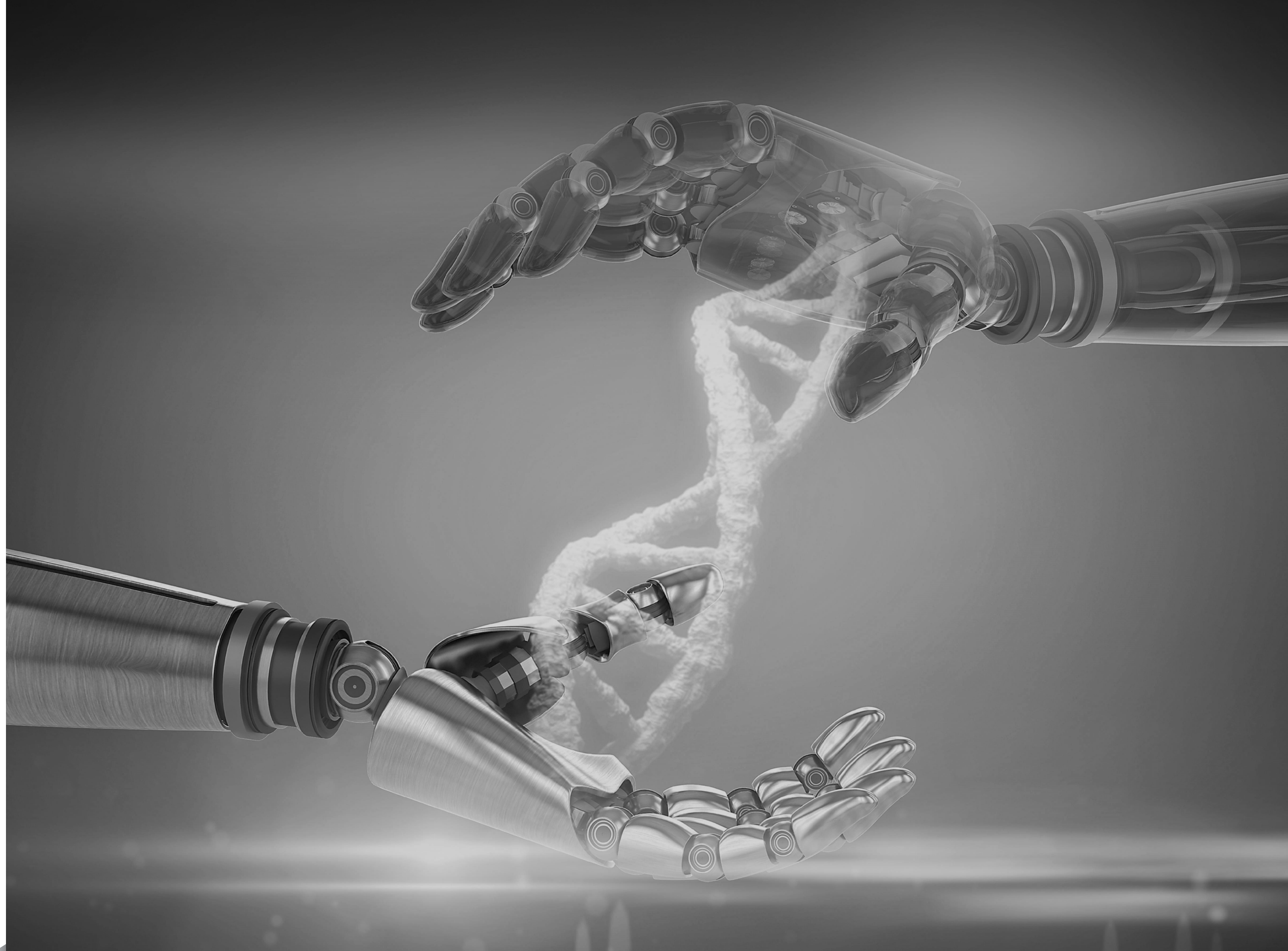
STOCKS DOWN UNDER

5 APRIL 2022

Emerging Stocks Down Under

"The world doesn't pay you for what you know, it pays you for what you do."

- Jack Canfield (b.1944), Entrepreneur and author



ARTRYA

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Stocks Down Under rating: ★★★★

ASX: AYA
Market cap: A$59.7M

52-week range: A$0.94 / A$1.75
Share price: A$1.05

Over the last few decades, there have been several Australian medtech companies to conquer the American market with Cochlear (ASX: COH) and ResMed (ASX: RMD) being the most prominent examples. Artrya, with its Salix suite of software products, is hoping to follow in these footsteps. Salix aims to improve the detection and treatment of Coronary Artery Disease (CAD) - which is a major cause of heart attacks. But can Artrya make it in the USA and how long will the path be? It's all up to American regulators.

Share price chart

Source: Tradingview

Preventing heart attacks

Artrya was founded in mid-2018, began operations in mid-2019 and listed on the ASX in November 2021 having raised $40m at $1.35 per share. Heading the company as non-executive chair is former Imdex boss Bernie Ridgeway along with former IBM executive John Konstantopoulos and management consultant John Barrington. The company's first product, the Salix Coronary Anatomy (SCA), uses AI to provide clinicians with rapid reporting of vulnerable plaque. Vulnerable plaque is one of the strongest predictors of heart attacks, but it's difficult and time-consuming to identify manually. And this is before you begin to consider the skill shortage in physicians on one hand and the rise in demand for cardiac CT scans in the years ahead on the other. North America alone is expected to see a jump from 11.1m in 2021 to 19.5m in 2025.

SCA generates a personalised 3D heart model depicting the extent of so-called Vulnerable plaque among other biomarkers. Vulnerable plaque comprises of varying degrees of fat and calcium attached to the wall of a coronary artery. Because the plaque is unstable, prone to rupture and can cause sudden blockages, it is one of the strongest predictors of future heart attacks. SCA requires no hardware installation and can be used 24/7 - all a doctor or radiologist needs is an internet connection. It delivers a full report within 15 minutes of scanning, allowing the data to be presented to patients quicker and in a format easier to comprehend than conventional scans.

SCA is delivered primarily through a subscription model and can be installed remotely although the company allows a 30-day "freemium" period for new clients plus the option of a single flat fee per image scanned. The company may eventually also license the software to Original Equipment Manufacturers (OEM). Its SaaS model would allow this to be readily implemented.

So, the ASX listing is done - now what?

The company is hoping to achieve two milestones in 2022. The first is to generate its first SCA revenues – it is already a Class 1 medical device in the Australian Register of Therapeutic Goods – and it has begun commercial pilots Down Under.

The second is to obtain FDA approval. It is also hoping for approval in Canada, Europe and the UK, but undoubtedly FDA approval is the big prize. This is for two reasons. Firstly, because the US is the world's largest healthcare market generally and for cardiovascular disease – over US$200bn is spent annually, representing 34% of the global market. Secondly, the FDA is the world's most stringent healthcare regulator – approval would give the company confidence it could "make it" in any country with any regulator. Last month, the company hired Ted Schwab and Jory Tremblay as Co-CEOs in the US and opened up its American headquarters in Los Angeles.

However, Artrya is not just sitting back and waiting. It already has TGA Class 1 approval, but is looking to have it approved for reimbursement as part of the Medicare bulk-billing process and for a further pilot site in addition to its existing site in Perth with Envision Medical Imaging. It is also looking for an American clinical partner to conduct a proof of concept study and research.

Artrya has a handful of other products under development, most notably the Salix Coronary Flow (SCF), which assesses coronary blood flow – another condition that can cause heart attacks. Although SCF is still in the validation and testing phase, Artrya has told shareholders it anticipates SCF will be ready for assessment by regulators in the second half of the year. The company closed the 2021 calendar year with $43.7m in cash.

Shareholders' hopes and hearts all hinge on FDA approval

The company has significant potential, but much of it will only be realised if the FDA gives it the green light. There is a risk approval will not be given, or it could be delayed – the FDA may ask the company to provide further information or to conduct further clinical trials.

There is also a risk that if it doesn't hit the ground running, shareholders will lose patience with the company – as has happened with 4D Medical (ASX: 4DX), a med tech, which listed already having FDA approval. But after going up from its IPO price nearly fourfold, the stock retreated as its rollout progressed slower than shareholders anticipated. A market selloff (as we saw in December and January) can make things worse than they otherwise would be. But if Artrya delivers, there is still upside from here. Considering it already has TGA approval, we are giving it the benefit of the doubt and giving it four stars.

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