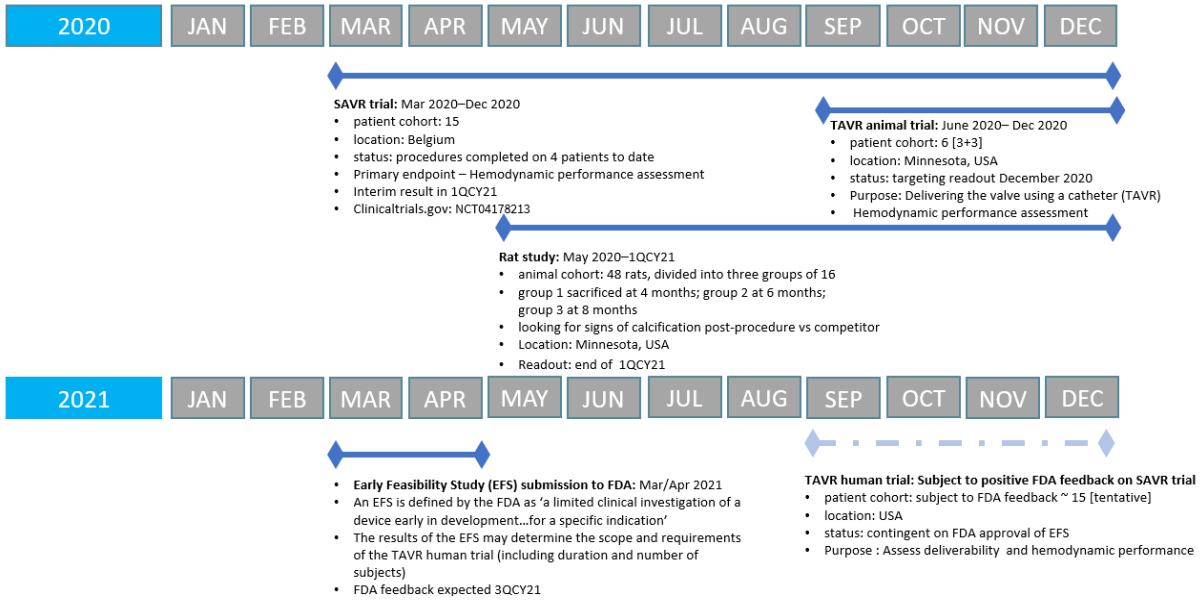
The Commercial Landscape and the Path to Market

Commercialising the DurAVR™ Valve through Licencing or Acquisition

Subject to positive findings in current and planned studies and FDA approval of the EFS submission, we expect the human TAVR trial of the DurAVR™ valve could commence by end-3Q CY2021. A similar trial design to the current SAVR trial could render preliminary findings by 1Q CY2022 and, if positive, would most likely be interpreted as clinical validation given the amount of clinical evidence to date.

With clinical validation established, commercialisation would most likely take the form of either a licencing deal or an outright acquisition of the company given recent trends in the TAVR market.

Exhibit 17 – Timeline of events over the next 12 months



Source: Anteris, MST Access.

Competitive Landscape: A Big and Competitive Market, Lots of Opportunities

TAVR market and tissue engineering more broadly

Four companies dominate the global TAVR market, led by Edwards Lifesciences and Medtronics with about 60% and >30% respectively, followed by Abbott and Boston Scientific. The market was valued at around US$4b in 2019 with 5-year CAGR of ~12% by Edwards Lifesciences. Given the attractive market fundamentals, competition is intense with all four major players investing heavily in new product development and growth by acquisition which bodes well for smaller medtechs with innovative and competitive technologies such as Anteris. At least 10 different TAVR technologies have gained CE Mark since 2007 with the latest being the Indian group Meril Life Sciences.

Exhibit 18 – TAVR valve competitive landscape

Valve/valve range	Originator	CE marked	Notes
Sapien	Edwards Lifesciences	Sep-07	Valve also approved in US
CoreValve	Medtronic	Sep-10	Valve also approved in US
JenaValve	Jenavalve Technology	Sep-11	
Acurate	Symetis	Sep-11	Company acquired by Boston Scientific
Portico	St Jude Medical	Nov-12	Company acquired by Abbott Laboratories
Direct Flow valve	Direct Flow Medical	Jan-13	Company ceased trading in 2016
Lotus	Boston Scientific	Oct-13	Valve also approved in US
Allegra	NVT	Apr-17	
Centera	Edwards Lifesciences	Feb-18	
Myval	Meril Life Sciences	Apr-19	

Source: Evaluate.

When considered in the context of regenerative medicine more broadly, the tissue engineering industry is extremely competitive given the multitude of therapeutic applications available and large potential markets being targeted. These include, most notably, skin repair as in chronic wound care, musculoskeletal and soft tissue reinforcement of abdominal wall, pelvic floor, musculotendinous tissue repair in orthopaedics, and cardiovascular tissue repair and reconstruction as in the case of the market targeted by Anteris.

Multiple opportunities for ADAPT® tissue products

The ADAPT® technology platform provides the company with multiple regenerative tissue opportunities beyond TAVR. Therapeutic areas either currently being investigated (e.g., CABG) or previously considered by Anteris include:

Tissue-engineered vascular grafts for use in coronary artery bypass surgery (CABG)

More than 300,000 coronary bypass operations are performed each year in the United States alone. Current treatments include autografting, which uses a section of veins or arteries from alternate sites of the patient, or the insertion of cadaveric or synthetic grafts, to bypass the blocked or diseased portion of the coronary artery and bring blood to the muscle of the heart. Each approach carries its own risks and limitations, including secondary wound sites, additional scarring, and potential for infection for autografting, rejection of cadaveric grafts which are also often in short supply, and poor integration of synthetic grafts with the patient's surrounding native tissue. ADAPT® tissue-engineered blood vessels could address these risks if approved.

Dura repair

The dura mater is the outer membrane enveloping the brain and spinal cord which is often damaged during traumatic brain injuries (TBI). In the US alone, the Centers for Disease Control estimate around 275,000 hospitalisations per annum related to TBI. Global sales of soft tissue repair related products were ~A$300m in 2019[14] .

Abdominal hernia and pelvic floor reconstructions

Abdominal hernia repair represents the most common type of abdominal wall procedure performed by surgeons, while pelvic floor reconstructions are major surgical procedures designed to restore strength and integrity to the pelvic floor following childbirth. Global sales of related soft tissue products were ~ A$1.7b in 2019[15].

[14] Grand View Research
[15] Grand View Research

Financials – Rightsizing Costs to Match Narrowed Focus

Key Reported Profit & Loss Numbers

Anteris posted A$3.9m in revenue for 1H2020 under its manufacturing agreement with LeMaitre Vascular Inc. for CardioCel® and VascuCel® products. Other income of A$3.3m included A$2.2m in license revenue from 4C Medical Technologies Inc. on transferring the sterilisation method for use with Anteris's ADAPT tissue. Gross profit for 1H2020 was A$818,000, representing a gross margin of 21%, largely reflecting the manufacturing contract with LeMaitre Vascular Inc. and the wind-down of the infusion segment. Selling, general and administrative expenses for 1H2020 of A$10.6m, down from A$17.2m in the previous corresponding period, were attributed to lower employee, travel and conference costs associated with reduction in headcount. A net loss of A$6.4m in 1H2020 compared with a net loss of A$11.9m in 1H2019.

Key Reported Cash Flow Numbers

Anteris reported ~A$5.6m in net cash (A$6.9m gross) at 30 June 2020. We estimate current cash burn of ~ A$1m per month and, in our opinion, the company will likely need to raise capital by 1Q21, which we estimate at ~A$10m. We expect this should fund the completion of the current DurAVR™ valve studies ahead of the EFS submission for FDA approval of the in human TAVR trials in 2H CY2021.

Our Forecasts: Key Points to Highlight

Revenues: Our near-term forecasts largely reflect revenues expected under the manufacturing agreement with LeMaitre Vascular Inc. for CardioCel® and VascuCel® products.

R&D tax credits: Anteris' 'other income' at 1H2020 included R&D tax credits of A$785,000 commensurate with a 45% cash rebate of R&D conducted in Australia in FY2019. We expect additional studies commenced in 2H CY2020 will increase R&D spend and forecast R&D tax credits of A$900,000 in CY2021.

COGS: We assume the gross margin of 20% on supply of CardioCel® and VascuCel® products under the LeMaitre Vascular Inc. agreement will remain stable.

Operating expenses: Anteris trimmed operating expenses significantly in CY2020 following the streamlining of the company and narrow focus on the advancement of its DurAVR™ valve. We assume A$10m and A$2m in employee benefits and corporate costs respectively in CY2021 and CY2022.

Tax: We estimate accumulated losses on the balance sheet at 30 June 2020 totalling A$125.5m will offset income tax payable over the medium term depending on licencing deals negotiated for the company's DurAVR™ valve. As such, based on modelling used in our valuation of the company, we expect these accumulated tax losses to be used up by 2025.

Licencing: We think at this point, assuming the strength of results rendered by studies so far continue to impress, a licencing deal could be struck, most likely 2H CY2021.

Exhibit 19 – Summary financial statements

Financial Summary (AUD 000's)	FY18a	FY19a	FY20e	FY21e	FY22e	FY23e
PROFIT & LOSS						
Total Revenue	25,601	17,075	7,042	6,802	7,483	8,231
Other income* (includes licencing revenue)	111	25,490	3,264	56,593	1,037	30,765
Cost of sales	-13,163	-8,773	-5,296	-4,762	-5,238	-5,762
Operating expenses	-37,248	-39,974	-23,324	-24,402	-16,386	-12,820
EBITDA	-25,884	-5,032	-17,458	35,242	-12,190	21,420
EBIT	-27,295	-6,649	-18,176	34,557	-12,849	20,782
Tax	0	0	0	0	0	0
NPAT (Reported)	-25,168	-6,325	-18,314	34,231	-13,104	20,415
NPAT (Underlying)	0	0	0	0	0	0
Minority Interest	-482	-362	0	0	0	0
Shares Outstanding (m)	589.9	590.8	590.8	590.8	590.8	590.8
EPS (Underlying) cps	-7.93	-0.99	-3.10	5.79	-2.22	3.46
Dividend per share (cps)	0	0	0	0	0	0
BALANCE SHEET						
Current Assets	22,920	20,583	12,487	46,903	33,957	54,509
Cash	12,036	8,968	872	35,289	22,343	42,895
Receivables	4,192	9,802	9,802	9,802	9,802	9,802
Inventory	6,692	1,812	1,812	1,812	1,812	1,812
Other Assets	0	0	0	0	0	0
Non-Current Assets	8,940	5,421	5,203	5,018	4,859	4,721
PP&E	3,475	1,590	1,511	1,454	1,413	1,383
Intangible assets	5,466	1,699	1,560	1,432	1,315	1,207
Other Non-current Assets	0	2,131	2,131	2,131	2,131	2,131
Current Liabilities	8,770	7,302	7,302	7,302	7,302	7,302
Payables	6,783	4,921	4,921	4,921	4,921	4,921
Short Term Debt	0	1,113	1,113	1,113	1,113	1,113
Provisions & Tax	1,587	528	528	528	528	528
Other financial liabilities	400	740	740	740	740	740
Non-Current Liabilities	1,611	3,167	3,167	3,167	3,167	3,167
Long Term Debt	0	0	0	0	0	0
Provisions	0	603	603	603	603	603
Other financial liabilities	1,611	2,564	2,564	2,564	2,564	2,564
Net Assets	3,629	15,535	7,221	41,452	28,347	48,762
Share Capital	137,737	137,758	147,758	147,758	147,758	147,758
Reserves	-2,941	-2,724	-2,724	-2,724	-2,724	-2,724
Retained Earnings	-113,678	-119,498	-137,812	-103,581	-116,686	-96,271
Minority Interests	362	0	0	0	0	0
Total Equity	21,479	15,535	7,221	41,452	28,348	48,762
CASH FLOW						
Operating Cash Flow	-22,205	-22,867	-17,596	34,916	-12,446	21,052
Maintenance Capex	-611	-67	-500	-500	-500	-500
Expansion Capex	0	0	0	0	0	0
Acquisitions	0	0	0	0	0	0
Investing Cash Flow	-1,011	20,573	-500	-500	-500	-500
Equity Issued	35,411	0	10,000	0	0	0
Debt Issued	5,000	1,000	0	0	0	0
Dividends	0	0	0	0	0	0
Financing Cash Flow	27,149	9	10,000	0	0	0
Change in Cash Balance	3,933	-2,286	-8,096	34,416	-12,946	20,552

Source: Anteris, MST Access,* includes revenue from potential licencing deal scenario used in valuation

Valuation

We value Anteris at ~A$133m, or ~A$23 per share (undiluted), using a risk-adjusted net present value (rNPV) method to discount future cash flows through to FY2030. Our valuation approach assumes a partnering deal or out-licensing of the DurAVR™ valve versus outright acquisition of the company which is the norm in med tech. Under this scenario, the licensor would underwrite the development of the DurAVR™ valve through to commercialisation and pay Anteris an upfront payment plus royalties on sales. This scenario could include a manufacturing contract allowing Anteris to supply the finished product while retaining intellectual property around the ADAPT® technology and the commercial rights to other potential applications such as CABG.

Our model assumes a deal is achieved upon approval by the FDA to commence first in human TAVR trials of the DurAVR™ valve in CY21, based on an upfront payment of US$40m, 15% royalty rate on sales of the DurAVR™ valve and TAVR delivery system as a kit. We use a probability of success of 32%. Our key assumptions are tabled in Exhibit 20.

Exhibit 20: Valuation and key assumption metrics (base case)

Value driver	rNPV A$000s	rNPV per share (A$)	Probability of success	Launch	Key Assumptions
DurAVR™ valve and TAVR delivery system	127,331	21.6	32%	2023	US$40m upfront payment in CY21
Net Cash (at end June 2020)	5,646	1.0			Royalty rate of 15%
Total	**132,977**	**22.5**			TAVR pricing @ US$ 33,000
					Discount rate 12.5%

Source: MST Access, Industry data

Historically most deals in the TAVR and TVMR (transcatheter mitral valve replacement) space have involved the outright acquisition of privately held targets by one of the four major listed industry players (see Exhibit 21). Importantly, these deals, including the most recent Symetis acquisition by Boston Scientific, occurred when the intended treatment population extended to high and intermediate risk patients, and therefore only around half the current addressable market made possible by the FDA approval in low risk patients in 2019.

Exhibit 21 – M&A prior deals in the cardiac valve space

Year	Buyer	Target	Transaction size (US$m)	Comments
2003	Edwards Life Sciences	Percutaneous Valve Technologies*	125	TAVR pioneer (no CE mark or FDA approval)
2009	Medtronic	CoreValve	900	CoreValve did not have FDA approval
2015	Abbott	Tendyne	225	Transfemoral Mitral Valve Replacement (TMVR)
2015	Edwards Life Sciences	CardiAQ	350	Transfemoral Mitral Valve Replacement (TMVR)
2017	Boston Scientific	Symetis	435	Symetis had CE approval but no FDA approval

Source: Company reports, Capital IQ (*EW acquisition of PVT for ~US$125m upfront plus $30 million in milestone payments).

Sensitivity Analysis

Our base-case valuation of A$23 per share (rounded) incorporates pricing of US$33,000 for the TAVR device, licensing royalty rate of 15%, probability of success of 32% and a discount rate of 12.5%. We expect continuing clinical evidence of valve superiority will lead to lead to a licencing deal by one of the major players and include a sensitivity matrix highlighting the impact of both successfully gaining regulatory approval and TAVR pricing.

Exhibit 22: rNPV/share with different TAVR price and probability of success assumptions

	DurAVR™ valve and TAVR delivery system (US$)		
Probability of Success	20,000	25,000	33,000
55%	23	29	37
32%	15	18	23
20%	10	12	15

Source: MST Access

Risks to Our View

The investment case for Anteris is heavily reliant on the development of the DurAVR™ valve and hence the outcome of both the current SAVR trial and anticipated in-human TAVR trial subject to FDA approval. As such, Anteris is subject to various sensitivities common to single product development stage med tech companies, including the unpredictable outcome of trials, regulatory decisions, success of competitors, financing, and commercial risk.

Clinical trials

Anteris has a proven technology with extensive accumulated in-human data. Nonetheless, the near-term prospects rely heavily on the outcome of both its SAVR trial and animal TAVR studies to support progression to TAVR in human trials. Unfavourable results or other unforeseen circumstances related to the company's clinical program could result in delays or termination of the program. The current COVID-19 pandemic adds to the risk of delays given the pressure on healthcare systems and hospital capacity in developed countries.

Technology

Notwithstanding the major structural heart market players, the wider tissue engineering industry is extremely competitive, with many companies developing products for multiple therapeutic applications including cardiovascular. As such, risks remain of newer technologies emerging that match or surpass ADAPT®'s unique engineered tissue. Similarly, given the company's focus on TAVR valves, well-funded new product development programs amongst the majors may generate new technologies that supersede DurAVR™ valve's potential.

Funding risk

The company is currently funding all clinical programs and as such will need to raise capital over the near term based on current R&D spend. Any shortfall in the amount raised or underestimation of forecasted costs may add to funding risk and compromise the company's ability to raise capital in the future.

Regulatory

Anteris is seeking approval for new applications of the ADAPT® technology. Although Anteris has validated the technology and accumulated extensive in-human data, there is no guarantee that future products using ADAPT® technology will be approved by the FDA or international regulatory bodies for marketing in the US or ROW. Separately, in-country testing and generation of clinical data for ROW markets will most likely require a partner.

Commercialisation

The process of gaining market access and commercialisation can be costly. Assuming development costs are met and regulatory approvals achieved, the company will need to secure manufacturing at scale, quality control, marketing, and distribution of its products to appropriate medical specialists, such as interventional cardiologists. Beyond adoption by clinicians, from a technical perspective, product costs versus health economic benefits will be a consideration for hospital payors operating transcatheter valve programs with limited financial resources.

Reimbursement

Availability of reimbursement coverage for Anteris products is a key driver of adoption. While the Centers for Medicare & Medicaid Services (CMS) decided to cover TAVR in June 2019 under its national coverage policy for qualifying hospitals, the level of reimbursement could vary over time.

Intellectual property

We consider IP risk low. ADAPT® technology is patent protected and supported with extensive in-human data, both of which represent significant barriers to competition. Anteris continues to grow its patent portfolio, and the DurAVR™ valve is the subject of various patent applications the company has filed.

Board and Management

Expertise and experience across the management team appear well suited to advancing Anteris's new product development programs and commercialising its structural heart products, including the DurAVR™ valve.

Directors

Wayne Paterson, Managing Director/CEO: Mr Paterson has held numerous senior positions in multi-national companies and has lived in seven countries during the past 25 years. Through his career, he has been responsible for building and managing multibillion-dollar businesses throughout the world, including mergers, integrations, acquisitions and major restructures, in President and CEO roles.

John Seaberg, Chairman: Between 2007 and 2014, Mr Seaberg was Founder, Chairman and CEO of NeoChord Inc, a venture capital–backed company commercialising technology developed at the Mayo Clinic for the repair of the mitral valve via minimally invasive techniques.

Stephen Denaro, Non-executive Director and Company Secretary: Mr Denaro has extensive experience in mergers and acquisitions, business valuations, accountancy services, and income tax compliance gained from positions as Company Secretary and CFO of various public companies and with major chartered accountancy firms in Australia and the United Kingdom. He provides company secretarial services for a number of start-up technology, ASX-listed and unlisted public companies, including Anatara Lifesciences Ltd (ASX: ANR) and Oventus Medical Ltd (ASX: OVN).

Dr Wenyi Gu, Non-executive Director: Dr Gu currently works as a Research Fellow for the Australian Institute for Bioengineering and Nanotechnology at the University of Queensland (UQ) where he began his post-doctoral work in 2001. Dr Gu holds a master's degree in veterinary science and completed his PhD study in biochemistry and molecular biology at Australian National University (ANU) and later worked at John Curtin Medical School (ANU). He also held a Peter Doherty Fellowship (2006–2009) and was supported by the National Health and Medical Research Council (NHMRC) to work at Harvard Medical School (Harvard University) as a visiting fellow.

Dr Yanheng Wu, Non-executive Director: Dr Wu currently serves as President and Managing Director of Constellation International Group Holdings Ltd. Dr Wu also established Guangzhou Hearty-Care Biotechnology Ltd, a medical technology company. Dr Wu completed his PhD in tumour immunotherapy and nanocarrier technology at the University of Queensland. He holds multiple biomedical patents and is well published domestically and internationally. Before commencing his PhD, he worked at Sun Yat-sen University Cancer Center as a researcher. He also holds a Bachelor of Clinical Medicine from Guangzhou Medical University.

Key Management

David St Denis, Chief Operating Officer: Mr St Denis is an accomplished senior healthcare leader with a systematic and metrics-driven approach spanning 20 years of proven business results at the regional and global levels within the life sciences and pharmaceutical sectors. Most recently at Merck in Germany, he headed commercial operations for Europe and Canada. He has an extensive track record in charge of complex cross-functional and multi-cultural teams that have achieved impressive business objectives in both mature markets (US, Europe, Japan) and developing markets (Brazil, Russia, India, China and Mexico).

Matthew McDonnell, Chief Financial Officer: Mr McDonnell worked for KPMG for over 24 years, including 10 years as a partner. He has a broad range of industry experience and corporate governance acumen, having delivered audit, accounting, and advisory services to a broad range of sectors. During his time at KPMG, he worked predominantly in Australia covering financial services, transport, industrial markets, health, childcare and energy. He has experience in restructures, acquisitions, divestments, privatisations and other significant financial transactions.

Martha Engel, General Counsel: In March 2019, Ms Engel commenced as the group's General Counsel. As a registered patent attorney in the US, she has over a decade of legal experience providing advice to companies ranging from medical device manufacturers to craft breweries on all aspects of intellectual property law. She also has a well-rounded legal background on corporate, regulatory, and business transactions. Ms Engel was named an Up & Coming Attorney of the Year by Minnesota Lawyer in 2018. Prior to joining the company, she was a partner at the US law firm of Winthrop & Weinstine.

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

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

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

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

Samir Kapadia, MD: Cleveland Clinic, Cleveland, OH

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

GLOSSARY	
Abbreviation/Term	**Details**
Allograft	Tissue graft from donor of the same species
Aorta	Main artery that carries blood from the left ventricle to the rest of the body
Aortic stenosis	Narrowing of the aortic valve opening
Autograft	Tissue transplanted from one part of the body to another in the same individual
Bicuspid aortic valve	An aortic valve that only has two leaflets, instead of three
Bio-prosthetic	An implant consisting of an animal part or containing animal tissue
Bio-scaffold	An artificial structure, implanted in the body, on which tissue grows
Bovine	Derived from cows
CABG	Coronary artery bypass graft
Calcification	Build-up of calcium in tissues, which typically reduces their flexibility and durability
Catheter	Tubular medical device for insertion into canals, vessels, passageways, or body cavities usually to permit injection or withdrawal of fluids or to keep a passage open
CE mark	A certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA).
CMS	Centers for Medicare & Medicaid Services
Coaptation	Joining or fitting together of two surfaces
Collagen	Fibrous protein that makes up connective tissue
Comorbidities	Medical condition existing simultaneously, but independently with another condition.
Congenital	Present from birth
Cross-link	Bonds that link one polymer chain to another
Cytotoxicity	Effect of being toxic to cells
Durability	Ability to withstand wear, pressure, or damage
Echocardiogram	Test that uses ultrasound to show how your heart muscle and valves are working
ECM	Extracellular matrix
EFS	Early Feasibility Study
EOA	Effective orifice area (Most important parameter of valve prosthesis). portion of the valve orifice area through which the blood really flows
Extra-corporeal circulation	The circulation of blood outside of the body through a machine that temporarily assumes an organ's functions such as a heart-lung bypass machine.
Dura Repair	Repair of the dura mater (literally, "tough mother"), the dense, leathery membrane covering and protecting the brain and spinal cord
FDA	US Food and Drug Administration
Glutaraldehyde	A chemical used to stabilise the collagen structures in animal tissue
GOA	Geometric orifice area (Parameter of valve prosthesis)
Gorlin area	Parameter of valve prosthesis used in assessing level of aortic stenosis
Gradient	Typically refers to the pressure gradient across the aortic valve during ejection
Hernia	Rupture of wall/cavity containing an organ
Homograft	Tissue graft from a donor of the same species
Leaflet	Thin, triangle-shaped flap of a heart valve
Matrix	Substance in which tissue cells are embedded
Peak gradient	Difference between the peak left ventricular systolic pressure and the peak central aortic pressure
Percutaneous	Through the skin
Pericardium	Membrane enclosing the heart
Phospholipids	Compounds made up of fatty acids and phosphoric acid with nitrogeneous base
Porcine	Derived from pigs
Rheumatic fever	A disease that can affect the heart, joints, brain, and skin.
SAVR	Surgical Aortic Valve Replacement
Shear stress	Parameter used in assessing flow
Soft tissue	Tissues of the body that are not bone
Structural Heart	All non-coronary heart disease processes and associated interventions
Subclavian	Artery or vein which serves the neck and arm on the left or right side of the body
SVD	Structural Valve Deterioration
Syncope	To faint or pass out
TAVR	Transcatheter Aortic Valve Replacement (replacement using catheter mounted aortic valve)
Tissue	Group of specialised cells with a common structure and function e.g 'muscle tissue'
Tissue engineering	Engineering tissue for use in repairing tissue defects in patients
Transfemoral	Access via the groin and the most preferred route in majority of the TAVI procedures
Tricuspid	Valve located between the right atrium and right ventricle of your heart
Xenograft	Tissue graft or organ transplant from a different species to the recipient

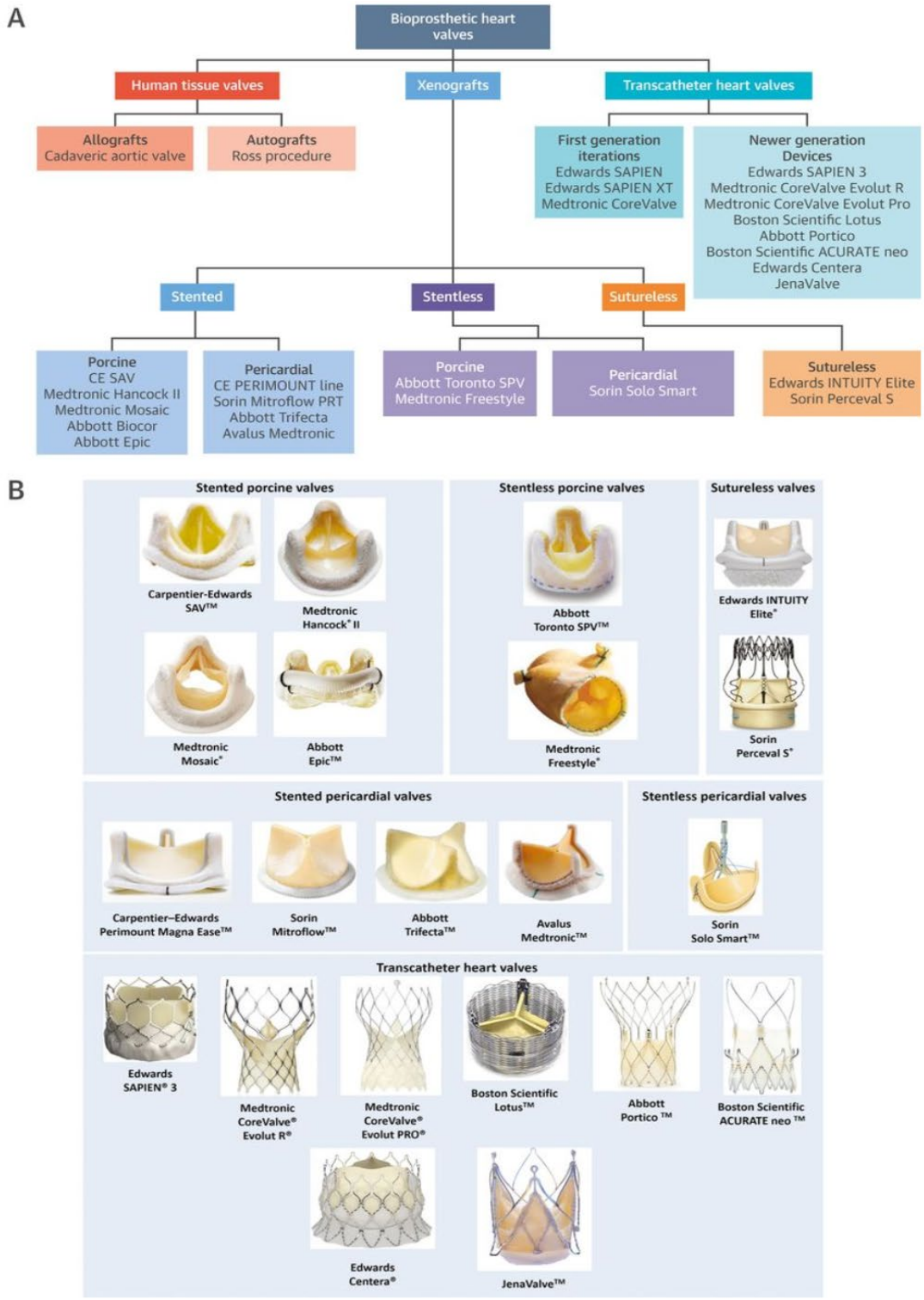
Appendix 1 –Aortic Stenosis Overview

Exhibit 23 – Overview of Aortic Stenosis

Aortic Stenosis Overview	
Aortic Stenosis	The aortic valve is a valve in the human heart between the left ventricle and the aorta. Its function is to allow blood to be forced into the arteries from the ventricles and to prevent blood from flowing back from the arteries into the ventricles. Aortic stenosis refers to a narrowing of the aortic valve opening. Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure to replace a narrowed aortic valve that fails to open properly.
Risk Factors of Aortic Stenosis	• Older age • Certain heart conditions present at birth (congenital heart disease) such as a bicuspid aortic valve • History of infections that can affect the heart • Cardiovascular risk factors, such as diabetes, high cholesterol and high blood pressure • Chronic kidney disease • History of radiation therapy to the chest
Symptoms of Aortic Stenosis	The severity of the Aortic valve stenosis can range from mild to severe. Many patients might not experience any symptoms until the disease reaches a high severity. Patients with severe aortic valve stenosis may experience the following symptoms: • Pain of tightness in the chest with activity (angina) • Feeling of dizziness of fainting during activity • Tiredness (fatigue) • Shortness of breath (dyspnoea) • Irregular heartbeats (arrhythmia) or heart palpitations • Swelling in your legs
Diagnosis of Aortic Stenosis	• Aortic stenosis usually leads to an abnormal heart sound (murmur). • If such a sound is heard during physical examination, the doctor will recommend tests such as ECG, Echocardiography and a six-minute walk test. • A CT and few other blood tests are recommended to confirm the diagnosis of aortic stenosis.
Treatment of Aortic Stenosis	About 7% of individuals over the age of 65 years suffer from degenerative aortic stenosis. Valve replacement is the only treatment option for good prognosis in patients with symptomatic severe aortic stenosis. However, due to surgical risk associated with patient frailty, comorbidities, age, and severe left ventricular dysfunction, about one third of the patients over the age of 75 years are not referred for surgery.
Transcatheter Aortic Valve Replacement	Transcatheter aortic valve replacement (TAVR) is an alternative, less invasive treatment for aortic stenosis. TAVR is a new and innovative approach for the treatment of severe aortic stenosis.
TAVR/TAVI Indicatros	TAVR is an alternative for individuals: • At low, intermediate or high risk of complications from surgical aortic valve replacement. • Unable to undergo open-heart surgery due to advanced age or presence of cardiovascular risk factors • With other comorbid conditions. • With a prior history of stroke, chest radiation, open heart surgery, COPD, frailty, renal insufficiency, advanced age and other conditions.
What are the risks of TAVR/TAVI?	TAVR has been found to be safe and effective. However, the procedure still carries some risk: • Valve leaks: Sometimes blood leaks around the new valve because the replacement is not big enough, did not fully expand, or has interference from calcium build-up. • Pacemakers: When valves open during placement, they can sometimes press on the heart's electrical system and make a pacemaker necessary. • Kidney damage: The contrast dye used for imaging can damage kidneys, but the problem is usually reversible. • Vessel damage: Passing catheters through arteries can sometimes damage them. The damage is usually repairable through a catheter or with open vascular surgery. • Stroke: A small percentage of people undergoing TAVR can develop a stroke, either during the procedure or in the days immediately following it.

Appendix 2

Exhibit 24 – Main surgical and transcatheter aortic bio-prostheses currently available



Source: https://www.onlinejacc.org/content/70/8/1013.

Appendix 3

Exhibit 25 – Commercially available products composed of intact extracellular matrix

Product	Company	Material		Form	Use
Acellular					
Osis	Healthpoint	Porcine small intestinal submucsa (SIS)	Natural	Dry Sheet	Partial and full thickness wounds; superficial and second degree burns
Xelma	Molnycke	ECM protein, PGA, water		Gel	Venous leg ulcers
AlloDerm	Lifecell	Human skin	Cross-linked	Dry Sheet	Abdominal wall, breast, ENT/head and neck reconstruction, grafting
CuffPatch	Arthrotek	Porcine small intestinal submucsa (SIS)	Cross-linked	Hydrated Sheet	Reinforcement of soft tissues
TissueMend	TEI Biosciences	Fetal bovine skin	Natural	Dry Sheet	Surgical repair and reinforcement of soft tissue in rotator cuff
Durepair	TEI Biosciences	Fetal bovine skin	Natural	Dry Sheet	Repair of cranial or spinal dura
Xenform	TEI Biosciences	Fetal bovine skin	Natural	Dry Sheet	Repair of colon, rectal, urethral and vaginal prolapse, pelvic reconstruction, urethral sling
SurgiMend	TEI Biosciences	Fetal bovine skin	Natural	Dry Sheet	Surgical repair of damaged or ruptured soft tissue membranes
PriMatrix	TEI Biosciences	Fetal bovine skin	Natural	Dry Sheet	Wound management
Permacol	Tissue Science Laborates	Porcine skin	Cross-linked	Hydrated Sheet	Soft connective tissue repair
Graft Jacket	Wright Medical Tech	Human skin	Cross-linked	Dry Sheet	Foot ulcers
Surgisis	Cook SIS	Porcine small intestinal submucsa (SIS)	Natural	Dry Sheet	Soft tissue repair and reinforcement
Durasis	Cook SIS	Porcine small intestinal submucsa (SIS)	Natural	Dry Sheet	Repair dura matter
Stratasis	Cook SIS	Porcine small intestinal submucsa (SIS)	Natural	Dry Sheet	Treatment of urinary incontinence
OrthADAPT	Pegasus Biologicas	Horse pericardium	Cross-linked		Reinforcement, repair amd reconstruction of soft tissue in orthopedics
DurADAPT	Pegasus Biologicas	Horse pericardium	Cross-linked		Repair dura matter after craniotomy
Axis dermis	Mentor	Human dermis	Natural	Dry Sheet	Pelvic organ prolapse
Suspend	Mentor	Human fascia lata	Natural	Dry Sheet	Urethral sling
Restore	DePuy	Porcine small intestinal submucsa (SIS)	Natural	Sheet	Reinforcement of soft tissue
Veritas	Synovis Surgical	Bovine pericardium		Hydrated Sheet	Soft tissue repair
Dura-Guard	Synovis Surgical	Bovine pericardium		Hydrated Sheet	Spinal and cranial repair
Vascu-Guard	Synovis Surgical	Bovine pericardium		Hydrated Sheet	Reconstruction of blood vessels in neck, legs, and arms
Peri-Guard	Synovis Surgical	Bovine pericardium		Hydrated Sheet	Pericardial and soft tissue repair
Cellular					
Dermagraft	Smith & Nephew	Fibroblasts, ECM, bioabsorbable scaffold		Frozen Sheet	Full thickness diabetic foot ulcers
OrCel	Ortec International	Bovine collagen cultured with human fibroblasts		Hydrated Sheet	Burn wounds
Apligral	Organogenesis Inc.	Human fibrablasts, collagen, secreted ECM		Hydrated Sheet	Venous ulcers, diabetic foot ulcers
Transcyte	Smith & Nephew	ECM secreted from human fibroblasts		Frozen Sheet	Mid to intermediated partial thickness burns

Source: https://www.sciencedirect.com/book/9780124201453/tissue-engineering.

Appendix 4 - Shareholder Register and Institutional Support

Exhibit 26 – Top 20 Shareholders

Ordinary Shareholders	Number	Percentage
CONSTELLATION INTL HOLDINGS LIMITED	730,192	12.35%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED - A/C 2	652,219	11.04%
CONSTELLATION IMMUNOTHERAPY LIMITED	402,093	6.80%
NATIONAL NOMINEES LIMITED <DB A/C>	373,228	6.31%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED -GSCO ECA	290,293	4.91%
STAR BRIGHT HOLDING LIMITED	173,680	2.94%
MERRIL LYNCH (AUSTRALIA) NOMINEES PTY LIMITED <MLPRO A/C>	169,733	2.87%
J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	87,768	1.48%
CITICORP NOMINEES PTY LIMITED	84,369	1.43%
MR PATRICK CHEW	73,670	1.25%
DR ABDUL AHAD KHAN	36,895	0.62%
MR DANIEL BERNARD CLOUGH	33,584	0.57%
THROUGH2 INVESTMENTS PTY LTD <THROUGH2 SUPER FUND A/C>	33,000	0.56%
MR ROGER ANTHONY PIERCE	32,673	0.55%
BULLDOG SHALE PTY LTD <BULLDOG SHALE S FUND A/C>	30,000	0.51%
CARRON SERVICES LIMITED	28,572	0.48%
MR JOSEPH JOHN DOYLE + MRS CHERYL ANNE DOYLE	23,527	0.40%
MR ATHANASIOS FARMAKIS	23,000	0.39%
ZCSF NOMINEES PTY LTD <ZOELLER SUPERFUND A/C>	20,505	0.35%
APPWAM PTY LTD	20,000	0.34%
MRS JANET LOUISE BOWTELL + MR GARY OWEN BOWTELL <BOWTELL SUPER FUND A/C>	20,000	0.34%
MR DALE ANTHONY REED	20,000	0.34%

Source: Company reports.

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