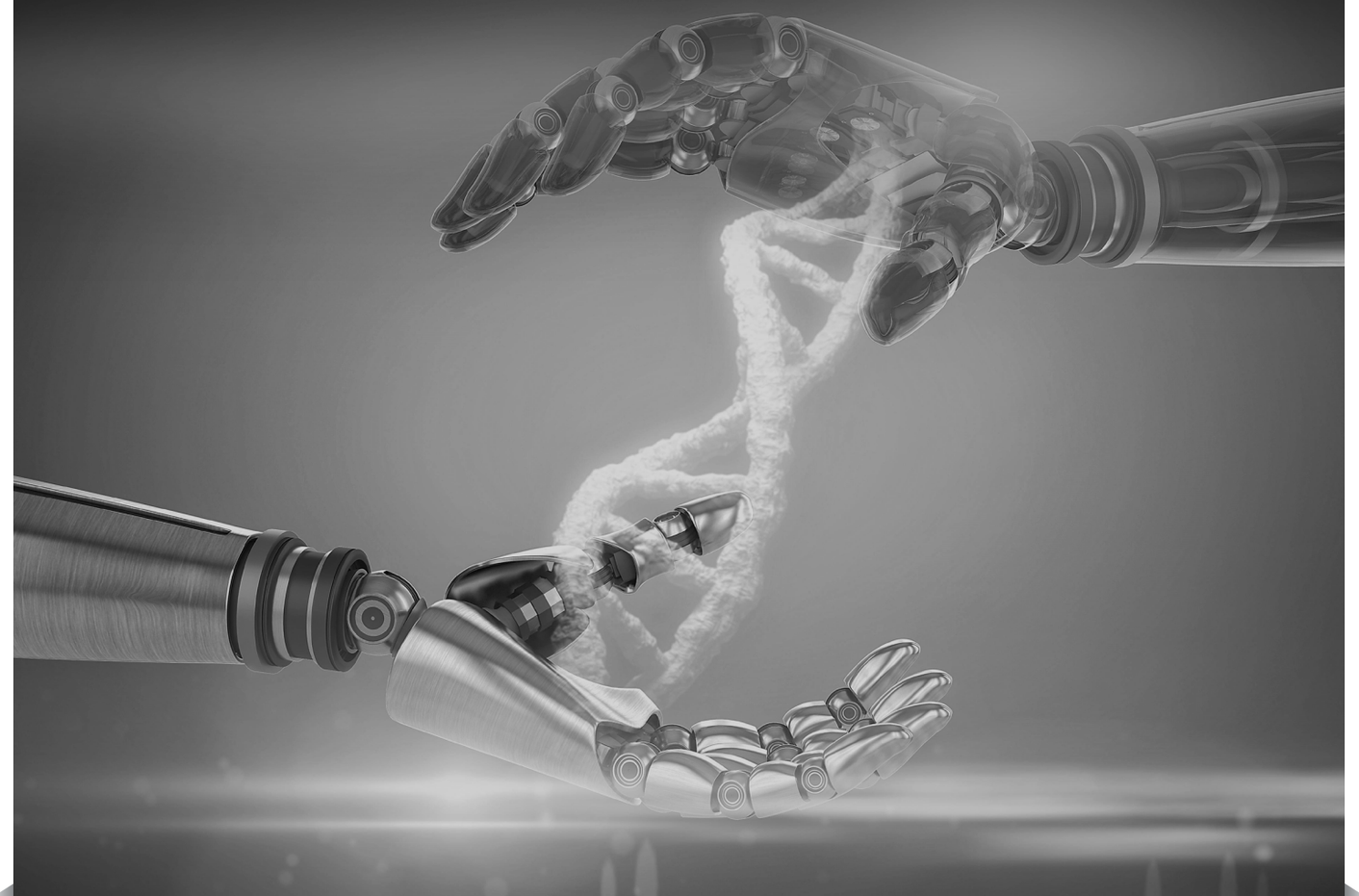
STOCKS DOWN UNDER

9 AUG 2022

Emerging Stocks Down Under

“The markets are moved by animal spirits, and not by reason.”

- John Maynard Keynes (1883-1946), Political economist



IMUGENE

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Stocks Down Under rating: ★★★★

ASX: IMU
Market cap: A$1.5BN

52-week range: A$0.13 / A$0.625
Share price: A$0.285

Imugene (ASX: IMU) is arguably one of the best examples of how crazy the bull market of 2020-21 was. It nearly reached $3bn in market capitalisation despite its assets only being at the clinical trial stage. But it has a few things in its favour that many other Biotechs do not. One is that it is chaired by industry veteran Paul Hopper, who sold Viralytics to Merck for $502m back in 2018. And another is positive clinical trial results back in June that led to this company's latest rally.

Share price chart

Source: Tradingview

A different cancer fighting technology

Imugene's original specialty was B-Cell immunotherapies. These are injected like vaccines and are designed to break down cancer cells without breaking down other cells, but also to engineer an anti-cancer immune response. Specifically, these are designed to treat tumours that over-express a certain receptor known as HER-2/neu that can occur in many cancers. It does so by activating B-cells to produce antibodies.

Imugene has two key B-Cell immunotherapies. The first and foundational B-cell peptide, HER-Vaxx, was discovered in 2012 at the University of Vienna before being reverse-listed on the ASX into Imugene in 2015. The second, PD1-Vaxx, was acquired in 2018 from Ohio State University and Mayo Clinic.

The reason chemotherapy is damaging to bodies is because it cannot tell the difference between cancer cells and healthy cells. Based on clinical evidence to date, HER-Vaxx just might be able to. The good news was a Phase I trial completed at Vienna roughly five years ago against late-stage ER-2+/++ cancers. The trial showed a strong vaccine response – the induced antibodies showed "potent anti-tumour activity". And recent results from a Phase II trial showed good results as well. The gastric cancer patients had a median overall survival of 13.9 months compared to those treated with just chemotherapy who lived for 8.3 months. The study also found there was no difference in safety events between the two treatment groups. These results were even better than what the company had found in interim results.

These B-cell therapies are not the only assets Imugene hangs its hat on. In 2019, it bought the global license for CF33, an oncolytic virus developed at California's City of Hope Comprehensive Cancer Centre and initially out-licensed to a private company of Paul Hopper's. As we noted the last time we covered Imugene, on 22 September 2020, the new oncolytic virus is based on vaccinia, the virus that long ago was used to create the smallpox vaccine. The City of Hope scientists discovered that vaccinia as an anti-cancer virus can work in test tubes at a fraction of the dose of comparable oncolytic viruses. It is only in Phase I though, so while it is an exciting prospect, you should expect to see HER-Vaxx progress faster.

The Corona Rally was good, but when's the next rally?

Imugene shares barely budged above 3 cents until May 2020. From that point, shares really began to take off. Obviously, the market rally, driven by cheap stimulus and record low interest rates, meant just about any company was a buy as long as the lights were on at the head office.

But Imugene had a lot of news flow that excited investors, including completing recruitment for its HER-Vaxx Phase II study, positive interim data from that trial as well as its Phase I PD1-Vaxx trial and the consequential decision to cap patient numbers at the former trial, patent awards, a licensing agreement with Hope Centre and presentations of data at industry conferences.

Obviously, the market conditions have changed in the last 6 months. But positive clinical trial results and regulatory approval may still be able to move the share price – just see Imugene's recent rally after its results in late June.

So, what's next for the company? Ordinarily a company would progress to a Phase 3 study. But Imugene is instead looking to do another Phase 2 trial, which will use a higher dosage rate and likely work with other treatment combinations. A Phase 3 trial would take longer and be more expensive. And we think it is more likely to be acquired before it reaches the market, like Viralytics. So, getting even stronger Phase 2 data may be a smart strategy.

Viralytics was bought for A$502m at a similar stage so on that basis you might argue Imugene is overvalued at $1.5bn and ask the question why it hasn't been bought already. But, in the oncolytic virus space there have been some bigger deals than Viralytics. For instance, Amgen bought BioVex in 2011 for US$1bn. FDA approval for BioVex's cancer immune therapeutic, called Imlygic, wasn't obtained until 2015. However, more than half of that deal was in milestones rather than cash up front.

Is it worth the risk?

It is possible that another successful clinical trial could justify a $1bn+ valuation for Imugene, but it is always risky to hang an investment thesis on hopes that a company will be acquired. Nevertheless, we have opted to give the stock four stars. We think that even though Imugene is higher valued than Viralytics, we think its therapies have shown significant promise in clinical results to date. We also like how it is chaired by someone who has been down this path before.

Still, our rating comes with a warning about the alternative path to market – namely, Imugene continuing clinical trials and seeking regulatory approval on its own. This is not an impossible path, but will be far slower. And markets could go through several cycles during that time – thereby putting shareholder value at significant risk.

Ultimately, we think this company is derisked enough given the clinical trial data to date and that it is led by people who have successfully taken cancer therapies through the clinic before.

Pitt Street Research Pty Ltd

3 Spring Street, Sydney, NSW 2000, Australia

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