ARROWHEAD
BUSINESS AND INVESTMENT DECISIONS

Due Diligence and Valuation Report

Arrowhead Code:	67-04-01
Coverage initiated:	June 17, 2020
This document:	June 17, 2020
Fair share value bracket:	$A22.86 and $A35.65
Share price (June 16, 2020):	$A5.27[i]

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Company:	Anteris Technologies
Ticker:	AVR
Headquarters:	Minneapolis, US
CEO	Wayne Paterson
CFO	Matthew McDonnell
Website:	www.anteristech.com

Market Data

52-Week Range:	$A3.01 – $A13.00[ii]
Average Daily Volume (3M Avg.):	6,035[iii]
Market Cap (June 16, 2020):	$A31.1 million (mn)

Financial Forecast (in $A) (FY Ending – Dec.)

$A mn	'20E	'21E	'22E	'23E	'24E	'25E
High Revenue	6.0	6.6	7.3	25.1	45.9	59.2
High EPS ($A)	(3.18)	(1.11)	(2.12)	0.58	0.89	3.34
Low Revenue	5.3	5.7	6.1	16.1	35.2	46.0
Low EPS ($A)	(3.36)	(1.37)	(2.07)	(0.93)	(0.90)	1.30

Company Overview: Anteris Technologies Limited (Anteris) develops first-in-class aortic valve replacement (AVR) devices using its ADAPT® technology. The first in-human trial of its SAVR device commenced in March 2020. Founded in 2011, Anteris Technologies Limited has evolved into a structural heart company, headquartered in Minneapolis, US, after completing divestment of non-core businesses in 2019.

Investment Highlights: **(1)** Its unique, bovine collagen bio-scaffold based on its patented ADAPT® technology has unmatched physical characteristics and is a potential disruptor in the $US6 billion aortic valve replacement market. **(2)** A unique claim to ten years of clinical data showing zero calcification. Approximately 20,000 patients have been implanted with ADAPT® bio-scaffold material used in aortic and surgical repairs. **(3)** Developed a unique DurAVR™ (single-piece 3D anatomically correct) aortic valve, solving the clinical problems of calcification and durability, hence offering superior outcomes over existing commercial valves for the AVR market. **(4)** Commenced a first-in-human 15-patient SAVR study of its DurAVR™ 3D single-piece aortic valve following approval by the Federal Agency for Medicines and Health Products (FAMHP) of Belgium in March 2020. **(5)** Previously, the company published positive results from its pre-clinical sheep study where its aortic valve replacement showed impressive functioning with no material failure.

Key Highlights: **(1)** Anteris commenced a 15-patient SAVR clinical study of its proprietary DurAVR™ (single-piece 3D) aortic valve at end Q1 2020 at the University Hospitals, Leuven (Belgium) with trial results expected in 2021. **(2)** The company received FDA clearance for an indication change to its ADAPT®-treated (bovine pericardium) tissue through the Special 510(k) pathway. The change universally extended ADAPT® tissue approval for use in cardiac defects, including intracardiac defects, septal defects and valve and annulus repairs. **(3)** Since October 2019, the company has up to a three-year contract to supply LeMaitre Vascular Inc. with its ADAPT® engineered aortic patches at a fixed margin above COGS. **(4)** The company expects a minimal impact from COVID-19 on its operations and, as part of its strategy, directors and senior executives took a 25% pay cut effective from May 2020.

Key Risks: (a) The company faces clinical failure risk, which may lead to abandoning the project; (b) difficulty in obtaining regulatory approval may lead to unnecessary adverse delays; (c) unsuccessful product commercialization can result in negative or restricted sales growth; (d) the industry is highly competitive and frequent innovations in devices can give competitors a distinct advantage; (e) inability to raise funds or enter into a partnership could jeopardize its research and development program.

Valuation and Assumptions[iv]: Based on due diligence and valuation estimates, Arrowhead believes that Anteris Technologies Limited's fair market value lies in the $A135.1 – $A210.6 mn bracket. We have valued the company using an adjusted discounted cash flow (DCF) method. Our DCF model suggests a fair value bracket of $A22.86 – $A35.65 per share.

Note: The company changed its name to Anteris Technologies Ltd on 22 May 2020 from Admedus Ltd.
The company's DurAVR™ aortic valve is the trade marked name for its single-piece 3D aortic valve designed for the TAVR and SAVR markets.

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1.(A) Investment Thesis

We are initiating coverage on Anteris Technologies Limited. It is a healthcare company which develops and sells cardiac products and devices. The company owns a unique tissue-engineering technology (ADAPT®), the basis for its novel products. In particular, it is developing the DurAVR™ single-piece 3D aortic valve for TAVR and SAVR procedures.

Well-positioned to capture share in the aortic valve replacement market with a unique single-piece device

Anteris Technologies is developing the DurAVR™ aortic valve for use in TAVR and SAVR procedures for patients needing aortic valve replacement. The DurAVR™ aortic valve is a single-piece 3D valve having a simple, yet distinct design, providing significant benefits, such as reduction in the number of sutures required, low paravalvular leak, reduced leaflet stress and increased coaptation surface. Following positive results from previously conducted lab tests and animal studies, the DurAVR™ aortic valve is undergoing a 15-patient clinical study at the University Hospitals, Leuven, in Belgium.

DurAVR™ aortic valves were successfully implanted in two patients since discharged; the first patient in April 2020 and the second in May 2020.

Lucrative market and a unique selling proposition (USP) to tap the growing TAVR market

The company's two target markets (the US and Europe) each represent growing markets with lucrative opportunities. More than 250,000 patients in Europe and North America underwent the SAVR procedure in 2018. The market for SAVR procedures is estimated to be $US1.1 billion (bn) in 2025. TAVR procedures, the company's primary target market, has tremendous growth potential after the US Food and Drug Administration (FDA), in September 2019, approved the treatment for low-risk patients (the majority of patients). The TAVR market is expected to show an 11.4% CAGR to reach $US7 bn in 2024.

Significant advantages and encouraging results from studies imply that the company is well-positioned to capture a sizeable share of the SAVR and TAVR markets. The company expects to commercialize the product in the US and Europe by 2023.

Ground-breaking ADAPT® technology forms the cornerstone for products

The DurAVR™ (single-piece 3D) aortic valve development uses the company's patented ADAPT® tissue engineering technology, lending it a competitive advantage over other companies in terms of durability and anti-calcification properties. Durability is a key factor to be addressed in the valve-replacement market, with less durable products requiring replacement, which might not be possible in all cases, leading to extra cost. The unique ADAPT® technology process enables it to make immune tolerant and durable valves, having proven anti-calcification properties (more than 10 years of published data) to its competitors' disadvantage. Studies revealed the valve remained functional after 400 mn simulated valve cycles (equal to 10 human years) when a competitor's product showed significant fatigue after 250 mn cycles.

Non-core businesses divested, raising up to $A42.5 mn in strategic transactions

In FY 2019, Anteris sold its Infusion business to BTC Health Speciality Pty Ltd for $A6.3 mn as a part of restructuring the company to its core business opportunity, i.e., aortic valve replacement products. The company then sold its CardioCel® and VascuCel® products to LeMaitre Vascular Inc for up to $A36.2 mn, including earnouts, with an upfront payment of $A21.2 mn. The two transactions helped fund the next development phases of the DurAVR™ aortic valve, delineating the change in the company's strategy.

Entering into partnerships and licensing deals the way forward

Anteris, with its distinct and advanced technology forming the basis of its DurAVR™ aortic valve, has garnered interest from other MedTech companies and investors. The company could enter a partnership with a top MedTech company on a profit-sharing basis, allowing it to leverage its brand and expand geographically to capture global market share. There is the opportunity to enter a licensing deal with one of these companies, where Anteris could receive an upfront payment and/or milestone-linked payments and a royalty fee on licensee sales. Both scenarios project positive cash inflows for the company, highlighting the company's strength in regard to its product uniqueness.

Key risks: (a) The company faces clinical failure risk which may lead to abandoning of the project; (b) difficulty obtaining regulatory approval may lead to unnecessary adverse delays; (c) unsuccessful product commercialization can result in negative or restricted sales growth; (d) the industry is highly competitive and frequent innovations in solutions can give competitors a distinct advantage; (e) inability to raise funds or enter into a partnership could jeopardize its research and development program.

1.(B) Key Developments

1) Anteris has implemented a COVID-19 mitigation strategy related to travel measures, personnel policy and manufacturing processes, with staff (excluding the staff working in the manufacturing and research & development (R&D) departments) and contractors working from home. The company expects minimal impact on the in-human study for SAVR, as the patients that it is treating are high-risk patients requiring urgent treatment. The company, however, is mindful of the increased demand caused by COVID-19's impact on hospital resources. It continues engaging with potential strategic partners and investors, despite medical conferences and events used for business development being on hold. Additionally, Anteris, as of April 2020, has not seen orders from LeMaitre Vascular decrease.

2) A second patient was successfully implanted with a DurAVR™ aortic valve at the University Hospitals, Leuven (Belgium), as part of the company's first-in-human SAVR trial. The trial aims to replicate the results of a preceding animal study completed in 2019. Fifteen patients with aortic valve insufficiency or stenosis will be implanted, with a six-month follow-up. Trial results are expected in 2021. The results will be key in the development of the company's TAVR device as essentially the same single-piece 3D aortic valve will be used in the transcatheter procedure.

3) The company reported revenue of $A2.3 mn in Q1 2020 with a substantial portion of it coming from the manufacturing agreement with LeMaitre Vascular. In addition, it recognized other income of $A2.2 mn related to contractual obligations with 4C Medical Technologies. The company had cash receipts of $A1.7 mn in Q1 2020 and ended the quarter with cash and cash equivalents of $A3.0 mn. The company further had $A8.1 mn in short-term deposits included within other receivables, for a total cash position of $11.1 million.

4) The company reported revenue of $A17.1 mn in FY 2019. The Patches business contributed $A10.2 mn (ten months' contribution until sold to LeMaitre Vascular Inc. in October 2019). ADAPT® reported 10.0% YoY revenue growth to $A8.8 mn for nine months (from $A8 mn for the corresponding period in 2018). The Infusion business contributed 33.3% ($A6.9 mn) until it was divested in May 2019.

5) The company sold the distribution rights of the CardioCel® and VascuCel® product portfolio to LeMaitre Vascular Inc. in October 2019 for up to $A36.2 mn. The consideration included a $A21.2 mn cash upfront payment with two installments of $A1 mn each to be received in 12 months and 36 months, respectively. The company retained the exclusive manufacturing rights of the product range for up to three years and kept all intellectual property of the ADAPT® technology. The transaction was non-dilutive, providing the company with additional funds for its TAVR program.

6) In February 2020, Anteris announced the completion of the transfer of its unique Sterilization Method to 4C Medical Technologies, Inc., for a final $US1 mn milestone payment. 4C Medical uses the ADAPT® technology in its transcatheter mitral valve replacement (TMVR).

7) The company sold its Infusion business to BTC Speciality Health Pty Ltd, a wholly owned subsidiary of BTC Health Ltd, for $A6.3 mn. The distribution rights of arcomed Ag branded products were not included in the sale. In August 2019, arcomed terminated its distribution agreement with the company.

8) The company signed a secured debt facility agreement for $A1 mn with SIO Partners Ltd. The term was 18 months at the rate of 12%, compounded monthly. A one-off facility fee of $A125,000 was capitalized to the loan, repayable at maturity in November 2020. The collateral was equivalent to $A1 mn. The funding was to help meet working capital and operational costs.

9) The agreement for the sale of all the shares of Anteris Vaccines Pty Ltd, holder of the company's Immunotherapies business segment of the company, to Constellation Therapeutics Ltd., was terminated. As a result, Anteris Vaccines appointed a voluntary administrator to liquidate the business as Anteris had stopped funding its research.

2. Business Overview[v]

2.1 Business segments

Anteris Technologies Limited is a structural heart company developing first-in-class aortic valve replacement products. Founded in 2011, through the merger of Allied Medical Ltd and bioMD Ltd, it changed its name from Allied Healthcare Group Ltd to Admedus Limited in 2013. On May 22, 2020, the company then changed its name to Anteris Technologies Ltd (Anteris) to reflect its repositioning as a structural heart company. Anteris owns the intellectual property rights of ADAPT® technology, pivotal to its operations. Its remaining non-core business, infusion pumps distribution in Australia and New Zealand, was divested in May 2019 as it transformed its focus to developing pioneering products using its ADAPT® technology, such as the single-piece 3D valve used in AVR to treat patients with aortic stenosis. The in-human study of the single-piece DurAVR™ aortic valve in SAVR started in Q1 2020. An animal study of its DurAVR™ aortic valve via transcatheter replacement (TAVR) is scheduled this year.

2.2 ADAPT® technology[vi]

Professor Leon Neethling, cardiac surgeon at the Royal Perth Hospital and the University of Western Australia, developed and patented the company's clinically superior ADAPT® technology. The technology underwent various animal trials from 2006 to 2007. Then, in the Bloemfontein study, patches developed using the ADAPT® technology were used to correct congenital heart deformities, with positive results. The ADAPT® technology has ten years of patient follow-up data showing no calcification, placing it ahead of its competitors.

The company has potential products undergoing trials for launch in the future. The products developed by the company rely on its distinguished ADAPT® technology for converting a xenograft (animal) tissue into durable bio-scaffolds for repairing and replacing soft tissues within patients.

ADAPT® technology's patented process involves eliminating phospholipids from harvested bovine pericardium before treatment to remove antigens, and glutaraldehyde processing to increase durability. A detoxification process removing any residual treatment material is done before sample sterilization. The sterilizer also serves as packing solution for transportation and storage.

Exhibit 1: DurAVR™: Key Areas

2.2.1 Transcatheter aortic valve replacement

TAVR is a minimally invasive procedure to replace a narrowed aortic valve that fails to open properly (aortic valve stenosis). The narrowing of the aortic valve restricts blood flow into the aorta supplying the rest of the body.[vii]

Company product[viii]: The company's product is the DurAVR™ (single-piece 3D) aortic valve developed using its ADAPT® technology. The unique structure of the valve leads to reduced leaflet stress. The device more closely mirrors native aortic valve anatomy and functionality. The company's TAVR device would have the same valve placed at the end of a

catheter. The company also plans to sell its DurAVR™ aortic heart valve as a separate product for use in SAVR procedures.

Market: As per Edwards Life Sciences, the current market ($US4 bn in May 2019) for TAVR is expected to show 11.8% CAGR to reach $US7 bn by 2024. Two big companies hold the majority of market share, with many smaller companies holding the balance. The US FDA recently approved TAVR procedures for use in lower-risk younger patients, who are expected to make up a large part of the patient population growth. This presents a significant opportunity to the company as it is better positioned to grab this market segment due to the increased durability it offers given its product's anti-calcification properties and valve design.

2.2.1.1 Benefits and characteristics[ix]:

- Superior anti-calcification and anti-degradation technology (ADAPT®).
- First and only clinical data showing zero calcification over ten years implies increased durability.
- First and only 3D single piece ADAPT® treated aortic valve demonstrating improved haemodynamics and 35% less wear on the leaflets compared with current valves.
- Simplified design structure reduces the number of sutures required compared with competitors' devices, which require 300-plus sutures
- Suitable for a younger patient population (low risk) due to its anti-calcification properties
- Reduces leaflet stress, helping increase valve durability
- Offers increased coaptation surface, preventing regurgitation

2.2.1.2 TAVR vs SAVR

In SAVR, an incision is made to open the chest, the heart is stopped, and the diseased valve is replaced. After restarting the heart, the chest is closed. In TAVR, the replacement valve is delivered via a major artery, making it less invasive.

Recovery after SAVR can take up to two or three months with hospital stays on average for one-week post-implantation, whereas in a TAVR procedure hospital stays last for less than a few days.

In a 2019 trial, TAVR was found to be superior to SAVR at preventing death, stroke or rehospitalization after one-year post treatment. TAVR was also associated with lower chances of atrial fibrillation.[x]

Procedure: An incision is made into the groin; a catheter is inserted through the femoral artery (a large artery) to transport the replacement valve to the aorta. The new valve displaces the old valve, taking over the regulation of blood flow.

The incision made in the femoral artery is called the transfemoral approach. The incision can also be made in the chest between the ribs, and the catheter can enter through a large artery in the chest or through the tip of the left ventricle (transapical approach).[xi]

Suitability: The TAVR approach is suitable for patients who are at an intermediate to high risk for surgery or complications. A trial conducted in 2019 showed TAVR was not inferior to SAVR in treating low-risk patients.

The TAVR approach is also suitable for patients with prior open-heart surgery. In 10-15 years, the bioprosthetic valves placed in an open-heart surgery start degenerating and failing. This necessitates a replacement. The new valve is placed on the orifice of the failed surgical valve via a catheter and the old valve gets pushed aside. This is also commonly known as the "Valve-in-Valve" procedure.[xii]

2.2.1.3 TAVR studies

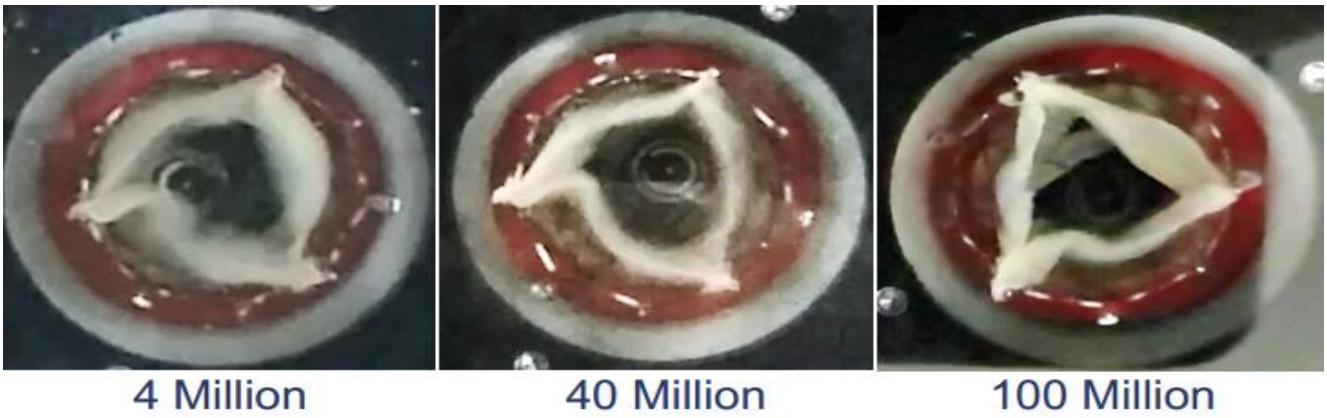
2.2.1.3.1 Animal study[xiii]

Preceding study

The company conducted lab tests to examine the durability of the single-piece 3D valves. Benchmarked against a competitor, the company's DurAVR™ 3D valves remained functional after 400 mn cycles (equivalent to ten human years) while the competitor's valve showed significant fatigue after 250 mn cycles. The company achieved the standard durability benchmark for cardiovascular implants. The study suggested the company's single-piece 3D valve could be

implanted in a younger patient population as well due to its durability. The findings suggested conducting a study on living subjects.

Exhibit 2: Anteris' TAVR valve after simulated cycles



Study Design

The company conducted clinical trials for its AVR device on sheep from 11 July 2018 for six months. The device was implanted to examine the device's safety and feasibility as well as anti-calcification properties. The study's purpose was to ascertain the merit in moving to a larger animal study and an in-human trial.

Interim Study Results

The device was implanted in six sheep. The echocardiographic data from four sheep after four weeks showed effective orifice areas (EOA) with a range of 2 – 2.5cm^2 (compared with 1.6 - 2cm^2 in commercially available valves). The echocardiograms suggested superior functional valves with optimal hemodynamic profiles.

No regurgitation was observed, and a low-pressure gradient was observed within the valves (4-6 millimeters of mercury (mmHg)).

Six-month follow-up data revealed a stable functioning valve, devoid of calcium deposits in what is considered to be a highly calcific model (juvenile sheep).

The study suggested the device can be implanted safely in living organisms with merit in progressing to in-human trials.

2.2.1.3.2 In-human study

The company received approval for an in-human SAVR study of its DurAVR™ 3D single-piece 3D aortic valve from the UZ Leuven Medical Ethics Committee. Professor Bart Meuris MD, PhD, Chief of Cardio-Vascular Surgery at the University Hospitals, Leuven, in Belgium, is conducting the study there. Admedus Regen Pty Ltd, a wholly owned subsidiary of Anteris, is the trial's sponsor. The study focus is on efficacy and safety, regardless of whether it is used surgically or in TAVR. Each patient will have a six-month follow-up period. Fifteen patients with aortic valve insufficiency or stenosis will be enrolled. The study began on March 26, 2020 with two patients successfully implanted and discharged thus far.

The study follows the previous animal study.

Study Design

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	15 participants
Intervention Model:	Single Group Assignment
Intervention Model:	Prospective
Intervention Model Description:	Non-randomized, single arm, single-center first-in-Human clinical investigation
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	First-in-Human Surgical Implantation of Single Piece ADAPT® Treated 3D Aortic Leaflet Repair (ALR), Feasibility and Clinical Safety Study
Primary Endpoints	• Mean pressure gradient (mmHg) across the valve (less than 20 mmHg) [Time Frame: 6 months following implantation • Derived Effective Orifice Area (EOA) range > 0.9 cm^2 (19mm valve) to > 1.6 cm^2 (27mm valve) [Time Frame: 6 months following implantation] • Rate of thromboembolism [Time Frame: 6 months following implantation] • Rate of valve thrombosis [Time Frame: 6 months following implantation] • Rate of major paravalvular leak [Time Frame: 6 months following implantation] • Rate of major hemorrhage [Time Frame: 6 months following implantation] • Rate of endocarditis [Time Frame: 6 months following implantation]
Secondary Endpoints	• Rate of Atrial Fibrillation 6 months after procedure [Time Frame: 6 months after procedure] • Number of days in ICU [Time Frame: 30 days after procedure] • New York Heart Association (NYHA) class Improvement Assessment [Time Frame: 6 months after procedure] • Number of days in hospital after procedure [Time Frame: 30 days after procedure] • Hemoglobin assessment [Time Frame: 6 months after procedure] • Alanine transaminase (ALT) [Time Frame: 6 months after procedure] • Aspartate transaminase (AST) [Time Frame: 6 months after procedure] • Rate of all-caused death [Time Frame: 6 months following implantation] • Rate of valve-related deaths [Time Frame: 6 months following implantation] • Rate of valve-related reoperation [Time Frame: 6 months following implantation] • Rate of valve explant [Time Frame: 6 months following implantation] • Rate of hemorrhage [Time Frame: 6 months following implantation] • Rate of all-cause reoperation [Time Frame: 6 months following implantation] • Rate of Device deficiency [Time Frame: 6 months following implantation]
Actual Study Start Date:	26 March 2020
Estimated Primary Completion Date:	January 2022
Estimated Study Completion Date:	January 2022

Exhibit 3: DurAVR™ First in Human study patient # 1[xiv]

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

Sold distribution rights to CardioCel® & VascuCel® Portfolio

The company, in order to shift its focus to development of the TAVR device and other new products, sold the distribution rights of the CardioCel® and VascuCel® product portfolio to LeMaitre Vascular, Inc. for up to $A36.2 mn in October 2019. The company received $A21.2 mn in cash up front. Two installments of $A1 mn each will be paid after 12 and 36 months, respectively. The rest of the consideration is subject to completing the following milestones:

- $A3.0 mn paid on obtaining certain regulatory approvals as per European Medical Devices Directorate Regulation,
- $A0.7 mn paid on completing all testing and documentation to extend the shelf life of the CardioCel® and VascuCel® products from 36 months to at least 60 months in the US,
- Up to $A3.73 mn if gross revenue from LeMaitre's CardioCel® and VascuCel® sales exceeds $A29.8 mn in the first 12 months or $A1.8 mn if gross revenue from product sales exceeds $A22.4 mn in the first 12 months,
- Up to $A3.73 mn if gross revenue from LeMaitre's CardioCel® and VascuCel® sales exceeds $A44.7 mn in the second 12 months, or $A1.8 mn if gross revenue from product sales exceeds $A33.5 mn in the second 12 months,
- $A0.2 mn was to be received on completion of reporting procedures by 31 October 2019.

The company retained the exclusive manufacturing rights of the CardioCel® and VascuCel® portfolio for up to three years, with a guaranteed 20% margin over the cost of production.

2.2.4 Regenerative Medicines R&D

The Regenerative Medicines R&D business segment includes the expenditure on new products developed and commercialized using the ADAPT® technology. The TAVR device development falls in this category. The company spent $A8.1 mn in FY 2019 on R&D in this segment.

Immunotherapies Division

The company had an Immunotherapies business segment, which included R&D of HPV and HSV vaccines. The company entered into an agreement to sell all the shares of Admedus Vaccines Pty Ltd (which held the Immunotherapies division) to Constellation Therapeutic Ltd (HK), but the agreement was terminated in April 2019. As a result of the agreement's termination and a lack of funding for further research, Admedus Vaccines appointed an administrator and the Immunotherapy division was placed into liquidation in June 2019, leading to the segment's deconsolidation.

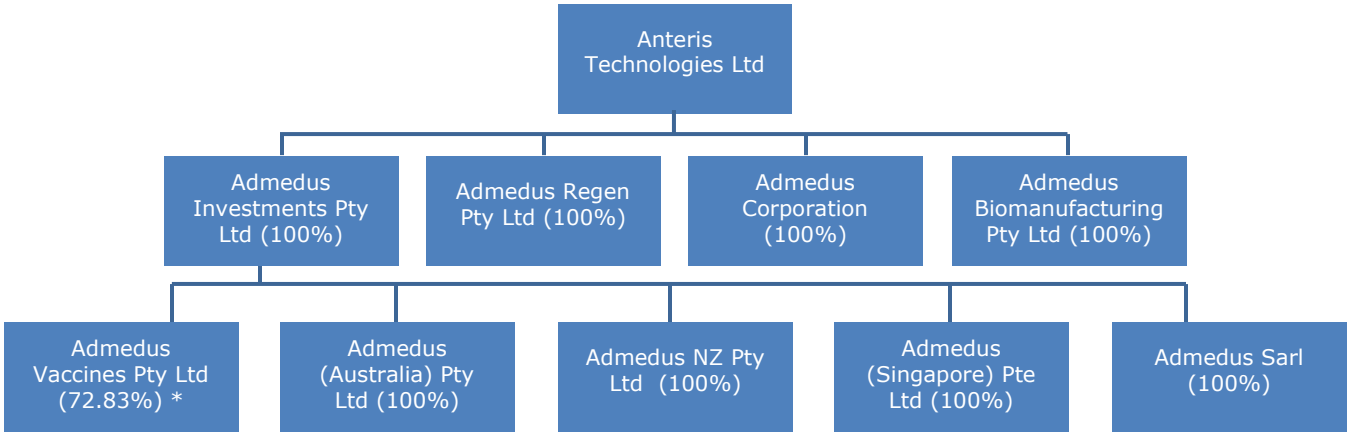
2.3 Patents[xv]

Title	Status	U.S. Patent Number	Patent Term
AN IMPLANTABLE BIOMATERIAL AND A METHOD OF PRODUCING IT	Granted in the US and other countries	9205172	August 28, 2032
STERILIZATION PROCESS	Pending in the US; Granted in other countries	NA	At least 2031
REPLACEMENT HEART VALVE WITH REDUCED SUTURING	Pending in the US and other countries	NA	At least 2038
STERILIZED PACKAGING SYSTEM FOR CATHETER	Pending in the US and other countries	NA	At least 2038
TAVR PATENT APPLICATONS	Pending in the U.S. and other countries	NA	At least 2038

Thus far this year, up to May 14, the company filed 18 applications worldwide for its DurAVR™ aortic valve and its novel sterilized packaging systems. If all the other filings proposed in the second half of 2020 are filed, then total patent applications filed for ADAPT® will be twice the 2019 levels.

2.4 Corporate Structure

Exhibit 4: Corporate Structure



*currently in liquidation

2.5 Key Clinical and Preclinical Programs

Exhibit 5: 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

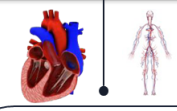
Assess optimal valve function and improved hemodynamics

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

2.6 Financial overview[xvi]

Q1 2020

Existing contractual agreements generate cash inflows for the company

Anteris posted $A2.3 mn in revenue for Q1 2020 under its manufacturing agreement with LeMaitre for CardioCel® and VascuCel® products. Additionally, the company generated $A2.2 mn from its contractual agreement with 4C Medical Technologies, Inc., including an additional $US1.0 mn received on account of the transfer of sterilization technology to 4C Medical Technologies.

Cash resources decline because of higher outflows

Anteris earned cash receipts of $A1.7 mn in Q1 2020. The company had net cash outflows from operating activities of $A6.0 mn, including $A0.7 mn spent on R&D activities. Staff costs were $A4.6 mn for the quarter and included annual staff incentive payments related to the 2019 financial year. Investing cash outflows of $A0.6 mn related to payments made for a prior-year acquisition while $A0.1 mn was for lease payments. The company had cash and cash equivalents of $A3.0 mn at the end of Q1 2020, decreasing by $A6.0 mn from the previous quarter.

In addition to cash, the company has short term deposits of $A8.1 mn with ANZ bank.

FY 2019

Solid top-line figures despite mid-year product portfolio divestments

The patches business (part of ADAPT®) was sold to LeMaitre Vascular, Inc. in October 2019. Prior to this deal, the segment contributed $A10.2 mn to FY 2019 revenue (ten months' contribution (59.8%) to the total revenue). ADAPT® showed 10.0% YoY revenue growth to $A8.8 mn for nine months (from $A8 mn for the corresponding period in 2018). Revenue contribution from the Infusion business was 33.3% ($A6.9 mn) until divestment in May 2019.

Total revenue reported in FY 2019 was $A17.1 mn. FY 2019 gross profit of $A8.3 mn represented a gross margin of 48.6%, which was the same as the previous year.

Reduction in employee count drove a decrease in selling, general and administrative (SG&A) expenses; gains from sale of peripheral businesses reduced net loss

The company reported a lower net loss for FY 2019 of $A6.2 mn compared with $A24.7 mn in FY18. Lower selling, general and administrative expenses of $A32.4 mn ($34.3 in FY18) were driven by lower employee benefits and travel and conference costs. The loss also included the proceeds from the sale of distribution rights from the ADAPT® patch business and the divestment of the Infusion business. The gain from the business sale was offset to an extent by the impairment of plant, property and equipment and intangible assets of $A4.5 mn.

In May 2019, the company entered a $A1 mn facility agreement with SIO Partners LP to fund working capital and operational costs. At 31 December 2019, the company's closing cash balance was $A9.0 mn, excluding $A7.1 mn held as a term deposit. The company saw a $A0.9 mn decline in net working capital during FY 2019, which included the reduced inventory levels due to divesting the Infusion business and ADAPT® patch business distribution rights.

2.7 Company Milestones

Exhibit 6: Anteris Technologies Milestones	
Year/ Period	**Event**
2011	• Incorporated as Allied Healthcare Group Ltd as a result of a merger between Allied Medical Ltd and bioMD Ltd
2012	• National Health and Medical Research Council (NHRMC) awarded $A200,000 grant to Ian Frazer (worked with Anteris on development of HPV vaccine) • Evidence of new tissue regeneration for CardioCel® found in heart valve reconstruction study • Successful result for Coridon's (in which the company had a 44.1% stake) HPV vaccine • First patients received CardioCel® to treat congenital heart defects
2013	• Acquired manufacturing facility for CardioCel® in Western Australia • Company changed name to Admedus Limited • First sale of CardioCel® in Europe • Received Janssen 2013 Emerging Company of the Year award at Ausbiotech's national conference • No calcification reported from Phase II CardioCel® Patients after five years • Phase I trial of HSV-2 Vaccine began • CardioCel® granted CE Mark • Increased stake in Coridon to 50.1% • CardioCel® awarded a grant of $A1.9 mn from Commercialization Australia • Lodged 510(K) with FDA for CardioCel® marketing approval • Received ISO 13485 Certification for CardioCel® • Raised $A4.6 mn through a shareholder purchase plan • ADAPT®-treated tissue showed advantages for abdominal hernia and pelvic floor reconstructions
2014	• HSV-2 vaccine Phase II received ethics approval to start immediately • HPV therapeutic vaccine showed positive preclinical data to progress towards Phase Ib study • Four hospitals in Singapore gained access to CardioCel® under the Singapore Health Sciences Authority Early Access Program • CardioCel® granted a medical device license in Canada by Health Canada • HSV-2 Phase I trial reached a safe end point and showed ability to generate a T-cell response • New biomanufacturing facility opened in Perth • Increased stake in Admedus Vaccines (formerly Coridon) to 66.3% • Raised $A18.4 in Shareholder Purchase Plan and Private Placement • First sales order of CardioCel® in the US • CardioCel® showed no calcification after six years • Awarded the Frost & Sullivan Australian Excellence Award • CardioCel® cleared for sale in the US
2015	• Raised $US5 mn through placement of shares to a US healthcare institutional investor • Added valve and annular repair in CardioCel® European label • First sale of CardioCel® in Malaysia • Successful valve reconstruction by CardioCel® in pre-clinical aortic tri-leaflet reconstruction study • Collaborated with the Ear Science Institute Australia for the delivery of stem cells on ADAPT® tissue in both vitro and vivo models • Started post-market clinical study for CardioCel® in aortic tri-leaflet reconstructions • Launched 2cm x 2cm CardioCel® bio-scaffold for repair and reconstruction of congenital heart defects • No calcification reported from Phase II CardioCel® Patients after seven years • Use of CardioCel® approved in Singapore • Second dose of the therapeutic vaccine in HSV-2 Phase II study given to patients • Launched 2cm x 8cm CardioCel® tissue patch in the US • Raised capital of ~$A28 mn through rights issue and private placement • First dose received by patients in HSV-2 Phase II study • Positive clinical results received in clinical study for repair of Dura mater using ADAPT® treated tissue • CardioCel® entered the Hong Kong market and the first centers in Italy and France used CardioCel®

2016	• Received market approval in collaboration with Genpharm for CardioCel® in United Arab Emirates (UAE) • Opened an executive office in Minneapolis • Received Food and Drug Administration (FDA) clearance to market VascuCel® in the US • Awarded 100% ownership of Adapt® regenerative technology by Federal Court of Australia • No calcification reported from Phase II CardioCel® patients after eight years • Received a five-year contract from Royal Adelaide Hospital in Australia for the installation of arcomed AG Chroma Infusion pump system • Awarded with 'Manufacturer of the Year' and 'Most Innovative Manufacturing Company' at 2016 Manufacturers' Monthly Endeavor Awards • Interim Phase II HSV-2 study showed no safety issues and a decrease in viral lesions in patients versus the baseline • First sale of CardioCel® in Middle East and North African region
2017	• Lodged IP submission for ADAPT® 'Hydropackage' as a part of TAVR project • Opened technical operations office in Adelaide to support infusion business at Royal Adelaide Hospital • First successful implantation of CardioCel® 3D at Melbourne's Royal Children's Hospital, Australia • Appointed David St Denis as new chief operating officer • Received FDA approval to market CardioCel® 3D curved patch in the US • PHASE IIA HSV-2 study reached its safe endpoint and showed positive immune response to vaccine • Launched Veeva CRM system and sales model for the global expansion of ADAPT® products • Appointed Wayne Paterson as chief executive officer and John Seaberg as chairman of the company • First sales of CardioCel® in Saudi Arabia • Appointed Simon Buckingham as a non-executive director of the board
2018	• Raised gross funds of $A19 mn from entitlement offer • Appointed Dr Kiran Bhirangi as chief medical officer • Commenced animal trial with the first successful live implantation of unique single-piece heart valve • Signed memorandum of understanding with Star Bright for long-term funding for Admedus Vaccines • Signed an agreement to commence animal trials in leading European reference laboratory for the development of TAVR project • Secured $A6 mn in funds through private placement • Signed a letter of intent with key investor, Star Bright, to fund immunotherapy business • TAVR project passed testing milestone by achieving a durability benchmark of 200 mn cycle tests • Entered into an agreement with a Group Purchasing Organization in the US for promoting ADAPT® products to 1,500 hospitals • Received regulatory approval to introduce CardioCel® 3D® and VascuCel® in Canada
2019	• Received $A21.2 mn as upfront payment for the sale of distribution rights to CardioCel® and VascuCel® patch business to LeMaitre Vascular Inc., US • Received regulatory approval for CardioCel® 3D® in Israel • Completed the divestiture process of infusion business • Signed an agreement to sell Infusion business to BTC Speciality Health Pty Ltd for $A6.3 mn • Received regulatory approval for CardioCel® 3D® and VascuCel® in Europe • Announced positive results from TAVR feasibility report
2020	• Completed the transfer of sterilization technology to 4C Medical Technologies • Received approval for first in-human study of DurAVR™ 3D single-piece heart valve • Implanted DurAVR™ 3D aortic valve in two patients as part of the in-human study • Received approval from the US FDA for extension of use of ADAPT® tissue for cardiac defects • Changed company name to Anteris Technologies Ltd

2.8 Corporate strategy and future outlook

2.8.1 Strategy[xvii]

The company's strategy revolves around development of novel, groundbreaking devices for structural heart indications using its ADAPT® technology, primarily focused on its DurAVR™ aortic valve. The company's near-term strategy involves negotiating deals with potential target partners (large strategic MedTech companies). Such deals may include several components, such as licensing ADAPT® technology for products such as surgical valves (SAVR and TAVR) for existing commercial products. This would generate near-term revenues by way of royalties and potential large-scale supply agreements. Separate deals could also include co-development of the unique DurAVR™ aortic valves (TAVR and SAVR) products as next generation entries into the global AVR market.

Top management appointments in 2017 stimulated a change in the strategy and positioning of the company. The new management realized the growing TAVR market potential and decided to move its focus to the valve-replacement products. The company recognized ADAPT® as its main opportunity and initiated a restructuring process to divest its non-core business to enable further development of ADAPT® products.

The company sold its Infusion business to BTC Speciality Health Pty Ltd, a wholly owned subsidiary of BTC Health Ltd, for a consideration of $A6.3 mn in May 2019. The transaction excluded the distribution of the arcomed line of Infusion pumps.

The distribution rights of the CardioCel® and VascuCel® (ADAPT® technology) product portfolio were sold to LeMaitre Vascular in FY 2019 for a consideration of $A36.2 mn including earn-outs. The company retained the entire intellectual property portfolio of ADAPT® to enable continued development. The transaction led to a transfer of distribution rights but retained the intellectual property rights of the ADAPT® technology. The transaction was completed to reduce operational costs and to provide the company with additional funding for further development of the TAVR device, as it neared an in-human study.

With the two transactions, the company was able to reduce its staff by almost half.

2.8.2 Outlook

The company's outlook appears bright, as data collected over ten years for its unrivalled ADAPT® technology has not shown any evidence of calcification. The company looks to capitalize on its technology, with the development of the TAVR device and other new products.

Following positive results of an animal study for its single-piece 3D aortic valve, the company was prepared to conduct an in-human study in early 2020. Partnership for the development of the device was being pursued, and the company had discussions with potential target partners. The clinical study commenced on 27 March 2020, with a DurAVR™ aortic valve implanted in the first patient with positive initial results. The second patient was implanted with a DurAVR™ aortic valve in May 2020. The company expects the results from the study between Q1 2021 and Q3 2021, assuming minimal delays due to the current global healthcare scenario.

The **COVID-19** scenario is expected to have a limited impact on the company's operations as it implemented a coronavirus mitigation strategy regarding travel policies, personnel policies and manufacturing continuity. The recruitment and treatment of patients for the in-human study of SAVR is expected to go on uninterrupted unless hospital resources are diverted to tackle the pandemic. Despite disruption to medical conferences and events, the company continues to have discussions with potential partners and investors for the device's development. Furthermore, the company, as of April 2020, has not seen a decrease in demand for orders from LeMaitre Vascular. Staff at its manufacturing and R&D departments continue to work.

2.9 Company premiums[xviii]

Unprecedented ADAPT® technology: ADAPT® technology is the company's tissue engineering technology, used in its product development. The technology helps produce biomaterial scaffolds which inhibit anti-calcification and regenerative properties. The market needs an effective and durable product. ADAPT® technology-enabled products possess both these characteristics. The ADAPT® technology can help the company manufacture revolutionary products and be among the leaders in the market.

Experienced management: The company's management has extensive experience in the life sciences and pharmaceutical sectors, having held top positions in large global health care companies. The company's management comprises industry veterans with experience in diverse fields such as restructuring, mergers and acquisitions, distribution and development.

Sound intellectual property: The company has a strong patent and intellectual property base covering its technology, its processes and its devices. The steps involved in utilizing the ADAPT® technology to make collagen scaffolds are all patented to maintain the company's competitive advantage and prevent imitation of its devices.

Proven commercial potential of ADAPT: The company sold the distribution rights of its CardioCel® and VascuCel® product portfolio distribution rights to LeMaitre Vascular, Inc. The transaction serves as an example of the company's ability to utilize its medically superior technology to create products that are medically and commercially significant.

2.10 Company risks[xix]

Clinical trial risk: Companies in the medical device industry face the risk of clinical trial failure, rendering the investment into development of the product worthless. The company may have to scrap its development program, significantly affecting its current and future operations.

Regulatory risk: Any medical device needs the appropriate regulatory body approval. Failure to get the approval can lead to program abandonment. Approval delays can also affect the company, allowing competitors time to capitalize on it.

Commercialization risk: After successful development and regulatory approval, the product of a medical device company faces the risk of commercial failure. The product might not be possible to manufacture on the necessary economic scale or it might not be marketed attractively to users. It might also not be accepted by physicians, patients and the medical community at large, despite its benefits, leading to a negative or a subdued return on investment for the company.

Competition: The company faces the risk of new substitute products by its competitors. The medical device industry is highly competitive and marked by frequent technology innovations and upgrades. The advent of new, superior products is an inexorable risk, which poses a significant threat to the company and its products. Companies such as Meril Life Sciences, St. Jude Medical, Baxter, Boston Scientific, Medtronic and Edwards Lifesciences pose a considerable threat to Anteris with their products.

Lack of funding/partner: Medical device development and products require a huge investment. Medical devices companies usually raise funds or partner up with other companies for the development and commercialization of new products. Anteris is in discussions with Key Opinion Leaders (KOL) and medical device companies for a potential partnership for the development of its DurAVR™ aortic valve development. Inability to raise funds or strike a partnership could jeopardize the entire program and may lead to its abandonment.

2.11 Shareholding Pattern

The company had 5,910,304[xx] shares of common stock issued and outstanding on June 16, 2020.

Exhibit 7: Top 7 Shareholders of the company (as of June 16, 2020)[xxi]

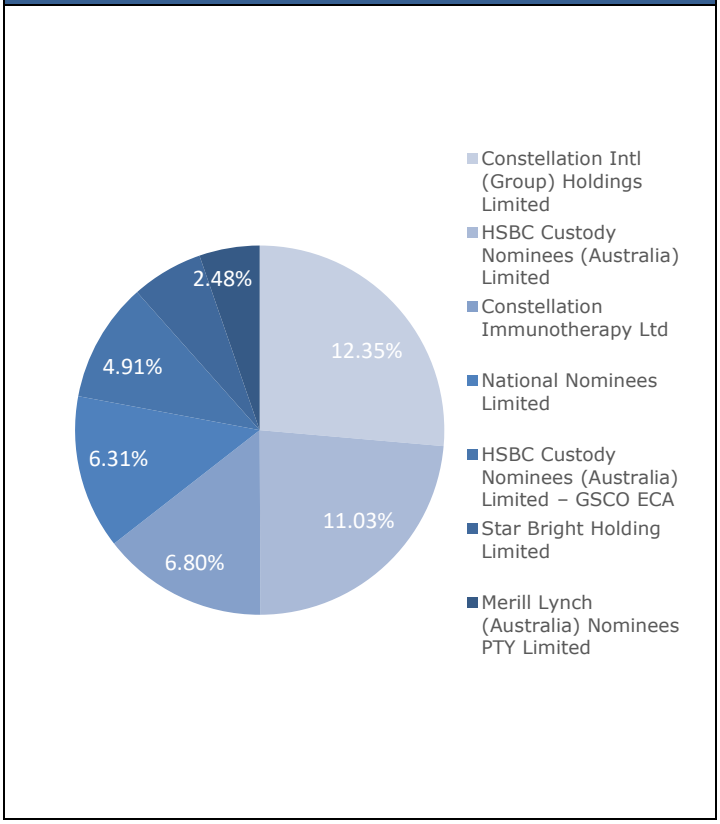


Exhibit 8: Top 7 Shareholders of the company

Shareholders	No. of Shares	% of total
Constellation Intl (Group) Holdings Ltd	730,192	12.35%
HSBC Custody Nominees (Australia) Ltd	651,961	11.03%
Constellation Immunotherapy Ltd	402,093	6.80%
National Nominees Ltd	373,228	6.31%
HSBC Custody Nominees (Australia) Ltd – GSCO ECA	290,353	4.91%
Star Bright Holding Ltd	173,680	2.94%
Merill Lynch (Australia) Nominees PTY Ltd	146,376	2.48%

*The SIO holdings are held through HSBC and NAB on the shareholder report. Note that as these entities also represent some other shareholders, the stock balances of HSBC plus National exceed the position of SIO.

2.12 Listing and Contact Details[xxii]

Anteris Technologies Limited (Ticker: AVR) is listed on Australian Securities Exchange Ltd (ASX).

Company Contacts

Registered Address: Toowong Tower, Level 3, 9 Sherwood Rd, Toowong QLD 4066, PO Box 1159, Milton 4064
Phone: 1300 550 310
Fax: 1300 880 398
Website: www.anteristech.com

3. News[xxiii]

- **Name Change:** On 22 May 2020, the company changed its name to Anteris Technologies Ltd.

- **Anti-calcification comparison study:** On 19 May 2020, the company announced that it has commenced a preclinical study to compare the anti-calcification properties of its ADAPT® tissue with other bovine and porcine tissues which are currently being used in SAVR and TAVR valves currently available in the market. The study will be conducted in Minneapolis, US.

- **Implantation of 3D aortic valve in second patient:** On 11 May 2020, Anteris Technologies announced that a second patient was implanted with its DurAVR™ aortic valve, following the first patient's positive results.

- **Announced Q1 2020 results**: On 22 April 2020, Anteris announced its Q1 2020 results from contract manufacturing agreements with LeMaitre Vascular, Inc. It earned another $A2.2 mn from its contractual agreements with 4C Medical Technologies, Inc.

- **First patient implanted with DurAVR™ aortic valve in SAVR in-human study discharged**: On 6 April 2020, Anteris Technologies announced that the first patient implanted with its DurAVR™ valve on 27 March 2020, in the SAVR clinical study, was discharged from the hospital and showed positive initial results.

- **Received approval from US FDA for ADAPT® tissue**: On 6 April 2020, Anteris announced that it had received approval from the US FDA extending the use of ADAPT® tissue in cardiac defects, including intracardiac defects, septal defects and annulus repairs.

- **Received approval for in-human study of its single-piece 3D aortic valve**: On 11 March 2020, Anteris announced receiving approval for an in-human study of single piece 3D aortic valve from the Federal Agency for Medicines and Health Products (FAMHP) of Belgium, implying that the study could commence in March 2020.

- **Announced FY 2019 results**: On 28 February 2020, Anteris announced its FY 2019 results. The company reported revenue of $A17.1 mn in FY 2019, decreasing from $A25.6 mn in FY 2018, as the company sold off its Infusion business and the distribution rights of its CardioCel® and VascuCel® products during the year. The company recorded a gain of $A24.9 mn from the divestment activities mentioned before. The company spent $A8.1 mn on R&D largely related to the TAVR program and ended the year with a cash balance of $A9.0 mn. The company also held term deposits of $A 7.1 mn.

- **Transfer of sterilization technology to 4C Medical Technologies**: On 3 February 2020, Anteris announced the transfer of its sterilization technology to 4C Medical Technologies for $US1.0 mn in addition to $US0.4 mn which the company had already received. The agreement allows 4C Medical Technologies to use the technology to sterilize the ADAPT® tissue it uses in its mitral valve device.

- **Announced Q4 2019 results**: On 31 January 2020, Anteris announced its Q4 2019 results. Revenue was $A2.3 mn for the quarter. The ADAPT® business segment contributed $A1.4 mn while the Infusion business segment contributed $A0.9 mn. The YoY decline in revenue from $A4.1mn was a function of the divestment of the Infusion business divestment and the sale of distribution rights to the CardioCel® and VascuCel® product portfolio, linked to its transformation into a structural heart company. The company's cash balance was $A9.0 mn at the end of Q4 2019.

- **Approval of in-human SAVR study of single-piece 3D aortic valve:** On 22 January 2020, Anteris announced receiving approval for a 15-patient clinical study of its single-piece 3D aortic valve. The study, starting Q1 2020, will provide important insights for the TAVR device development.

- **Announced Q3 2019 results:** On 31 October 2019, Anteris announced its Q3 2019 results. Revenue was $A4.1 mn in Q3 2019. The ADAPT® business segment contributed $A3.1 mn (up 2% YOY) while the Infusion business segment contributed $A1.0 mn. The revenue declined from $A6.3mn was due to the Infusion business sale. The cash balance was $A1.7 mn at the quarter's end. The Company received $A21.2 mn from an upfront payment for the patch business distribution rights sale to LeMaitre Vascular, Inc. in October 2019.

- **End of trading halt**: On 14 October 2019, Anteris announced the end of its trading halt, which started on 15 April 2019, ahead of its recapitalization plan.

- **Sale of distribution rights of CardioCel® and VascuCel® product range to LeMaitre Vascular, Inc:** On 14 October 2019, Anteris announced selling the distribution rights to CardioCel® and VascuCel® in a deal worth up to $A36.2 mn (including all earnouts). An amount of $A21.2 mn cash was paid upfront, with two installments of $A1.0 mn each to be received after 12 months and 36 months, respectively. The remaining amount will be received, subject to achieving specific milestones. Anteris retains the manufacturing rights for a period of up to three years, with a 20% margin over cost assured, as per the agreement.

- **CardioCel® 3D approval for sale in Israel:** On 4 September 2019, Anteris announced receiving regulatory approval for the sale of the CardioCel® 3D product portfolio in Israel. The approval allowed Anteris to provide a solution for the repair of high-complexity congenital heart defects in Israel.

- **Announced H1 2019 financial results:** On 23 August 2019, Anteris announced its H1 2019 financial results. Revenue was $A10.7 mn in H1 2019, down 16.4% on a YoY basis. The company earned $A5.7 mn in revenue from its ADAPT® business in H1 2019, a 16.7% rise on a YoY basis from $A4.9 mn in corresponding H1 2018, due to increased North American region sales and higher contract manufacturing sales from the 4C Medical Technologies, Inc. partnership agreement. Infusion business sales decreased 36.9% on a YoY basis to $A5.0 mn from $A7.9 mn, due to a contract with GO Medical Industries concluding in June 2018 and the Infusion business sale in May 2019. The company's gross profit margin reduced to 44.3% in H1 2019 from 47.1% in H1 2018 due to higher production costs. Cash and cash equivalents were $A4.9 mn at the end of H1 2019.

- **Termination of distribution agreement with arcomed Ag:** On 8 August 2019, Anteris announced receiving notice from arcomed Ag of its intention to terminate the distribution agreement for the supply of arcomed branded products in Australia and New Zealand.

- **Publication of study of performance of CardioCel® in 'The Annals of Thoracic Surgery' journal:** On 24 June 2019, Anteris announced publishing study assessing the performance of CardioCel® in the prestigious journal, 'The Annals of Thoracic Surgery'. The study results showed that 96% of the patients were free from reintervention at three and five years. The performance was also consistent over the three patient groups. The study collected data from 377 patients (the largest series of data collected on use of CardioCel® in humans) and showed no evidence of calcification.

- **Sale of part of the Infusion business:** On 31 May 2019, the company announced completing the Infusion business sale. The company sold the business to BTC Speciality Health Pty Ltd., a wholly owned subsidiary of BTC Health Ltd, for a consideration of $A6.3 mn.

- **Resignation of non-executive director:** On 31 May 2019, Anteris announced that Lishan Zhang had resigned as a non-executive director.

- **Annual General Meeting:** On 14 May 2019, Anteris announced the results of its Annual General Meeting results. In the meeting, the re-election of John Seaberg, Yanheng Wu, Wenyi Gu and Stephen Denaro as directors was approved.

- **Secured debt facility agreement signed with SIO Partners Ltd:** On 8 May 2019, Anteris announced that it had signed a secured debt facility agreement with SIO Partners Ltd. Per the agreement, the secured debt facility of $A1.0 mn would be available for a period of 18 months at an annual interest rate of 12% (to be compounded monthly).

- **Announced Q1 2019 results:** On 26 April 2019, Anteris announced its Q1 2019 results. Revenues were $A5.1 mn in Q1 2019, down 17.7% on a YoY basis. ADAPT® business sales increased 18.2% on a YoY basis to $A2.6 mn, driven by growth in the U.S. and European markets. The Infusion business contributed $A2.5 mn, a decrease of 37.5% on a YoY basis from $A4.0 mn, due to conclusion of the GO Medical contract and, also, due to increased demand from a major customer in Q1 2018. Cash balance was $A4.6 mn on March 31, 2019.

- **Termination of agreement for sale of Admedus Vaccines:** On 23 April 2019, Anteris announced the termination of the agreement between Constellation Therapeutics Ltd and the other shareholders of Admedus Vaccines Pty Ltd

for the sale of all the shares of Admedus Vaccines. Due to the termination and a lack of funding for operations, an administrator was appointed for Admedus Vaccines.

- **Announced FY 2018 annual results:** On 12 April 2019, the company published its Annual Report for FY 2018. Revenue was $A25.6 mn in FY 2018, up 19.6% from the 12-month period ended December 31, 2017. ADAPT® business sales increased 54.2% to $A11.1 mn in FY 2018 from the 12-month period ended December 31, 2017, due to increased US sales. Infusion business revenues increased 2.0% to $A14.5 mn in FY 2018. The company had an operating cash outflow of $A22.2 mn in FY 2018 due to increased R&D expenditure on ADAPT®. Cash balance was $A12.0 mn on December 31, 2018.

- **Regulatory approval in Europe for CardioCel® 3D® and VascuCel®:** On 11 March 2019, the company announced that its CardioCel® 3D® product portfolio and VascuCel® had received regulatory approval (CE mark) in Europe.

- **Interim results of TAVR animal study:** On 19 February 2019, the company announced the interim results of the AVR (aortic valve replacement) animal study were positive. The study demonstrated the device can be implanted safely without the risk of any major adverse impact. The study, conducted on five sheep, had encouraging results with the company confirming it could initiate a clinical trial for AVR earlier than expected.

- **Issuance of new shares and options worth $A19.0 mn through an Entitlement offer:** On 18 December 2018, the company announced issuing 237,052,479 shares and 237,052,479 options (exercisable within three years at a price of $A0.08). The Entitlement offer was open from 4 December 2018 until 13 December 2018. In the process, the company raised $A19.0 mn (before fees and costs).

- **Appointment of non-executive directors:** On 12 December 2018, the company announced appointing Lishan Zhang and Dr. Yanheng Wu as non-executive directors, representing its major investor Star Bright Holding Ltd.

- **Appointment of new Chief Medical Officer:** On 4 December 2018, the company announced appointing Dr. Kiran Bhirangi as its new Chief Medical Officer (CMO).

- **Appointment of interim CFO:** On 26 November 2018, the company announced appointing Matthew McDonnell as its interim Chief Financial Officer (CFO), replacing Catherine Costello, who left the company on 16 November 2018.

4. Management and Governance[xxiv]

The management and governance team have extensive experience in the field of R&D in biotech and pharmaceuticals, as well as experience in managing operations and finance for multiple businesses. The team also has deep sales and business development experience.

Exhibit 9: Management and Governances

Name	Position	Past Experience
Wayne Paterson	CEO	• Before joining Anteris Technologies in 2016, he held several key positions in multinational pharmaceutical companies and oversaw mergers, acquisitions and restructuring as President and CEO of multi-billion-dollar businesses • He has a degree in business studies from the Queensland University of Technology and an MBA from University of Southern Queensland • He has also completed business courses from Kellogg School of Management in the US, IMD Business School in Switzerland, INSEAD Business School in France and Hong Kong University of Technology in Hong Kong • He worked at Roche Pharmaceuticals from 1999 to 2005, holding positions such as Head of Pharmaceuticals for Roche's South Korean operations and Head of Commercial Operations at Roche China • He served at Merck Kgaa, holding several key positions such as the Global Head of Cardiovascular Medicine, President of Australian, Canadian and European Operations, President of Japan, President of Emerging Markets and President of Asia Pacific • He also served as Non-Executive Director at Cepheid Inc (NASDAQ CHPD) from April 2015 to November 2016
David St Denis	COO	• He has 20 years of experience in the Life Sciences and Pharmaceutical sectors, developing competencies in operations management, strategy development, marketing, product launch, market access and pricing • He has an extensive record of managing cross-functional and multi-cultural teams operating in both mature markets and developing markets • He has a Bachelor of Science degree from the University of Connecticut and a Master of Arts from Boston University • He also has an MBA in Global Management and International Marketing from Babson College • He has been Head of Commercial Operations for Canada and Europe at Merck • He joined Anteris Technologies in 2017
Matthew McDonnell	CFO	• He worked at KPMG for over 24 years, serving as a Partner at the company for ten years. He delivered audit, accounting and advisory services, predominantly in Australia, to financial services, transport, industrial markets, health, childcare and energy sectors • He has valuable experience in managing restructuring, acquisitions, divestments, privatizations and other financial transactions • He was involved in restructuring and privatization of entities owned by the Queensland Government, including the relisting of Linc Energy and the acquisition of Skywest by Virgin Australia

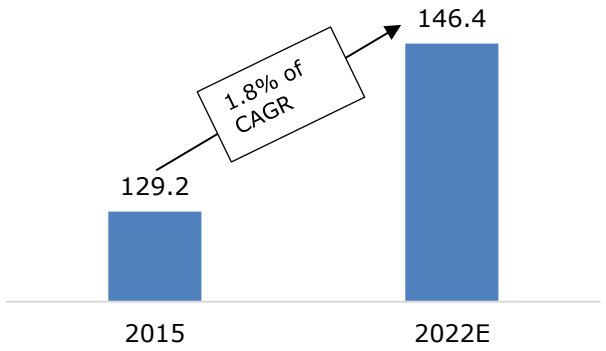
		• He also served as Director of the State Library of Queensland and the Chair of the Audit and Risk Management Committee for eight years
Dr. Kiran Bhirangi MD	CMO	• He is a qualified vascular surgeon and has substantial experience in medical affairs and clinical research in the field of cardiology • He has wide knowledge of complex international regulatory and reimbursement environments, having experience in the development, launch and evaluation of devices • He holds a Bachelor of Medicine, Bachelor of Surgery and a Master of Surgery from Bombay University. He also has a Fellowship of Surgeons from the Royal College in Scotland • He has conducted industry-sponsored research and has authored various publications • He served as the Vice President of Clinical Development and Medical Affairs at Cardiome AG, Head of Medical Affairs for Europe Shire Human Genetic Therapies and Medical Director at OrthoBiotech

5. Industry overview

5.1 Cardiovascular diseases (CVDs) market[xxvxxvi]

CVDs refer to the medical problems related to the heart and blood vessels. CVDs are divided into coronary heart disease, rheumatic heart disease, congenital heart disease, stroke, aortic aneurysm and dissection, peripheral arterial disease and deep venous thrombosis and pulmonary embolism. CVDs are the leading cause of death globally. Around 17.9 mn people die every year due to CVDs, and these account for 31% worldwide deaths. The market for CVDs is expected to show 1.8% CAGR from $US129.2 bn in 2015[xxvii] to $US146.4 bn in 2022.

Exhibit 10: Market for Cardiovascular Disease (in $US bn)



5.1.1 Factors leading to CVDs

High blood pressure: High blood pressure conditions increase the risk of valve disease. A study of 5.4 mn adults in the UK, using patient data from 1 January 1990 to 31 December 2015, identified people with systolic blood pressure above 115 mmHg had higher risk of aortic stenosis and valve regurgitation and every 20 mmHg increase was associated with a 41% higher risk of aortic stenosis and 38% higher risk of aortic regurgitation. Therefore, people with systolic blood pressure of 161 mmHg have a higher risk (around two times) of being diagnosed with aortic stenosis and regurgitation.[xxviii] High cholesterol can lead to heart disease as it might get deposited on the arterial walls and narrow them, potentially blocking the flow of blood in the heart.

The number of people with high blood pressure increased from 594 mn in 1975 to 1.13 bn in 2015 globally.[xxix] The prevalence rate of high blood pressure has been determined at around 40% in adults aged 25 years and above in 2008, which is a high rate covering both high-risk and low-risk patients. This rise in patient numbers has led to increasing demand for cardiovascular treatment and drugs.

Diabetes: Diabetes is a medical condition in which the blood glucose level of an individual is too high. The prevalence rate of diabetes in 2019 was 9.3%, i.e. 463 mn globally, and is expected to reach 10.2% (578 mn) by 2030 and 10.9% (700 mn) by 2045.[xxx] It is a serious medical condition impacting people's lives. It increases the probability of developing a heart disease and further increases the chances of a heart attack or stroke.[xxxi]

Obesity: Obesity is a condition in which fat gets accumulated in the body. In 2016, around 650 mn adults and around 340 mn children (under five years of age) were obese worldwide.[xxxii] There is a direct relationship between obesity and cardiovascular disease as an increased amount of body fat contributes to heart disease via atrial enlargement, ventricular enlargement and atherosclerosis.[xxxiii]

Smoking: There are around 1.1 bn smokers (WHO data) globally, 80% of whom are from low- and middle-income countries[xxxiv]. Around 933 mn people are daily smokers – one in every four people smoke. Smoking increases the risk of CVDs and can cause stroke and coronary heart disease. These two are the leading causes of deaths in the US. Smoking constricts the heart muscles leading to a higher rate of heart beats. It also leads to the formation of clots in the blood vessels. The blockages caused by smoking reduce the blood flow from the heart to the rest of the body. It has been determined that any person smoking more than five cigarettes a day can develop CVD symptoms.[xxxv]

Apart from the above-mentioned factors, there are some other factors such as age, over-consumption of junk food, family history and high cholesterol which lead to CVDs.

5.2 Tissue Engineering

Tissue engineering is a combination of biomedical, biotechnological and engineering techniques aimed at maintaining and replacing tissue organs. It is part of an integrative field termed regenerative medicine and includes other areas such as stem-cell research, molecular biology, gene therapy, biomaterials and nanotechnology. The global tissue engineering industry was valued at $US10.8 bn in 2016. The industry is expected to show 12.9% CAGR to reach approximately $US22.3 bn in 2025.[xxxvi]

There have been certain advances in tissue engineering and regenerative medicine, leading to improvements in living standards by restoring, maintaining and enhancing the functions of tissues and organs. Companies such as Cook, Baxter, Medtronic, Stryker, Zimmer Inc., DePuy Synthes Companies and Acelity are the major players in the tissue engineering market. The evolution of tissue engineering and its applications in the development of biological substitutes for diseased and defective tissues has been one of the driving factors for the scaffolds market.[xxxvii]

Exhibit 11: Global Tissue Engineering Market (in $US bn)

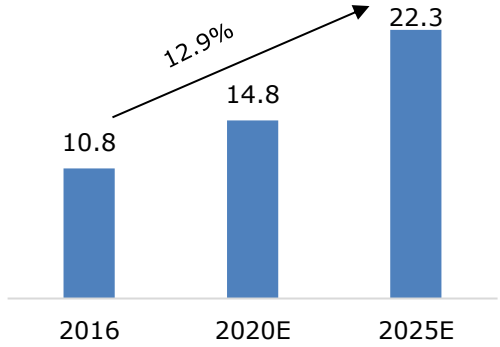
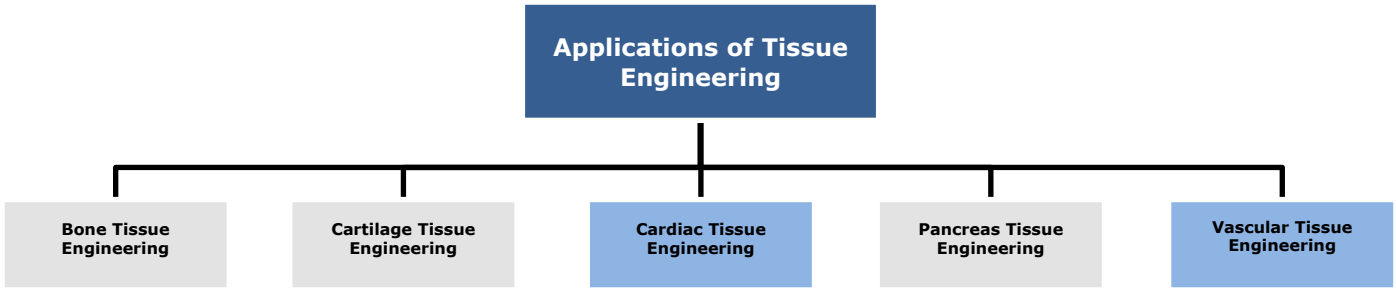


Exhibit 12: Applications of Tissue Engineering



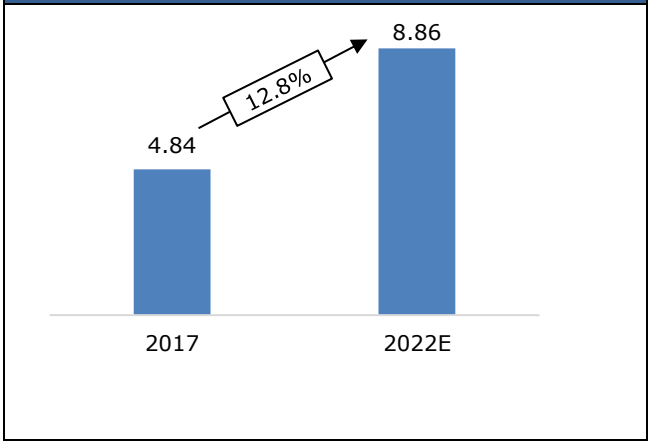
Tissue engineering is now widely used in the treatment of cardiac issues (heart-related issues). Cardiac tissue engineering is either used to create whole-heart substitutes or tissues that can efficiently be implanted in the patient, leading to proper functioning of the heart.[xxxviii] Tissue engineering is also being used for the creation of scaffold patches and tissue valves, which are widely implanted in humans for the treatment of aortic stenosis.

5.2.1 Aortic stenosis

Aortic stenosis is a condition in which the heart's aortic valve narrows reducing in reduced blood flow from the heart to the other body parts. Due to this blockage, the heart has to work harder to pump blood to the rest of the body, which may weaken the heart muscle. Aortic stenosis is becoming a serious issue affecting 12.4% of the global population above 75 years, with a mortality range of 2-5 years if left untreated. The prevalence rate is 3% among people over 75 years of age. In the US, around 300,000 patients are diagnosed with severe aortic stenosis every year.

Prosthetic valves are currently being used to replace diseased valves in patients. The global market for prosthetic valves is expected to show 12.8% CAGR from $US4.84 bn in 2017 to $US8.86 bn by 2022.[xxxix] The market growth is expected to grow due to poor eating habits, an increasing geriatric population, fitness issues and poor nutrition levels. The prosthetic valves are divided into categories, such as donor valves, tissue valves and mechanical valves.

Exhibit 13: Prosthetic valve market (in $US bn)



Donor heart valves are used in heart valve replacement surgery and reconstructive cardiac surgery. In this procedure, valves are used to replace absent, damaged or diseased valves in infants and adults. This option is used in patients who cannot take blood thinners and have tissue infections. In reconstructive cardiac surgery, valves are flexible and can be customized. Donated valves carry less risk of infection compared with other valves and they do not require blood thinners. The risk of blood clots is lower compared with other valve types.

Tissue valves are basically created from animal tissue and are flexible. These valves are long-lasting (10-20 years) and do not require long-term use of medication. These valves are also referred to as bioprosthetic valves. These valves are derived from animal tissue such as porcine (pig), bovine (cow) and equine (horse) models.[xl]

3D Valves[xli] are customized valves as they are specifically created for a single patient based on his/her unique anatomy. Under this technique, a unique model is created of the heart valve by collecting data of the patient's valve using software. An artificial valve is created with the help of a printer containing supportable biomaterials. The patient's data such as the size and shape of the diseased valve are collected by CT scan of the aorta and are transmitted to the software. This software then creates the digital model of the heart valve. The entire process of creating a digital model of this valve is quick and takes around ~1.5 hours. Such 3D valves reduce the chances of paravalvular leakage. These valves are economical compared with the other valves currently available in the market.

Doctors usually suggest two types of procedures to treat this disease, i.e. TAVR and SAVR. SAVR was developed around 50 years earlier whereas TAVR has only gained attention in recent years.

In a study of around 141,905 patients who underwent a SAVR procedure between 2002 and 2010, 80% were at low risk, 13.9% at intermediate risk and 6.2% patients at high risk.[xlii]

5.2.2 Procedures for valve replacement

SAVR[xliii]: This involves open-heart surgery where the patient is anaesthetized. The surgeon makes an incision in the chest to access the heart. The heart is then stopped, and the patient is put on a heart-lung machine to perform the required task with the heart stopped. The diseased valve is then removed by the surgeon and is replaced with an artificial valve. Once the replacement is made, the heart is restarted, and the incision is closed. The SAVR market is estimated at $US1.1 bn currently, with more than 250,000 procedures performed in Europe and North America in 2018.[xliv]

TAVR[xlv]: Introduced in 2002[xlvi], TAVR does not require open-heart surgery. In a TAVR procedure, the diseased valve is replaced with an artificial valve using a catheter (a thin tube that can be inserted into a blood vessel) and a special x-ray. This artificial valve pushes the leaflets of the diseased valve aside and controls blood flow. This entire procedure takes less than an hour to complete.

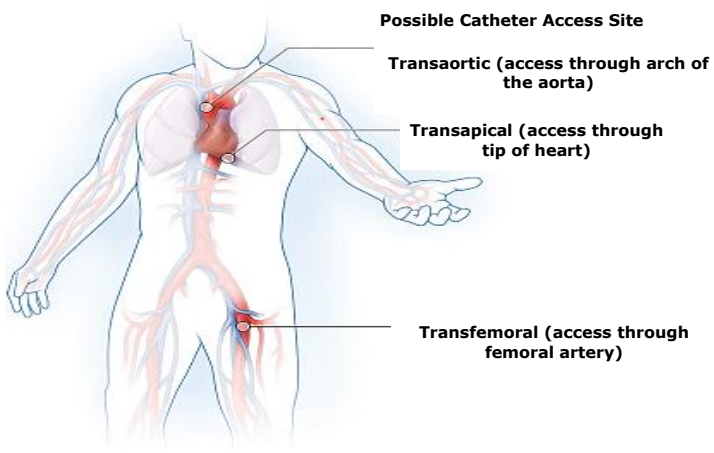
TAVR is a procedure which is widely accepted in the industry by many surgeons for treating aortic stenosis. In the period from 2007-17, TAVR was performed on more than 400,000 patients worldwide. It is expected to grow at a rate of 40% annually[xlvii]. TAVR serves as a better treatment option for people who would be at an intermediate to high risk in relation to the SAVR procedure.[xlviii]

5.2.3 Types of TAVR procedures[xlix]

The procedures are further divided into 1) transfemoral implantation, 2) transapical implantation and 3) transaortic implantation.

Transfemoral implantation: Valve insertion is done through a catheter with the patient anesthetized. A hollow tube called a sheath is inserted into the femoral artery from an incision in the patient's leg. The new valve is placed in the tube and is compressed along with the balloon to make it fit through the sheath. The balloon carrying the valve is pushed up to the native aortic valve. Once in position, the new valve is expanded securing it in place. The new valve pushes aside the leaflets of the existing valve. The existing valve then holds the new valve in place. Then, the balloon is deflated and removed. Before closing the incision on the leg, the surgeon ensures that the new valve is working properly.

Exhibit 14: Types of TAVR



Transapical implantation: A new valve is inserted via catheter into the anesthetized patient. A tiny incision is made between the ribs and the chest, to access the lowest part of the heart where a sheath is inserted. The rest of the procedure is the same as Transfemoral Implantation.

Transaortic approach: Just like the other two procedures, the patient is anesthetized. An incision is made in the upper chest where a sheath is inserted, with the rest of the procedure being the same as the other two.

5.2.4 Market potential

In 2019, the market size of TAVR procedures was estimated at around $US4 bn and is anticipated to reach $US7 bn by 2024, growing at a CAGR of 11.8%. The demand for TAVR procedures is expected to grow significantly due to its minimally invasive and less-risky nature.[l]

TAVR's positive clinical evidence has grown its use in the US. The number of US sites performing TAVR procedures increased from 156 in 2012 to 587 in August 2018. Furthermore, commercial US TAVR rose from <5,000 in 2012 to ~50,000 in 2017.[li] TAVR has also progressed from being a high-risk procedure to a standard-of-care procedure. The length of stay, which used to be six days post-surgery in 2013, has reduced to two days in 2017.

In 2019, the results of the Partner 3 trials (sponsored by Edwards Lifesciences) proved that TAVR was at least non-inferior to SAVR. These Partner 3 trials were conducted across 71 centers (in the US, Canada, Australia, New Zealand, Japan) on 1,000 patients through Sapien 3 transcatheter valves or SAVR. The results were better in the case of TAVR as all cases of death were observed at 8.5% compared with 15.1% for SAVR. Moreover, patients who were treated with TAVR faced low rates of stroke, death and/or life-threatening and major bleeding compared with patients treated with SAVR.

A study conducted by Medtronic showed that 5.3% of patients who were treated through TAVR either died or had a disabling stroke compared with 6.7% of the patients who had undergone surgery. The mortality rate due to various causes was the same in TAVR and SAVR, whereas disabling strokes affected 1.1% of TAVR patients and 3.5% of SAVR patients.

Both studies depicted that low-risk patients who were treated with TAVR had a low rate of death, stroke, or rehospitalization at the end of one year.

In August 2019, the FDA approved TAVR use to treat low-risk patients. The low-risk patient category includes patients in the younger age-bracket of the population and those who are less prone to medical complications. The FDA approval

of the use of the TAVR procedure in low-risk patients resulted from favorable and positive clinical trial results.[lii] The positive development bodes well for companies looking to expand or launch their devices for the TAVR market.

5.2.5 SAVR vs. TAVR

After SAVR surgery, the patient is kept in an intensive care unit (ICU) for two days and up to a week in hospital in order to reduce the chances of complications such as bleeding, blood clots, infection, irregular heartbeat and stroke. However, it takes around 4-8 weeks for the incision to heal and the total recovery time can extend to three months.

Introduced in 2020 as a substitute to open-heart surgery, the recovery time taken by TAVR patients is less when compared with patients treated through SAVR procedures. As per the Journal of the American College of Cardiology, the high-risk patients treated with TAVR and SAVR were observed to have recovered at the same rate five years after the aortic valve replacement.[liii]

Exhibit 15: TAVR VS SAVR in Low-Risk Patients[liv]

	Study 1	Study 2
Objective	To assess the safety and efficacy of TAVR with SAVR in low-risk patients. (N,1403), 24 month follow up	To evaluate TAVR compared with SAVR among low-risk patients. (N1000), 1 year follow up
Primary Endpoint	All-cause mortality or disabling stroke (24 months)	All-cause mortality, stroke, or rehospitalization (one year)
TAVR vs. SAVR	5.3% vs. 6.7% ($p < 0.05$ for noninferiority, $p > 0.05$ for superiority)	8.5% vs 15.1% ($p < 0.001$ for noninferiority, $p = 0.001$ for superiority)
TAVR vs. SAVR	• At 2 years, all-cause mortality was 4.5% vs. 4.5% ($p > 0.05$) • Disabling stroke was 1.1% vs. 3.5% ($p < 0.05$)	

5.2.6 Cardiovascular and Vascular Patches[lvlvilviilviii]

These are laboratory-grown patches used to replace a damaged part of a patient's organ before the entire organ gets affected. These patches are created from sheets of interconnected cells or by binding the cells in a scaffold of material that is used to create a replica of the native extracellular matrix. Some modifications can also be made to these cell patches for co-delivery of peptides, which could increase the chances of cell survival and improve the cell repair mechanisms. Cardiac patches are basically used for the treatment of heart attacks or to avoid heart failure. Cardiac patches can help in restoring regular cardiac tissue properties and minimizing the need for a heart transplant.

The patches are made up of materials such as autologous pericardium, and allogenic or xenogeneic pericardium.

Autologous pericardium is used when the tissue is taken from the patient's body. It is then used to patch up or repair the heart valve. This patch has excellent handling characteristics. It also bears qualities such as non-porosity (it has no pores), so blood doesn't leak out. Compared with other synthetic products, it is less prone to infections.

An allogenic pericardial patch comes into play when a tissue is taken from another donor. It is used when an autologous tissue/patch is not available. However, the functionality of both tissues is the same.

A xenogeneic patch is used when the tissue is taken from another mammal to repair a human heart. The xenogeneic patch has the advantage of blood and tissue compatibility.

Engineered cardiovascular tissue is an upcoming alternative to synthetic patches. It is an expensive option but appears very promising as it increases the chances of the body accepting a foreign patch.

The size of the global cardiovascular patch market was estimated at around $US3.28 bn in 2018[lix] and is expected to show 8.2% CAGR, reaching ~$US8.56 bn in 2019. Medical problems such as atrial septal defects, ventricular septal defects, double outlet ventricles, hypoplastic left heart syndrome, and ischemic heart disease are the major forces driving the market. The US market is expected to be one of the fastest-growing markets between 2012 and 2022, mainly driven by the developed healthcare infrastructure. Every year almost 790,000 US citizens suffer from heart attacks, making cardiac patches a large potential market.

The size of the vascular patches market was $US4.1 bn in 2017 and is expected to reach $US6.1 bn by 2023, a CAGR of ~6.9% for the period 2018-23. These patches are used globally to treat blood vessels (arteries and veins).

5.3 TAVR Demand Drivers

Rise in number of cardiovascular patients: There has been a significant rise in the number of cardiovascular patients and CVDs have been the major cause of death. In 2016, the number of deaths due to CVD stood at 635,260.[lx]

Rise in geriatric population: The population of people aged 60 has increased (almost tripling) rapidly since 1950 to reach 600 mn in 2000 and surpassing 700 mn in 2006.[lxi] The rising old-age population is one of the key factors which may lead to a rise in demand for TAVR as ~5% of the global population is at risk of developing valvular heart disease.[lxii]

Less invasive: Compared with open-heart surgery, TAVR is a less invasive procedure as valve replacement is performed using a catheter. This catheter is used to implant the valve inside the heart. The degree of incision made is also comparatively smaller in the TAVR procedure than in open-heart surgery.

Increase in healthcare expense globally: There has been a significant rise in healthcare expenses globally with 10% of the global gross domestic product is spent on healthcare.[lxiii] This rise consists of government expenditure, health insurance, employer-provided health programs and activities by non-governmental organizations.

Reimbursement of TAVR procedures: In June 2019, Centers for Medicare and Medicaid Sciences (CMS) finalized the decision to cover TAVR under its national coverage policy (in the US). CMS insisted that hospitals and physicians maintain a TAVR program. The coverage of the TAVR procedure by CMS is expected to increase demand for the procedure.

Approval for treating low-risk patients: In 2019, the US FDA approved the TAVR approach for treating aortic valve stenosis in low-risk patients. This is expected to increase the number of patients opting for TAVR treatment. The TAVR approach is less invasive in nature and involves a smaller incision compared with open-heart surgery. The recovery time taken is much shorter than in case of open-heart surgery.[lxiv]

5.4 Market challenges

Requirement of funds: In order to commercialize the product, the company must incur high direct and indirect expenses combining research costs, selling and general expenses and costs related to FDA clinical approval. Millions of dollars are required to run the clinical trials and obtain FDA approval.[lxv] In order to meet such expenses, the company must secure decent funding from a partner or sponsor, which itself can be a huge challenge.

High cost of treatment: TAVR procedure costs are high due to the costs associated with implant procedures. The cost of the TAVR kit (valve, balloon, sheath) is around $US32,500 whereas the surgical valve cost is only $US5,000.[lxvi]

Associated high risk: There are several risks associated with the TAVR procedure, such as heart attack, inconsistent heart rate, blood clotting, anemia, breathing complications, valve movement, leaking of blood around the valve, unstable blood pressure, pain near the incision site and other medical risks.[lxvii]

Regulations: The company must comply with the regulations across various countries wherever it intends to provide this technology/product. In the US, the company must comply with "class III" device requirements laid down by the US FDA authority, whereas in Europe it has to comply with "Council Directive 90/385/EEC" on Active Implantable Medical Devices.

5.5 Regulations[lxviii]

5.5.1 FDA

The US FDA ensures the protection of public health by forming certain guidelines to be followed by drug and device manufacturers. The FDA has classified medical devices into class I, II and III. Class I devices require least regulatory control whereas class III require the most.[lxix] In addition, class III devices require clinical evidence for approval.

Class I devices require approval by registration, after complying with general guidelines such as good manufacturing practices. Class II require additional special controls such as specific labelling, fulfilling requirements related to guidance documents, device tracking and design controls.The pathway followed for regulatory approval is the Premarket Notification program through which most medical devices are marketed. Similarly, class III devices, which are high-risk devices, follow a regulatory pathway for premarket approval. To ensure that the device is safe and effective, detailed bench testing, pre-clinical animal studies and clinical data are assessed.

Aortic valves are classified under class III. These devices are approved using the Premarket Approval (PMA) pathway. PMA is a typical application required by the FDA. PMA should contain proper scientific analysis and evidence showing devices are totally safe and effective in use. To ensure this, the FDA insists the device manufacturers record data on enrolled patients for ten years to track product safety and effectiveness.

Earlier, TAVR was mainly used for high-risk patients only but, in 2019, the FDA approved the applicability of TAVR for low-risk patients. The FDA is the first regulatory authority to approve the use of these devices for treating low-risk patients. However, this application should not be used in patients facing challenges with blood-thinning medications. Further, devices which have a titanium or nickel frame should not be used in patients sensitive to these metals.[lxx]

5.5.2 Regulations in Europe[lxxi]

Medical devices in the EU must undergo a conformity assessment demonstrating that they meet legal requirements ensuring they are safe and perform as intended. EU Member States can designate accredited notified bodies to conduct conformity assessments.

The conformity assessment usually involves an audit of the manufacturer's quality system and, depending on the type of device, a review of technical documentation from the manufacturer on device safety and performance.

Manufacturers can place a Conformité Européenne (CE) mark on a medical device once it has passed a conformity assessment. The adoption of Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In-Vitro Diagnostic Regulation (IVDR) changed the European legal framework for medical devices, introducing new responsibilities for EMA and for national competent authorities. Both regulations entered into force in May 2017 with a staggered transitional period. The MDR came into full force on 26 May 2020.

The IVDR has a transition period of five years and will fully apply from May 26, 2022.

During the transition period, manufacturers can place devices on the market under the currently applicable EU Directives (93/42/EEC, 98/79/EC and 90/385/EEC) or under the new Regulations if they fully comply with these.

Medicinal products including medical device ('combination products'): Medicines can be marketed for use in combination with a medical device, usually to enable the delivery of the medicine.

If the principle intended action of the combination product is achieved by the medicine, the entire product is regulated as a medicinal product under Directive 2001/83/EC or Regulation (EC) No 726/2004.

There are two types of combinations:

Integral: the medicinal product and device form a single integrated product, e.g., pre-filled syringes and pens, patches for transdermal drug delivery and pre-filled inhalers.

Co-packaged: the medicinal product and the device are separate items contained in the same pack, e.g. reusable pens for insulin cartridges, or tablet delivery systems with a controller for pain management.

Medical devices with an ancillary medicinal substance: A medical device may contain an ancillary medicinal substance supporting its proper functioning. These products fall under the medical devices legislation and must be CE marked.

Companion diagnostics ('in-vitro diagnostics'): A companion diagnostic is an in-vitro diagnostic test supporting the safe and effective use of a specific medicinal product by identifying whether patients are suitable or not for treatment.

Medical devices made of substances that are systemically absorbed: Some medical devices are made of substances that are absorbed by the human body to achieve their intended purpose.

Borderline products: Borderline products are complex healthcare products where uncertainty exists over which regulatory framework applies. Common borderlines are between medicinal products, medical devices, cosmetics, biocidal products, herbal medicines and food supplements. These invasive devices are normally introduced into the human body via an orifice or applied to the skin.

5.5.3 FDA vs Europe Regulations

FDA norms are more detailed and have comprehensive technical standards and requirements for the evaluation of devices compared with norms in Europe. The FDA is more stringent in terms of data requirements pertaining to clinical safety and insists on pre-clinical evaluation as this plays a vital role in determining long-term durability should any serious issues arise in the bench and animal studies. This stringency in the evaluation process could lead to a delay in the timing of the launch of some devices in Europe and the US.

5.6 Competitors

1. Edwards Lifesciences[lxxiilxxiii]
Founded in 1958 and based out of Irvine, California, Edwards Lifesciences develops and manufactures devices for structural heart diseases, providing innovative solutions to improve the lives of patients. The company provides devices under the categories annuloplasty rings, catheters, transcatheter heart valves, hemodynamic monitoring, pressure monitoring, and accessories and instruments.

Edwards Lifesciences developed the Sapient valve tri-leaflet, available in various sizes. These valves are made of bovine pericardium placed on a balloon-expandable stainless-steel stent. In a test, the valve durability was shown to be more than ten years. These valves are delivered through transfemoral approach and transapical approach.

SAPIEN XT valve: This is a new and modified version of the Sapien valve. The valve consists of a cobalt chromium, balloon-expandable stent with an integrated tri-leaflet bovine tissue valve and an inner fabric skirt on the ventricular side. The valve is available in three sizes: 23 mm, 26 mm and 29 mm.

SAPIEN 3 valve: This is the newest addition to the Sapien valve family, created to treat aortic problems and reduce the diameter of the delivery system. Sapien 3 is the modified version of the previous Sapien valve with a smaller crimped profile and a longer stent frame than the previous generation valves. This longer length helps in better positioning of the valve and prevents the leaflets from sinking. It is available in four sizes: 20 mm, 23 mm, 26 mm and 29 mm.

CENTERA valve: This self-expanding valve developed by Edwards Lifesciences is available in 23 mm and 26 mm sizes. The valve's self-expansion feature of the valve helps in repositioning and retrieval. The Centera valve is a bit shorter compared with other self-expanding valves, allowing it to align itself with the center.

2. Medtronic
Founded in 1949 and headquartered in Dublin, Ireland, Medtronic manufactures and distributes medical therapies to hospitals, physicians, clinicians and patients globally. It operates in four segments: minimally invasive therapies group, restorative therapies group, cardiac and vascular group and diabetes group.

Medtronic provides TAVR heart-valve devices which work like a natural heart valve. The company provides TAVR systems such as Core Valve, Evolut™ R, and Evolut™ PRO, which are available in different sizes.

CoreValve is manufactured by stitching up three leaflets and a skirt. Its nitinol valve frame is self-expandable. CoreValve is available in four different sizes: 23 mm, 26 mm, 29 mm and 34 mm.

The Medtronic CoreValve Evolut R system and Medtronic Core Valve PRO system consist of a transcatheter aortic valve (TAV), delivery catheter and a loading system. Both the Evolut R system and Evolut PRO system include a supra-annular, self-expanding nitinol frame, with a porcine pericardial tissue. Initially, these systems were used for the treatment of aortic stenosis in high-risk patients but now it has been approved for low-risk patients as well.

3. St. Jude Medical[lxxiv]
Incorporated in 1976 in Minnesota, US, St. Jude Medical is a manufacturer and distributor of medical devices for cardiovascular, diabetes and neuromodulation. The company provides products for vascular care, structural heart, heart failure, cardiac rhythm management, and neuromodulation.

The company offers several products for treating structural heart disease, such as the Epic™ Mitral valve, and Trifecta valve.

Epic Mitral valve: The valve is engineered with Linx™ anti-calcification (AC) and delivers durable performance. It reduces the risk of blood leakage and allows easy implantation.

Trifecta valve: It is designed for supra annular placement in the aortic position. It was designed to deliver excellent performance in areas such as hemodynamics, durability, and implantability.

4. Boston Scientific[lxxv]
Founded in 1979 and headquartered in Massachusetts, US, Boston Scientific designs, manufactures and distributes medical devices which are used in interventional medical specialties comprising interventional radiology, interventional cardiology, neuromodulation, neurovascular intervention, electrophysiology, peripheral interventions, cardiac surgery, vascular care, endoscopy, urology, oncology, and gynecology.

Under the transcatheter heart-valve specialization, the company offers two products – the Acurate Neo Aortic Valve and the LOTUS Edge Aortic Valve System.

Acurate Neo is a self-expandable valve with supra annular valve leaflet position and nitinol frame. The valve frame is made up of nitinol. The valve is available in three sizes: 23 mm, 25 mm and 27 mm. It is delivered by a transfemoral approach.

Lotus valve is made of natural tissue extracted from the bovine heart and attached to a nickel-titanium frame. This valve is available in 23 mm, 25 mm and 27 mm sizes and is compressed and loaded in a catheter.

5. Meril Life Sciences
Founded in 2006 and headquartered in Gujarat, India, Meril Life Sciences is a medical device company operating in more than 100 countries. The company offers products under verticals such as cardiovascular, diagnostic, orthopedic, and endo-surgery.

Meril provides a balloon-expandable TAVR system with a bovine pericardium tri-leaflet valve on a nickel cobalt alloy frame with a hybrid honey-comb design. The valve is available in 20 mm, 23 mm, 26 mm, 29 mm, 21.5 mm, 24.5 mm, 27.5 mm, 30.5 mm and 32 mm sizes.

Exhibit 16: Competitors Landscape

Company	Revenue (in $US mn)	Market Capitalization (in $US mn)	Valves Product	Patches Product
Edwards Lifesciences	4,348 (FY 2019)	43,482	Sapien 3, Sapien XT, INSPIRIS RESILIA aortic valve, INTUITY Elite valve system, Carpentier, and CENTERA Valve	Duravess, Edwards bovien precardical patch
Medtronic	28,913 (FY 2020)	128,569	Core Valve, Evolut™ R, and Evolut™ PRO, Avalus Bioprosthesis, Hancock, Mosaic and Freestyle	Parietex and Veriset
St. Jude Medical	-	-	Epic™ Mitral valve, and Trifecta valve	-
Boston Scientific	10,735 (FY 2019)	52,890	Acurate neo Aortic Valve and LOTUS Edge Aortic Valve System	-
Meril Life Sciences	-	-	Myval and Miltonia	MeRes100
CryoLife	276.2 (FY 2019)	874	On-X and CryoValve	PhotoFix and CryoPatch
Baxter	11,362 (FY 2019)	42,955	-	VASCU-GUARD peripheral vascular Patch and VASCU-GUARD Bovine Pericardium Patch

Note: Market Capitalization, as of June 16, 2020. St Jude was acquired by Abbot in 2017 and Meril is a private company.

6. Valuation

The fair market value for all the company shares stood at between $A135.1 mn and $A210.6 mn on June 16, 2020. The fair market value for the company's publicly traded shares stood between $A22.86 and $A35.65 per share, as of June 16, 2020, using an adjusted discounted cash flow valuation.

6.1 Discounted Cash Flow Method

Valuation	
WACC	
Risk-free rate	0.92%[lxxvi]
Beta	1.0[lxxvii]
Equity Market return	7.58%[lxxviii]
Additional Premium	6.3%[lxxix]
Cost of Equity	13.9%
Cost of Debt (after tax)	0.0%
WACC (Discount Rate)	13.9%

Year Ending- Dec	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E
FCFF (Low)								
Net cash from operating activities	**(20,546)**	**(5,915)**	**(8,296)**	**(264)**	**(358)**	**13,387**	**30,077**	**35,447**
Capital expenditure	(212)	(284)	(304)	(644)	(1,056)	(1,379)	(1,235)	(1,209)
Free cash flow to firm	**(20,758)**	**(6,199)**	**(8,600)**	**(908)**	**(1,414)**	**12,008**	**28,841**	**34,239**
Discount factor	0.93	0.82	0.72	0.63	0.55	0.49	0.43	0.38
Present value of FCF	(19,349)	(5,074)	(6,181)	(573)	(784)	5,844	12,325	12,848
FCFF (High)								
Net cash from operating activities	**(19,602)**	**(4,404)**	**(8,607)**	**8,883**	**10,335**	**25,634**	**46,652**	**53,991**
Capital expenditure	(241)	(331)	(364)	(1,005)	(1,378)	(1,777)	(1,599)	(1,592)
Free cash flow to firm	**(19,843)**	**(4,735)**	**(8,971)**	**7,878**	**8,957**	**23,857**	**45,053**	**52,399**
Discount factor	0.93	0.82	0.72	0.63	0.55	0.49	0.43	0.38
Present value of FCF	(18,496)	(3,876)	(6,448)	4,972	4,964	11,610	19,253	19,663

*In model we have considered projections till 2029

Arrowhead Fair Value Bracket	High	Low
Terminal Value (TV)	574,684	426,318
Present Value of TV	166,289	123,359
Present Value of FCF	73,075	32,063
Net Debt	5,344	5,344
Illiquidity/Small Cap Discount	10%	10%
Equity Value Bracket	210,619	135,070
Shares O/s (000's)	5,908	5,908
Fair Share Value Bracket ($A)	**35.65**	**22.86**
Current Market Price ($A)	5.27	5.27
Upside/(Downside)	576.4%	338.8%
Current Market Cap. ($A 000)	31,137	31,137
Target Market Cap. Bracket ($A '000)	210,619	135,070

Approach for DCF Valuation

Time Horizon: The Arrowhead fair valuation for Anteris Technologies Ltd is based on a DCF method. The time-period chosen for the valuation is 114 months (2020E-2029E).

Terminal Value: Terminal value is estimated using multiple based on EV/Sales of peers.

Prudential nature of valuation: It should be noted that this Arrowhead Fair Value Bracket estimate is a relatively prudential estimate, as it discounts the eventuality of any new products being launched in the market or any significant change in the strategy.

Important information on Arrowhead methodology

The principles of the valuation methodology employed by Arrowhead BID are variable to a certain extent depending on the subsectors in which the research is conducted, but all Arrowhead valuation research possesses an underlying set of common principles and a generally common quantitative process.

With Arrowhead Commercial and Technical Due Diligence, Arrowhead extensively researches the fundamentals, assets and liabilities of a Company, and builds solid estimates for revenue and expenditure over a coherently determined forecast period.

Elements of past performance, such as price/earnings ratios, indicated as applicable, are present mainly for reference purposes. Still, elements of real-world past performance enter the valuation through their impact on the commercial and technical due diligence.

Elements of comparison, such as multiple analysis may be to some limited extent integrated in the valuation on a project-by-project or asset-by-asset basis. In the case of this Anteris Technologies Limited report, there are no multiple analyses integrated in the valuation.

Arrowhead BID Fair Market Value Bracket

The Arrowhead fair market value is given as a bracket. This is based on quantitative key variable analysis, such as key price analysis for revenue and cost drivers or analysis and discounts on revenue estimates for projects, especially relevant to those projects estimated to provide revenue near the end of the chosen forecast period. Low and high estimates for key variables are produced as a tool for valuation. The high-bracket DCF valuation is derived from the high-bracket key variables, while the low-bracket DCF valuation is based on the low-bracket key variables.

In principle, an investor who is comfortable with the high-brackets of our key variable analysis will align with the high-bracket in the Arrowhead fair value bracket, and likewise in terms of low estimates. The investor will also take into account the Company intangibles – as presented in the first few pages of this document in the analysis on strengths and weaknesses and other essential Company information. These intangibles serve as supplementary decision factors for adding or subtracting a premium in the investor's own analysis.

The bracket should be understood as a tool provided by Arrowhead BID for the reader of this report and the reader should not solely rely on this information to make his decision on any particular security. The reader must also understand that on one hand, global capital markets contain inefficiencies, especially in terms of information, and, that on the other hand, corporations and their commercial and technical positions evolve rapidly. This present edition of the Arrowhead valuation is for a short to medium-term alignment analysis (one to twelve months). The reader should refer to important disclosures on page 37 of this report.

7. Appendix

7.1 Anteris Technologies Financial Summary

Exhibit 17: Financial Summary

Low Bracket Estimates

Year Ending Dec	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Revenue ($A '000)	5,307	5,678	6,076	16,101	35,192	45,954	61,771	67,145	90,640
Operating Profit ($A '000)	(19,252)	(6,679)	(9,714)	(2,078)	(1,103)	12,499	29,063	34,365	57,145
Net Income ($A '000)	(19,830)	(8,090)	(12,234)	(5,498)	(5,303)	7,699	24,564	30,585	54,985
EPS ($A)	(3.36)	(1.37)	(2.07)	(0.93)	(0.90)	1.30	4.16	5.18	9.31
EBITDA ($A '000)	(18,297)	(5,871)	(9,007)	(1,402)	(358)	13,387	30,077	35,447	58,328
Growth rates (%)									
Revenue	(69%)	7%	7%	165%	119%	31%	34%	9%	35%
Operating Profit	NM	NM	NM	NM	NM	NM	133%	18%	66%
Net Income	NM	NM	NM	NM	NM	NM	219%	25%	80%
EPS	NM	NM	NM	NM	NM	NM	219%	25%	80%
EBITDA	NM	NM	NM	NM	NM	NM	125%	18%	65%
Margins (%)									
Gross Margins	20%	20%	20%	100%	100%	100%	100%	100%	100%
Operating Profit Margin	(363%)	(118%)	(160%)	(13%)	(3%)	27%	47%	51%	63%
Net Profit Margin	(374%)	(142%)	(201%)	(34%)	(15%)	17%	40%	46%	61%
EBITDA Margins	(345%)	(103%)	(148%)	(9%)	(1%)	29%	49%	53%	64%
Ratios									
ROA	(187.2%)	(88.0%)	(146.4%	(126.2%	(55.9%)	44.9%	67.0%	50.8%	57.8%
ROE	461.7%	65.3%	49.7%	18.3%	15.0%	(30.9%	(7203.6	101%	64.5%

Exhibit 18: Financial Summary

High Bracket Estimates

Year Ending Dec	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Revenue ($A '000)	6,021	6,623	7,286	25,117	45,934	59,233	79,966	88,468	120,377
Operating Profit ($A '000)	(18,229)	(5,154)	(9,996)	6,836	9,450	24,550	45,395	54,537	85,700
Net Income ($A '000)	(18,806)	(6,565)	(12,516)	3,416	5,250	19,750	40,895	48,851	60,567
EPS ($A)	(3.18)	(1.11)	(2.12)	0.58	0.89	3.34	6.92	8.27	10.25
EBITDA ($A '000)	(17,270)	(4,334)	(9,266)	7,583	10,335	25,634	46,652	55,897	87,207
Growth rates (%)									
Revenue	(65%)	10%	10%	245%	83%	29%	35%	11%	36%
Operating Profit	NM	NM	NM	NM	38%	160%	85%	20%	57%
Net Income	NM	NM	NM	NM	54%	276%	107%	19%	24%
EPS	NM	NM	NM	NM	54%	276%	107%	19%	24%
EBITDA	NM	NM	NM	NM	36%	148%	82%	20%	56%
Margins (%)									
Gross Margins	20%	20%	21%	100%	100%	100%	100%	100%	100%
Operating Profit Margin	(303%)	(78%)	(137%)	27%	21%	41%	57%	62%	71%
Net Profit Margin	(312%)	(99%)	(172%)	14%	11%	33%	51%	55%	50%
EBITDA Margins	(287%)	(65%)	(127%)	30%	22%	43%	58%	63%	72%
Ratios									
ROA	(157.8%)	(53.9%)	(113.3%	21.7%	16.7%	38.6%	47.0%	37.9%	35.8%
ROE	574.9%	66.7%	56.0%	(18.0%)	(38.4%)	216.6%	81.8%	49%	38.0%

7.2 Anteris's Technologies Balance Sheet Forecast

Exhibit 19: Consolidated Balance Sheet

All figures in $A '000, unless stated differently *Low Bracket estimates*

Year Ending Dec	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Total current assets	6,279	5,401	5,332	1,368	6,190	13,339	32,642	56,076	90,597
Total non-current assets	4,313	3,789	3,021	2,990	3,301	3,792	4,014	4,140	4,589
TOTAL ASSETS	**10,593**	**9,191**	**8,354**	**4,358**	**9,491**	**17,131**	**36,656**	**60,216**	**95,185**
Total current liabilities	3,762	3,318	2,613	984	964	5,951	7,943	20,938	8,934
Total non-current liabilities	11,125	18,257	30,359	33,490	43,946	36,084	29,054	9,035	1,022
TOTAL LIABILITIES	**14,887**	**21,576**	**32,972**	**34,474**	**44,910**	**42,036**	**36,997**	**29,972**	**9,956**
Total shareholder's equity	(4,295)	(12,385)	(24,618)	(30,116)	(35,419)	(24,905)	(341)	30,244	85,229
TOTAL LIABILITIES & EQUITY	**10,593**	**9,191**	**8,354**	**4,358**	**9,491**	**17,131**	**36,656**	**60,216**	**95,185**

Exhibit 20: Consolidated Balance Sheet

All figures in $A '000, unless stated differently *High Bracket estimates*

Year Ending Dec	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
Total current assets	7,582	8,334	7,929	12,355	27,594	46,592	82,107	123,701	163,591
Total non-current assets	4,338	3,849	3,118	3,377	3,869	4,562	4,904	5,136	5,796
TOTAL ASSETS	**11,920**	**12,183**	**11,048**	**15,731**	**31,464**	**51,154**	**87,011**	**128,837**	**169,388**
Total current liabilities	4,031	3,677	2,919	984	964	5,951	7,943	20,938	8,934
Total non-current liabilities	11,160	18,342	30,480	33,683	44,186	36,084	29,054	9,035	1,022
TOTAL LIABILITIES	**15,191**	**22,019**	**33,399**	**34,667**	**45,150**	**42,035**	**36,997**	**29,972**	**9,956**
Total shareholder's equity	(3,271)	(9,836)	(22,352)	(18,936)	(13,686)	9,119	50,014	98,865	159,431
TOTAL LIABILITIES & EQUITY	**11,920**	**12,183**	**11,048**	**15,731**	**31,464**	**51,154**	**87,011**	**128,837**	**169,388**

8. Analyst Certifications

I, Natasha Agarwal, certify that all the views expressed in this research report accurately reflect my personal views about the subject security and the subject Company, based on the collection and analysis of public information and public company disclosures.

I, Sumit Wadhwa, certify that all the views expressed in this research report accurately reflect my personal views about the subject security and the subject Company, based on the collection and analysis of public information and public company disclosures.

Important disclosures

Arrowhead Business and Investment Decisions, LLC will receive further fees in 2019 and will receive further fees in 2020 from Anteris Technologies Limited for researching and drafting this report and for a series of other services to Anteris Technologies Limited including distribution of this report and networking services. Neither Arrowhead BID nor any of its principals or employees own any long or short positions in Anteris Technologies Limited. Arrowhead BID's principals intend to seek a mandate for investment banking services from Anteris Technologies Limited and intend to receive compensation for investment banking activities from Anteris Technologies Limited in 2020 or 2021.

Aside from certain reports published on a periodic basis, the large majority of reports are published by Arrowhead BID at irregular intervals as appropriate in the analyst's judgment.

Any opinions expressed in this report are statements of Arrowhead BID's judgment to this date and are subject to change without notice.

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Investors must make their own investment decisions based upon their specific investment objectives and financial situation utilizing their own financial advisors as they deem necessary.

Investors are advised to gather and consult multiple sources of information while preparing their investment decisions. Recipients of this report are strongly advised to read the Information on Arrowhead Methodology section of this report to understand if and how the Arrowhead Due Diligence and Arrowhead Fair Value Bracket integrate alongside the rest of their stream of information and within their decision-making process.

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9. Notes and References

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[ii]Source: Bloomberg: 52 weeks to June 16, 2020
[iii]Source: Bloomberg: 3 months to June 16, 2020
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