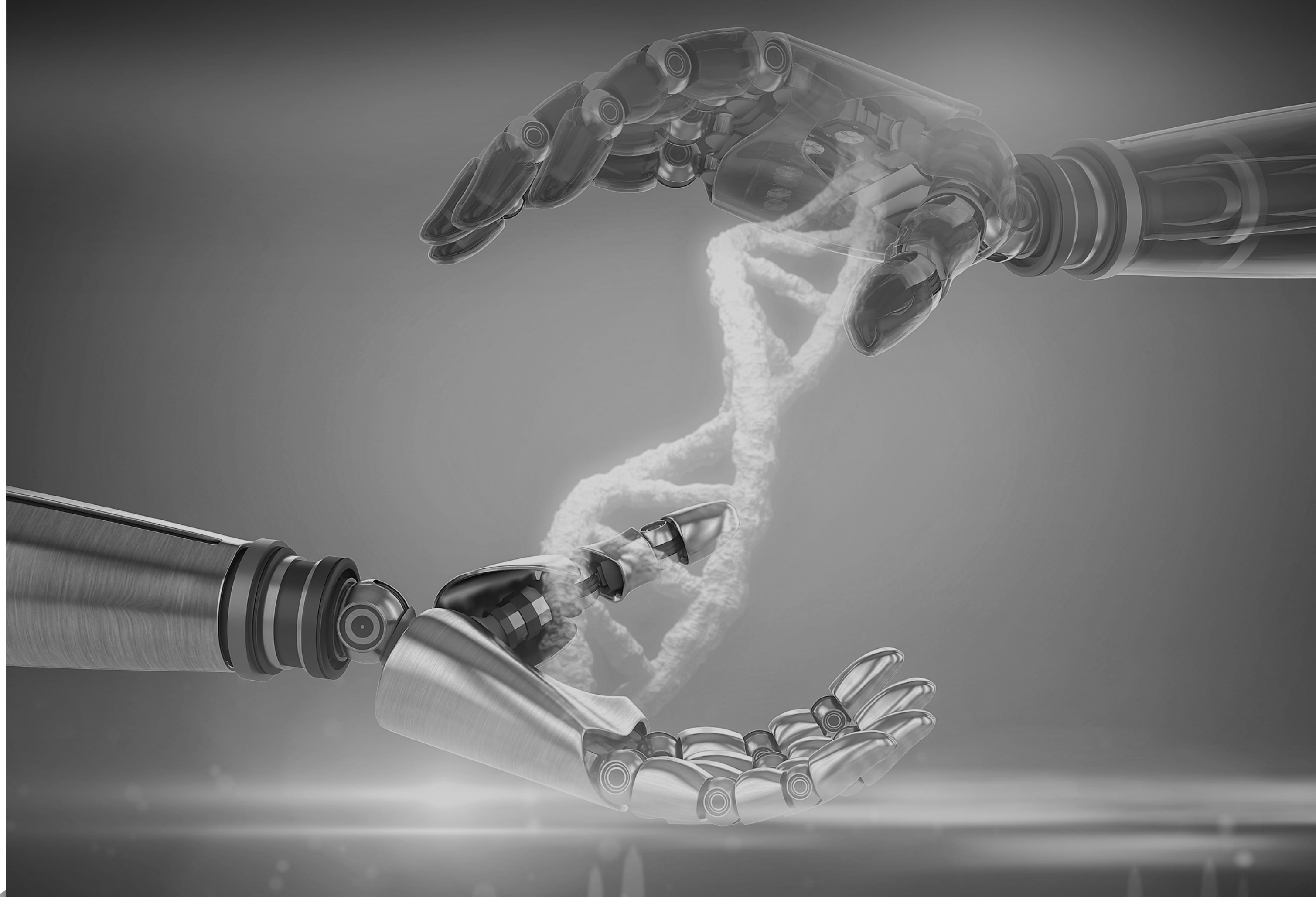
STOCKS DOWN UNDER

26 JULY 2022

Emerging Stocks Down Under

"Make sure you have the right people on the bus, before figuring out where to drive the bus."

- James Collins (b. 1958), Business consultant & author



TISSUE REPAIR

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Stocks Down Under rating: ★★

ASX: TRP
Market cap: A$15.2M

52-week range: A$0.22 / A$0.83
Share price: A$0.35

This week in Emerging Stocks Down Under, we look at another biotech, but this time it's a newer company that arguably hasn't had a chance to shine. Tissue Repair (ASX: TRP) listed in November last year at $1.15 per share and now sits at only 30 cents. Ouch! Arguably, it timed its IPO poorly, just as the equities boom of 2020-21 was fading. But it has some things that few biotechs have, let alone new listees – a completed Phase II program. So, has it been unfairly treated?

Share price chart

Source: Tradingview

Substantial growth since listing

Tissue Repair is developing an advanced wound healing technology (TR-987). TR-987 is a gel that targets applications in the chronic wound and cosmetic procedure market. The aim is for the technology, via a unique active ingredient, to behave like a decoy cell and simulate a yeast infection, resulting in the stimulation of the body's own wound repair pathways. It was invented by Graham Kelly, who you might recognise from other biotechs including Noxopharm (ASX: NOX).

The company was founded in 2012 and has progressed TR-987 past Phase II, the first stage to officially compare a medical technology's performance against a peer. Now, the company is looking at a Phase III trial, which is typically a fait accompli, but is done on more patients and takes longer. The company is also developing another product, TR Pro+ that is a post-procedure gel, which is used following minimally invasive cosmetic procedures.

Tissue Repair wants to enter the USA given the size of the market. The chronic wound market in the USA alone costs the federal healthcare system up to US$50bn per year and the active wound care biologics market is US$1.5bn. Since listing Tissue Repair has made some progress. Most notably, it obtained its first US patent approval, for the method of manufacture of its unique and proprietary active pharmaceutical ingredients. And being at Phase III might excite investors, but judging by the share price, they aren't. So, what's going on?

Only an FDA green light can satisfy shareholders

We think shareholders have been spooked by two disastrous episodes to strike particular ASX companies. The first of these was Lumos Diagnostics (ASX: LDX), which listed at $1.25 in June last year but is barely over 10c now after the FDA rejected its application for 510(k) clearance.

The second of these is Factor Therapeutics (ASX:FTT), which was wiped out after its wound-dressing drug failed a Phase II trial. It has since recapitalised as resources explorer Dominion Minerals (ASX:DLM). The latter drop was back in 2018, but is still notable because there have been few, if any, wound care biotechs since then. But arguably the first is more relevant here, depicting that it is ultimately up to the FDA as to whether or not you go to market. Cyclopharm (ASX: CYC) is one company that has been trying for years but hasn't cracked the cookie yet. Bear in mind, Cyclopharm has never been formally rejected, just asked to provide further information. But investors still didn't like it. Now, because Tissue Repair has not even begun Phase III, you could argue that Judgement Day is still some time away and that even if it ultimately fails, you'll make a good profit once it passes Phase III and could then cash out without having to worry. Neuren Pharmaceuticals (ASX: NEU) is one recent company that proves the latter point. But bear in mind that Tissue Repair has not begun Phase III yet and even its entry to that point is up to the FDA.

The most recent news out of the company was on 1 July in which it submitted a Type C Meeting request with the FDA. The company is seeking to clarify matters required to progress into the Phase III stage. It is anticipating a response in August. The FDA has to sign off on Tissue Repair's chemistry manufacturing and controls, the raw material it uses, the toxicology program and clinical trial protocols. But even that won't be the final OK. That is expected in early 2023.

There's growth potential, but it'll be a long time coming

Shareholders need not worry about a capital raising, the company claims to have reserves enough to deliver a Phase III outcome. So that's a win. The company has also expressed interest in further applications in the future, including in burns, over-the-counter/pharmacy wound products, atopic dermatitis or scaffold products. But of course, it is focusing first and foremost on its current Phase III trial.

Once a medical technology has passed Phase II, Phase III is de-risked, but as Opthea (ASX: OPT) has shown, it takes a long time during which shareholders can get bored. And whatever industry you're in, history has shown there are few companies that can completely recover from a major sell off post-IPO. Tissue Repair's product has potential, but in the current market environment, we would rather wait at least until it is beginning Phase III (which it won't until next year) and preferably until it is closer to the FDA's final decision. Therefore, it's two stars from us.

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