STOCKS DOWN UNDER

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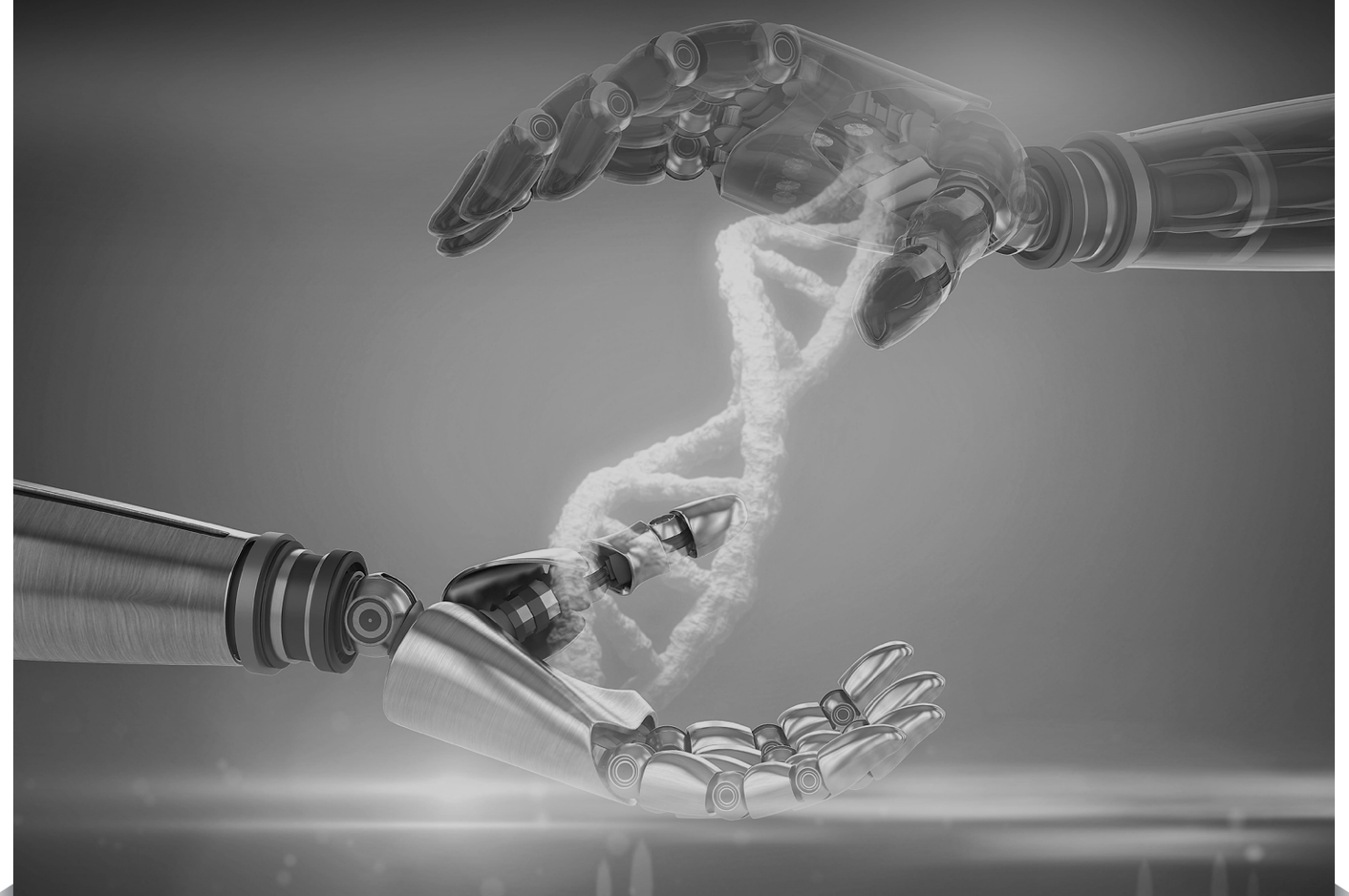
Emerging Stocks Down Under

> *Capital markets reward you for what you learn that other people have yet to ascertain.*
>
> **- Kenneth Griffin (b.1968), Owner & CIO of Citadel Investment Group**



EBR SYSTEMS

Will it win investors' hearts?

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Stocks Down Under rating: ★★

ASX: EBR
Market cap: A$151.6M

52-week range: A$0.58 / A$1.10
Share price: A$0.59

For the second week in a row, we're looking at a medtech company that is a recent entrant to the ASX and is trying to prevent fatal heart problems with new technologies. EBR Systems has a device called WiSE that operates as an implantable cardiac system. It has made no secret of wanting to be like Cochlear (ASX: COH) with CEO John McCutcheon telling journalists post-IPO he wanted to follow in its footsteps. Can it?

Share price chart

Source: Tradingview

Preventing heart failure

While last week's subject Artrya (ASX: AYA) was founded in mid-2018, EBR has a longer history having begun in 2003 in Silicon Valley. EBR's WiSE system (Wireless Stimulation Endocardially) uses wireless technology to deliver pacing stimulation directly to the inside of the left ventricle of the heart thereby preventing heart failure. WiSE does this when the heart slows, becomes irregular or when the two ventricles become unsynchronised.

WiSE competes with so-called CRT (cardiac resynchronisation therapy) devices. CRT devices typically last no more than 10 years before the battery needs to be replaced and have a ~4% failure rate, which can be fatal. There are existing products that work like WiSE for the right-side ventricle, but the left side is harder to access. This is because the left side circulates arterial blood straight to the brain as opposed to the right side which circulates through the lungs.

WiSE is the size of a cooked grain of rice – 5% the size of a conventional pacemaker – because it has no battery in the heart. It is currently halfway through a Phase III clinical trial and targeting US regulatory approval and commercialisation in the second half of 2023. Although it is approved for use in Europe and for research procedures in the US and Australia, and has breakthrough device designation in the US, it is waiting for FDA approval to commercialise.

EBR estimates WiSE has an initial addressable market opportunity of approximately US$2.1bn, a figure purely based on global CRT sales. But the company thinks this could grow by expanding potential applications. The company has told Stocks Down Under the market has expanded by US$400m following the recent announcement that leadless pacemakers will be included in the current pivotal study.

So, the ASX listing is done - now what?

EBR listed last November at $1.08 per share in a deal valuing the company at ~$344m. This made it one of the largest Life Sciences IPOs in recent memory. Major backers, who got in before the company's listing, include super fund AustralianSuper, Hesta, Hostplus and venture capitalist Mark Carnegie. The largest, with a stake of over 7%, is Minnesota-based venture capital firm Split Rock Partners.

The company's share price has declined since its IPO. Obviously, it didn't time it's IPO well, coming onto the market just as the Omicron downturn set in, which hit pre-revenue companies particularly hard. EBR has had limited newsflow since listing and it has not generated much excitement. Arguably the biggest news was the FDA agreeing for it to include leadless pacemakers as a co-implant in the current trial. This is the pivotal study prior to FDA approval and it has been a long time coming - the FDA granted WiSE an Investigational New Device (IND) in 2016. The current trial had to be redesigned because of the pandemic, although the company is halfway through the trial, having completed the first of two phases.

We also think this company has suffered from being a US company. The ASX has made efforts to attract US-domiciled companies too small to list on the NASDAQ. Many of them have not performed well although there have been some exemptions. It is worth noting that shareholders don't directly own company shares, but instruments called CDIs that give "beneficial ownership" as if you had the shares but not legal title. As well as this, by listing on the ASX, companies typically have to exclude most US investors from investing in them given US securities regulations.

You won't be diluted (for a while), but you'll have to wait

On the positive side, EBR anticipates its current cash position of US$78.2m / A$107.8m to last it through the current Phase III study, the FDA submission process and early commercialisation. This means shareholders will not be diluted for now.

As we mentioned, EBR hopes to have the trial complete and FDA approval next year. Meanwhile, fellow heart disease fighter Artrya (ASX: AYA) - which we covered in last week's edition - is targeting FDA approval this year. And while companies will do their best to obtain FDA approval, the regulator could send them back to the drawing board by requesting further information – as happened to Cyclopharm (ASX: CYC) last year. Furthermore, shareholders can be impatient if a company doesn't hit the ground running quickly.

All things considered, it's two stars from us. Yes, EBR's CE Mark approval and solid cash position does de-risk it, plus positive clinical trial results will no doubt boost the company. However, we would prefer to wait until the company has FDA approval or is at least closer to the time of expected approval and that is what we think investors should do here.

Pitt Street Research Pty Ltd

3 Spring Street, Sydney, NSW 2000, Australia

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