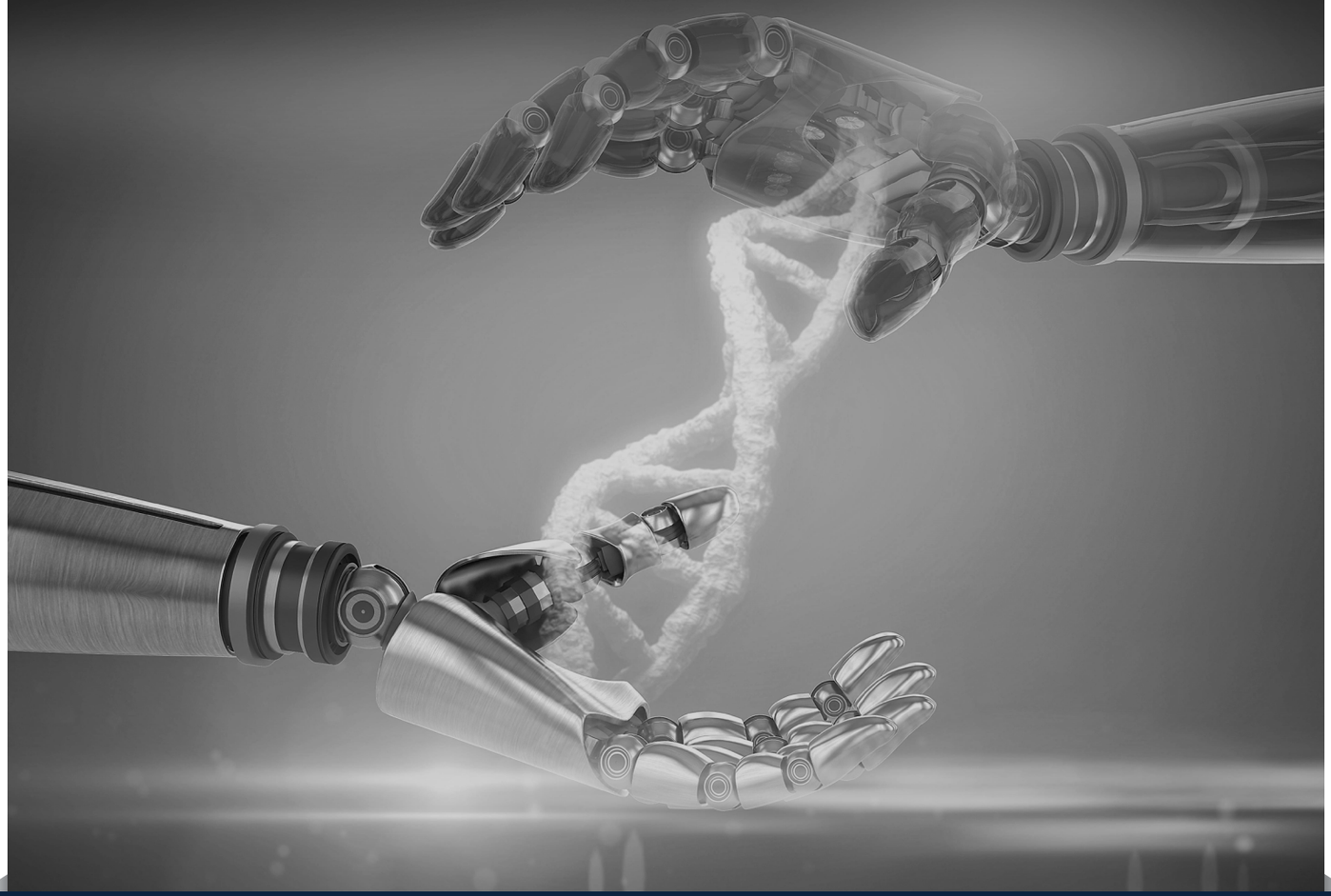
STOCKS DOWN UNDER

15 FEBRUARY 2022

Emerging Stocks Down Under

> *You can, you should, and if you're brave enough to start, you will.*
>
> **- Stephen King (b. 1947), Author**



CYCLOPHARM

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Stocks Down Under rating: ★★★★

ASX: CYC
Market cap: A$154.1M

52-week range: A$1.49 / A$2.95
Share price: A$1.65

Cyclopharm shareholders haven't had the start to the new year they were hoping for. They hoped Cyclopharm's Technegas product would receive FDA approval in the June quarter, but earlier this month the company told them they'd likely have to wait until 2023. The share price drop suggested some investors just didn't have the patience to wait that long – but were they making a mistake in exiting now?

Share price chart

Source: Tradingview

Technegas already sold in 60 other countries

Cyclopharm's product Technegas is a gas-like, radioactive compound that is delivered throughout the pathways of a lung, allowing a gamma camera to create a functional ventilation image of the lung and diagnose problems such as pulmonary embolisms. Technegas is known in all markets where it is avaliable as the nuclear medicine of choice, for three main reasons; ease of administration to the patient, safer for front line workers to use and, most importantly, superior clinical outcomes by facilitating 3D imaging reliably.

Cyclopharm is still at the research, development and growth stage for indications beyond pulmonary embolism, but distributes Technegas to 60 countries around the world. As of January 27, 2022, the company has a $28m net cash position and expected FY21 revenue between $17.5m and $18m, representing 19-22% growth compared to FY20. Technegas has been used on over 4.4 million patients in 60 jurisdictions.

A long tunnel, but there is light at the end

But the United States is not one of those countries Cyclopharm sells Technegas in. The company has been trying to crack this market ever since its IPO way back in 2007. Despite successful clinical trials, the FDA has been slow to approve Technegas. Cyclopharm shares rallied from $1.37 to $3.10 in the last few months of 2020, thanks to successful Phase 3 trial results and shareholders thought FDA approval would be a formality from there.

But shares fell by over 35% in June 2021 when the FDA instead issued a Complete Response Letter (CRL), requesting further information not contained in the initial submission. Cyclopharm met with the FDA in January 2022, seeking further clarification to the CRL. The company now expects to submit a further response in Q3 2022 and, given the FDA has up to 6 months to complete its review, shareholders will be left hanging until early next year.

So, what about the FDA?

You might be forgiven for thinking Cyclopharm is wasting its time focusing on the US, considering its efforts over so many years haven't led to approval and it is active in over five dozen other markets. But the US is easily the world's largest healthcare market and the biggest target market for Technegas. Cyclopharm told shareholders at its most recent AGM in May last year that the market size was ~480,000 procedures.

With the FDA's global reputation as the world's most stringent regulator, approval in America could also potentially open the door for other markets easier, in that the company could potentially re-use the clinical data from the FDA study to gain approval in other markets.

In our view, Cyclopharm's current position is similar to Avita Medical (ASX: AVH) back in 2017. Avita is a MedTech company with a spray-on product (Recell), which treats burns. Despite Recell being used successfully in the Bali Bombings and winning its inventor Fiona Wood Australian of the Year in 2003, the share price stagnated for many years without regulatory approval. But once the FDA gave the green light, there was no looking back and its share price took off.

Of course, the case study of fellow lung imaging company 4DX Medical (ASX: 4DX) illustrates that FDA approval can only get a company so far if it doesn't hit the ground running. But having waited so long to get the green light, Cyclopharm has planned to do just that once it has the green light. Despite 4DX's rollout going slowly and its share price well off its all-time highs, it still trades at 46x its CY22 revenues, while Cyclopharm trades at 6.8x. Unfortunately, we can't use EV/EBITDA to value these companies, because both are expected to have negative EBITDA until at least 2024.

What will it take to believe Cyclopharm will win FDA approval?

Judging by the recent share price drop, it's clear shareholders are taking a 'Seeing is believing' approach for Cyclopharm and its endeavours to get FDA approval for Technegas. But there are reasons to be optimistic that these efforts will ultimately pay off. Cyclopharm is not going at it alone – Technegas is supported by the 16,000-member Society of Nuclear Medicine and Molecular Imaging, which has requested the FDA fast track approval. And the FDA has conducted on-site inspections of Cyclopharm's Sydney facility – a rarity during COVID-19, especially overseas.

We concede that Cyclopharm's share price might not have much room to move until the FDA grants approval, but we believe the green light will come and the company will hit the ground running with US reimbursement already in hand. At that point, the shareholders that have been patient for so many years will be rewarded. Four stars from us.

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