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Bioshares

1 June 2020
Edition 845

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies

Companies covered: **ACR, ADO, AVR (formerly AHZ), CYC**

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-35.8%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - May '13)	3.1%
Year 13 (May '13 - May '14)	26.6%
Year 14 (May '14 - May '15)	23.0%
Year 15 (May '15 - May '16)	33.0%
Year 16 (May '16 - May '17)	16.8%
Year 17 (May '17 - May '18)	-7.1%
Year 18 (May '18 - May '19)	-2.3%
Year 19 (May '19 - May '20)	39.5%
Year 20 (May '20 - Current)	10.1%
Cumulative Gain	1099%
Av. Annual gain (19 yrs)	17.3%

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Extract from Bioshares –

Name Change for Admedus – Now Anteris Technologies

Admedus has changed its name to Anteris Technologies (AVR: $6.29). The company is now wholly focused on the development of heart valves that rely on the company's proprietary ADAPT tissue treatment technology to make cardiovascular tissue implants. The implants are arguably far less susceptible to calcification than rival tissue treatment methods.

The ADAPT process removes residual DNA from tissue used in implants, with residual DNA suggested as the driver of calcification (tissue hardening).

ADAPT tissue has been shown to have no DNA and has data showing no calcification occurring over 10 years in humans.

The company is developing DurAVR SHV for surgical aortic valve replacement (SAVR) and DurAVR THV for transcatheter aortic valve replacement (TAVR). Transcatheter intervention involves the implantation of a device using a catheter, usually via the femoral artery. The method avoids various risks associated with more invasive surgery.

TAVR Superior to SAVR in Low-risk Patients To Drive Need for Valves With Less Chance of Calcification

Edwards Life Sciences' PARTNER 3 trial showed in a 1,000 low-risk patient trial of its SAPIEN 3 TAVR device, that the device was superior to surgically implanted devices on the primary endpoints of all-cause death, all-cause stroke and re-hospitalisation.

In low-risk patients, the rate of death at one year for all cause death was 1% for SAPIEN 3 TAVR patients compared to 2.5% for surgical intervention (p=0.09), for all-cause stroke 1.3% versus 3.1% (p=0.04), for re-hospitalisation, 7.3% versus 11.0% (p=0.046). Of note was the difference in life threatening major bleeding, 7.7% versus 25.9% (p<0.001).

The market for TAVR devices for low-risk patients would benefit from devices with the least likelihood of developing calcification.

This is an opportunity for Admedus, either directly with its own TAVR device, or through the outlicensing of ADAPT to market leaders such as Edwards Life Sciences and Medtronic, which markets the Evolut PRO. For example, younger, low risk patients could be implanted with a device that could be functional for l5 years, well in excess of the five years time point when current valves begin to fail.

Anteris Technologies' heart valve products have the potential to deliver functional superiority to rival products in terms of both durability, tensile strength and mechanical performance, with ADAPT tissue having passed 400,000 cycles of stress testing, equivalent to 10 years of human use.

Cont'd over

Leaflet Repair Trial

The company announced in mid-May that a second patient had been implanted with an ADAPT treated leaflet, in a 15 patient trial underway in Belgium [NCT04178213]. The trial is recruiting patients with moderate or severe aortic stenosis and/or aortic insufficiency.

Anteris has stated that it will provide a further update once enrolment is completed, with the global SARS-CoV-2 pandemic a factor influencing recruitment.

The open label (unblinded) nature of the study means that progressive updates could be provided to the market regarding the immediate post-operative well-being of trial subjects, which is what the company has done with the first two patients in the trial in Belgium.

However, in our opinion, a 'soft' milestone for the company could be the implant of the eighth patient, or approximately half-way through the trial. Investors could then be informed of the rate of recruitment for the trial, in addition to receiving data concerning the discharge and recovery profile of the implanted patients, including hemodynamic data. Measures of hemodynamics which enable valves to be compared with others, include effective orifice area (extent of valve openness), and mean gradient and peak gradient of blood pressure.

The company also recently announced the initiation of an anti-calcification comparison study in 48 rats, to compare ADAPT treated tissue with tissue used in marketed SAVR and TAVR devices for which the tissue is treated using other methods. Tissue will be harvested and evaluated after four months for calcium and phosphorus levels.

The results of this comparison study will enable the company to present data on a head-to-head basis of the relative performance of the ADAPT treatment process compared to the tissue used in commercially available SAVR and TAVR devices.

A further milestone for the company this year will be the release of results from pre-clinical studies of the single piece DurAVR THV.

Anteris Technologies is capitalised at $36 million. The company retained cash assets of $11 million at March 31, 2020.

Bioshares recommendation: **Speculative Buy Class C**

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Single Piece (3D) Design

A point of difference for the heart valve prostheses being developed by Anteris Technologies is that they are formed as a single piece. Marketed devices combine leaflets sourced from bovine or porcine pericardium which are integrated with synthetic materials.

For example, Edwards Life Science's SAPIEN 3 heart valve is described as a "balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt."

Anteris believes that its single piece device is capable of creating a wider valve opening, thus producing improved blood flow, in addition to needing fewer stitches for implanting.

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Some Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Cogstate, Bionomics, LBT Innovations, Opthea, ResApp Health, Pharmaxis, Dimerix, Adalta, Actinogen Medical, Patrys, Cyclopharm, Emvision, Antisense Therapeutics, Heramed, Imugene, Exopharm, Immutep, Neuroscientific Biopharmaceuticals, Invex Therapeutics, Anteris Technologies