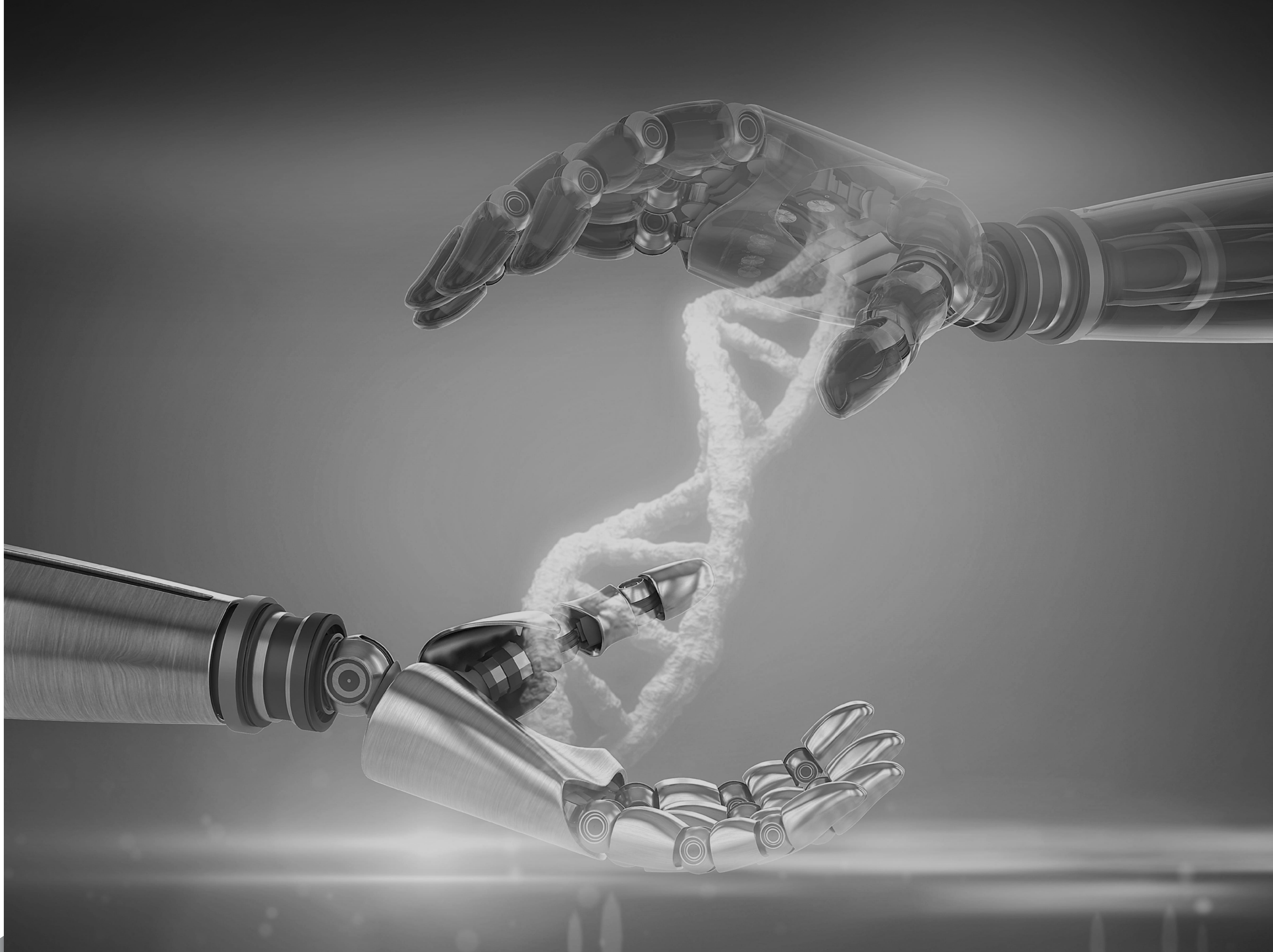
STOCKS DOWN UNDER

19 JULY 2022

Emerging Stocks Down Under

> *Investing in biotechnology is a challenge, not a gamble.*

- George Wolff (b. 1950), Author of 'The Biotech Investors' Bible'



IMPEDIMED

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Stocks Down Under rating: ★★

ASX: IPD
Market cap: A$91.4M

52-week range: A$0.054 / A$0.20
Share price: A$0.055

Founded by Mel Bridges in 1999 and listed in 2007, Impedimed is working on bioimpedance spectroscopy (BIS) devices. These devices aim to measure a patient's body water and fluid volumes at a cellular level and thereby detect diseases or other health problems earlier, particularly the risk of heart failure and Lymphedema. Lymphedema is the swelling of limbs in the arms and legs as a consequence of the removal of lymph nodes during cancer treatment. Unlike other Medtechs, Impedimed has been able to get the FDA onboard. But, to investor's discontent, it hasn't been able to get the medical community onboard to the extent it anticipated.

Share price chart

Source: Tradingview

Measuring fluids

Impedimed's flagship device is called SOZO, which measures a patient's L-Dex score, a unique measurement developed for earlier Impedimed devices, but surviving to this day. Essentially, it measures how easily electrical signals move through affected limbs compared to unaffected limb – the lower the score, the higher the prospect of Lymphedema. It can also detect skeletal muscle mass, body mass index, basal metabolic rate and the level of protein and minerals.

Compared to other devices, it doesn't require electrodes (and is consequently safer and cheaper) and can accurately measure fluid in 30 seconds. Of course, you could also use regular tape measures to examine the body, but that is relatively ineffective. SOZO is sold on a hybrid subscription model, based on US$5,000 for the machine itself and a monthly fee with additional software add-ons for other conditions.

SOZO and other Impedimed devices have passed clinical trials and received four separate FDA 510(k) clearances – meaning the device is safe and effective and can be sold for commercial applications. It first received FDA approval for unilateral lymphedema, then for chronic heart failure monitoring and bilateral lymphedema – all between October 2017 and April 2018. Finally, it obtained clearance for the SOZO heart failure index in April 2021 – just like the L-Dex score for lymphedema, it can detect the risk of heart failure. The company also has European consent for lymphoedema, heart disease and for a kidney condition called protein calorie nutrition (PCN).

Burning cash without a return

But Impedimed has had difficulties in obtaining market interest and therefore investor interest. This is not to say no one cares for the product, there has been interest in SOZO. Back in 2020, global pharmaceutical company Astra Zeneca ordered 75 SOZO units to measure fluid levels in patients enrolled for a trial of a combined heart and renal failure drug. This contract has been extended twice, most recently in March, taking the total devices to be used in the study to 223 and the expected contract revenues to $5.5m.

From a unit perspective, it has sold 840 SOZO units since sales began with 17 being sold in 3Q22, primarily to existing US customers. And in March 2022, it tested a record number of patients – over 39,000 (up 12% year on year). Not content with this, Impedimed is hoping to gain FDA approval for renal (kidney) failure and is working to set up a clinical trial that would help it obtain clearance in that indication.

But Impedimed has been burning through a hefty amount cash, $24m in FY19, $21m in both FY20 and FY21, plus a further $9m in 1HY22. Now, its revenues have been growing – in FY21 it generated $7.6m, up 64% from FY20's $4.7m - but in the current market environment, loss-making companies don't cut the mustard with investors like they used to. The company is trying to cut its losses – aiming for a net operation cash flow to be below $3m for 4Q22. But bear in mind, its total revenue for Q3 was just $2.7m and the company boasted that it was a record quarter.

To be fair, it has taken some actions to cut costs, such as paying 60% of directors fees in shares and increasing its average monthly license fees. It has a cash balance of $42.9m and claims this will be sufficient until break even. Impedimed has been impacted by COVID-19 as many ASX Medtechs have with non-essential medical trials and hospital sales being postponed, plus patients unwilling to risk infection by having non-life threatening problems attended to. And it has been pivoting to a SaaS business model and has $7.9m in Annual Recurring Revenue (ARR).

Needs more new suitors

Evidently, the problem is that it just isn't winning enough new customers. Increasing its license fees and publicly declaring it arguably won't help in a high inflationary environment. Bear in mind that it has already increased its average license fee by over 75% since SOZO's launch. In the company's favour is that it has public US Medicare funding, but it has not been able to gain traction among private insurers. And the kidney market may be an even tougher cookie to crack with the market being dominated by the duopoly of Fresenius and DaVita.

We think shorter term investors might find this appealing as a short-term trading opportunity given its cheap FY23 EV/Revenue multiple of less than 3x. But for long-term growth-oriented investors, it appears seeing will be believing so far as profitability is concerned, and it will be for us too. We might be prepared to take a punt on Impedimed before it was profitable if we saw a potential catalyst. This might be an FDA approval for a more significant market, a new management team or a major order from a brand-new client. But until anything like that happens, its two stars from us.

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