EVOLUTION CAPITAL

ASX: AVR

Anteris Technologies Limited

Announcement Update

30th November 2022

RECOMMENDATION: BUY

Share Price	$23.10
Price Target	$66.32

52-Week Range	$8.00 - $30.89
AVR Shares Outstanding	13.9m
Market Capitalisation	$319.70m
Cash (30 September 2022)	$22.8m
Enterprise Value	$296.9m
Substantial Shareholders	
Perceptive Advisors, LLC	13.2%
L1 Capital Pty Ltd	8.09%
Sio Capital Management, LLC	3.73%
Top 20 Holders	43.2%
Board & Management:	
John Seaberg	Chairman
Wayne Paterson	Managing Director/CEO
Stephen Denaro	Non-Executive Director
Dr Wenyi Gu	Non-Executive Director
David St Denis	Chief Operating officer
Mathew McDonnell	Chief Financial Officer

Source: Tradingview

ANTERIS

Overview: Anteris Technologies (ASX: AVR) focuses on the development and commercialisation of structural heart solutions for the multi-billion dollar aorticvalve replacement market.

AVR's FDA critical milestone

Anteris Technologies Ltd (AVR:ASX) has recently announced to the market that the U.S. Food and Drug Administration (FDA) has conditionally approved the DurAVR Transcatheter Heart Valve (THV) systems for investigational device exemption (IDE) application to commence an Early Feasibility Study (EFS). The study will evaluate the safety and feasibility of the DurAVR THV system in the treatment of subjects with symptomatic severe native aortic stenosis. Anteris has provided adequate data to support the initiation of a clinical study in the United States. The EFS will enrol 15 subjects at 7 different Heart Valve Centres of Excellence within the United States.
The study is anticipated to commence in early 2023.

The FDA has catergorised DurAVR in this study as a **CMS Category B device**, which permits the device to be sold during the study pending CMS approval. The FDA categorises a device for a particular trial within Category A or Category B based on the level of risk to patients. Designation as Category A means that the device is both; experimental and investigational, with the initial questions centred around the safety and efficacy. Category B means the device is investigational but not experimental for its intended use. This further means that the underlying questions around the safety and efficacy of the device type have been resolved and that the FDA has determined that the device type can be both safe and effective. An IDE is assigned to Category B if the trial involves a device that is only slightly modified from a device which has been proven safe and effective or an application of the device that is similar to an established FDA-approved use. We believe this is a critical milestone for the company, as it validates the research and development work done thus far and brings AVR one step closer to the hearts of the community with potential commercial sales in the future.

Investment Proposition

The transcatheter aortic valve replacement (TAVR) procedure: The procedure is less invasive than the traditional surgical procedure (open heart) and was designed primarily as a non-invasive solution for the treatment of patients with severe aortic stenosis who are deemed to be at high risk for surgical procedures. While the TAVR method was initially approved for the "high risk" category patients (usually those aged above 80 years), the FDA in 2019 approved the use of TAVR in younger patients. This has caused the average age of TAVR patients to decrease in a span of less than two years from 85 to 73, with a further fall expected over the coming years. This will effectively double the addressable market to US$ 8bn p.a. and highlights the need for more durable leaflet tissue technology to be used, such as the company's patented ADAPT® treated tissue.

DurAVR™ world's first 3D single piece aortic valve: Selected as "Best Innovation" at PCR London Valves, the world's leading interventional cardiovascular conference focused on transcatheter therapies for valvular heart disease. DurAVR™ is manufactured using 90% less sutures than the incumbent products from Edwards Lifesciences and Medtronic. The DurAVR™ valve has also shown to deliver increased orifice area for blood flow and a lower pressure gradient (less restriction) than the commonly used CoreValve and Sapien 3 TAVR device from its respective competitors.

Global market growing at a rapid pace: The global aortic valve replacement market has shown to grow at a CAGR of 16-20% over the past five years to US$4bn. This is forecast to grow at an annual rate of 14% over the next eight years. Most of the growth is expected to come from the growing TAVR market, particularly as the average age of eligible TAVR patients continues to decrease overtime.

Potential acquisition target: Anteris is attempting to enter a market dominated by two large medical device companies, Edwards (market cap $US47bn) and Medtronic (US$101bn). If the company continues to validate DurAV™ as a superior aortic replacement valve to existing solutions, it will create competitive tension potentially leading to an acquisition of the company. An example of this nature is Medtronic's acquisition of CoreValve who had developed a transfemoral TAVR solution for the treatment of severe AS called the Revalving System, which at the time was approved for sale in Europe (2007) and hadn't been approved in the US. This was a $900 million (USD) acquisition emphasising the strong strategic rationale of both Edwards and Medtronic's to continue their market dominance through bolt-on acquisitions.

Near-term catalyst: Anteris is expected to begin the EFS in early 2023, with significant expansion of the patient population in the US and Australia following the EFS. We maintain our **BUY** recommendation on Anteris, deriving a price target of $66.32 (undiluted), reflecting an implied return of 187% from current levels. This gives the company an overall valuation of $922m, which we believe is suitable given its consistency to clinically demonstrate the continued superiority of DurAVR™ in comparison to the approved TAVR and SAVR valves.

Anteris DurAVR™ Transcatheter Aortic Valve First-in-human study (FIH): impact of novel leaflet design

Anteris presented at the PCR London Valve 2022, which was held from the 27-29 November 2022. The conference was attended by over 3,000 attendees from over 100 countries. The FIH was presented on the preliminary echo, CT, and MRI evidence of improved haemodynamic and laminar flow characteristics associated with the DurAVR™ Transcatheter Heart Valve (THV) system. The prospective, non-randomised, single-arm, single-centre study to evaluate the safety and feasibility of DurAVR™ THV was conducted in a patient cohort of 13 subjects with severe symptomatic aortic stenosis including challenging anatomies such as Type 1 bicuspid and extreme leaflet calcium.

The study compared DurAVR™ to normal age-height-weight matched controls, other TAVI and SAVR patients. **The study demonstrated that the novel leaflet design of DurAVR™ restored ascending aortic flow haemodynamics, whereas the SAVR and other TAVI valves did not demonstrate the same physiological advantage**.

The post-procedural outcomes from the study demonstrated:

- Mean annulus diameter 22.3 $\pm$ 1.07mm
- Mean valve leaflet coaptation length of 8.3mm
- 100% procedural success
- No device related complications
- No moderate or severe paravalvular leak
- Excellent haemodynamic results at 30 days
- Consistent laminar aortic flow shown at 30 days echo and CT results
- Improved exercise capacity (first 5 subjects only)
- No changes in cardiac electrical conductivity at 6 months (first 5 subjects only)

We believe the FIH study provides encouraging evidence of the improved haemodynamics, and lamina flow characteristics associated with the single-piece, native-shaped leaflet design. Furthermore, the restoration of normal laminal aortic flow is emerging as a novel target mainly to reduce energy loss in the cardiovascular system. It should be noted that abnormal flow, including eccentric flow is associated with continued aortic dilation which will require further medical intervention.

With the value proposition largely stems from the fact that TAVI is being offered to a younger patient population and therefore restoration of normal laminar aortic flow is an important therapeutic goal, as it allows normal exercise functioning capacity and ability likened to that of a healthy individual. The DurAVR™ THV architecture appears to restore normal aortic flow and future studies are warranted to investigate the prognostic importance of restoration of normal aortic flow, with AVR's preliminary data emphasising the unique design characteristics of DurAVR™ which is potentially redefining how aortic heart valve performance is benchmarked.

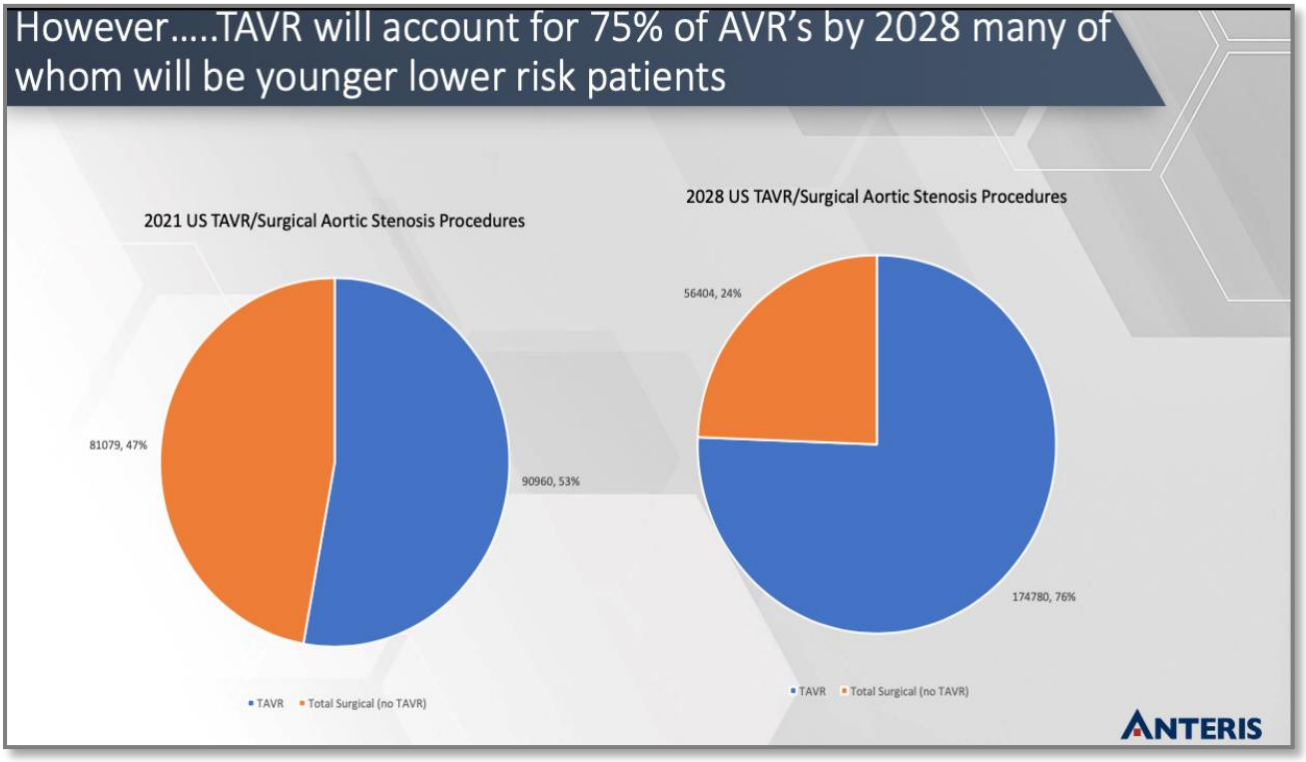
Market Overview

The global aortic valve replacement market has exhibited strong growth from 2015-2020. This number is set to expand further as demonstrated by a research study undertaken by Straits Research forecasting 14% annual growth through to 2030.

The growth drivers include increasing number of valvular diseases, as well as technological advances in the heart valve market. The world's population continues to age with a total number of older people expected to grow from 962 million in 2017 to 2.1 billion in 2050. The market growth will be further accelerated by the rise of minimally invasive surgeries like TAVR along with the development of valves that do not require stitches, which is expected to have a positive effect on the overall market.

In 2019, there were 72,991 TAVR procedures in the US, which for the first time exceeded the number of aortic valves implanted by open chest surgery, with the number totaling only 57,626. According to data released by Medicare and Medicaid, the number of people getting diagnosed over the age of 65 for AS is growing quickly, thus highlighting the need for and importance of new technologies and treatment options.

Along with this, good insurance and reimbursement policies are expected to be one of the most fundamental drivers of the AVR market in coming years. The Centers for Medicare and Medicaid Services (CMS), USA have stated that the Medicare National Coverage Determination policy would cover TAVR treatment procedures. In determining coverage for different procedures, different insurance providers have varying rates.



Source: Anteris

Competitive landscape

The global TAVR and SAVR markets is currently dominated by a few major medical device companies such as Edwards Lifesciences, Medtronic, Abbott Laboratories, and Boston Scientific. Edwards Lifesciences and Medtronic predominately command the greatest market share of aortic valve replacements. As of September 2022, Edwards Lifesciences and Medtronic each have market capitalisations of $52 billion and $108 billion respectively.

In the SAVR market, Edwards holds a 58.4% market share, while Medtronic and Abbott Laboratories each hold 19.7% and 16.3% market share respectively. Edwards Lifesciences has three separate SAVR products (Inspris Resilia, Edwards Intuity and the Magna Ease Valve).
On the other hand, Medtronic has seven types of SAVR products including both tissue (Avalus™ Bioprosthesis, Hancock™ II Bioprosthesis, Mosaic™ Bioprosthesis and Freestyle™ Aortic Root Bioprosthesis) and mechanical (Open Pivot ™ Aortic Valved Graft and Open Pivot™ Mechanical Heart Valves) while Abbott Industries has the Trifecta™ GT Valve.

The TAVR market is a duopoly dominated by Edwards, occupying a 63.3% market share and Medtronic taking 32.4% market share respectively. In this area, Edwards' has three products (Sapien 3 Ultra, Sapien 3, and Sapient XT), while Medtronic has two products (Evolut Pro and Evolut R). In August 2019, the FDA expanded indications for TAVR to include low-risk patients. The Sapien 3 and CoreValve Evolut R system both received approval for this indication on the same day. The approval was widely anticipated following the success of clinical trials with both products performing on par and/or better than traditional surgical methods. These two approvals greatly expand the number of patients that can be treated using a minimally invasive approach. It is also estimated that up to 50% of all TAVR patients could be catergorised as low risk by 2026. Many surgeons have also observed an increase in patients requesting TAVR over SAVR due to the minimally invasive nature of the procedure. However, the main limiting factor in this expansion is the lack of long-term durability clinical data as noted previously.

M&A Activity in the Cardiac Device Market

The cardiovascular medical device market is broad in nature and includes both invasive and non-invasive heart monitoring devices. Aortic valve replacements are considered to be in the highest risk category for medical devices, pertaining to the FDA category 3 device. As such, the most stringent clinical and regulatory measures are taken for a pathway towards commercialisation. The table below depicts a list of transactions which includes the acquisition of companies comparable to Anteris. The list outlines both aortic and mitral valve replacement devices, albeit at varying stages of commercialisation. As evident from the list below, there is a defined pattern involving transactions of privately held medical device companies who demonstrate positive results in preclinical and/or clinical trials and are notably acquired by one of the four major listed industry players in this space (Edwards, Medtronic, Abbott and Boston Scientific).

As highlighted below, transactions occurring from 2015 onwards, entails a relatively tight band for transactional values based on differential stages of target companies. To demonstrate this point further, the least advanced of the target companies, Tendyne was acquired for the lowest price of (US$225m) and was also acquired prior to commencing its enrolment for a European clinical trial. On the contrary, the other three target companies were in advanced stages of clinical trials and in the case of Symetic it had already received CE mark approval in Europe.

As such, we believe the previous transactions in the cardiac device space provides a good indication of a potential valuation and upside for Anteris, albeit noting, that the last material TAVR transaction had taken place in 2017 and hence, the addressable market for TAVR has increased materially due to the FDA approval in the younger and lower-risk patients.

Target	Exchange	Acquirer	Year	US$m	AU$m*	Summary
Symetis	Private	**Boston Scientific**	2017	435	570	Symetis had developed TAVR solutions to treat severe AS, also known as Accurate TA and Accurate neo/TF systems. The company had already received the CE mark at the time of acquisition
Tendyne	Private	**Abbott**	2015	225	298	At the time of acquisition, Tendyne was developing a TMR solution to treat patients with mitral valve regurgitation. The company planned to begin enrolments for a European study in 2016.
CardiAQ	Private	**Edwards Life Sciences**	2015	350	475	CardAQ Valve technologies Inc. was developing a TMVR solution to treat patients with mitral valve regurgitation. At the time of acquisition, the company had received an Investigational Device Exemption (IDE) from the FDA to conduct an early feasibility study for up to 20 patients. The company was also planning to initiate a CE mark study in Europe.
Twelve Inc.	Private	**Medtronic**	2015	458	639	Twelve Inc was developing a TMVR solution to treat patients with mitral valve regurgitation. At the time of acquisition, the company was undergoing a ten-patient cohort trial. It also hadn't received any regulatory approvals at the time of acquisition.
Ventor	Private	**Medtronic**	2009	325	509	Ventor Technologies was developing a transapically-implantable TAVR solution for the treatment of severe AS. The technology was called Ventor Embracer, which at the time was under clinical investigation in Europe and had not yet received clinical investigation approval in the US.
CoreValve	Private	**Medtronic**	2009	900	1,410	CoreValve had developed a transfemoral TAVR solution for the treatment of severe AS called the Revalving System, which at the time was approved in Europe (2007) and had the FDA approval pending for commencement of a pivotal trial in the US.

**Based on exchange rate at the time of acquisition.*

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