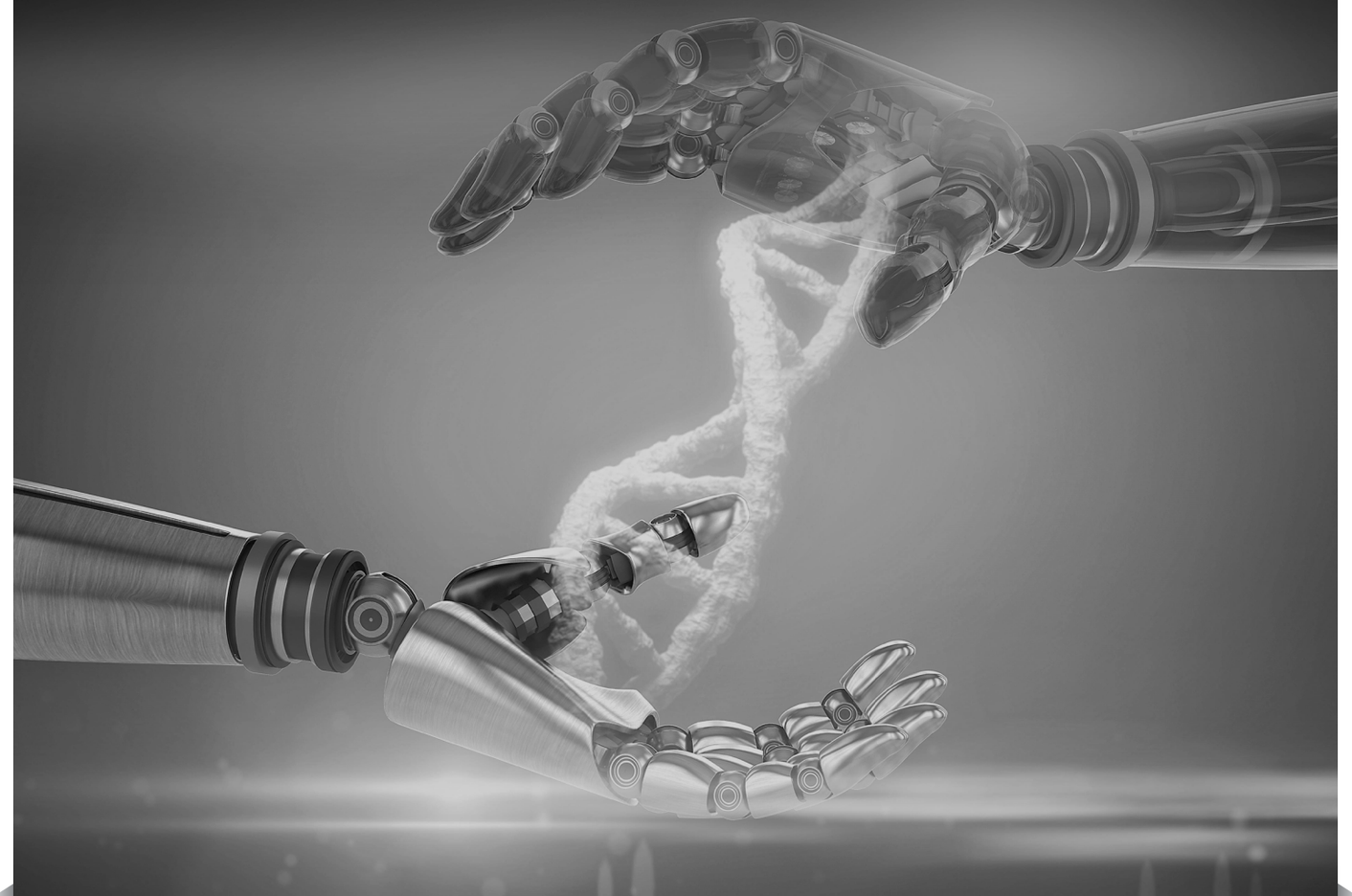
STOCKS DOWN UNDER

03 MAY 2022

Emerging Stocks Down Under

> *Money was for making things happen.*
>
> - Richard Branson (b.1950), Virgin Group co-founder



KAZIA THERAPEUTICS

A biotech taking on brain cancer

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Stocks Down Under rating: ★★★★

ASX: KZA
Market cap: A$105.6M

52-week range: A$0.78 / A$1.65
Share price: A$0.80

In the 12 months since we last covered Kazia, the company's shares have fallen 38%. But in the past two years, Kazia has gained over 150%. Early stage biotechs, such as Kazia have borne the brunt of the market sell off. However, the company and its flagship asset paxalisib have still made significant progress in its strides against brain cancers, including passing a Phase 2 trial. And we think for long term holders there is more good news to come out of the company, including results from a Phase 3 trial against glioblastoma, data from several Phase 1 and Phase 2 trials putting paxalisib to the test against other brain cancers and before too long, commercialisation.

Share price chart

Source: Tradingview

Finally getting somewhere in the fight against brain cancer

Kazia listed on the ASX in 1994. However, the only asset remaining from those days is it's ABN. Kazia has had multiple names and ventures over the years. It became one of the few ASX biotechs focusing on brain cancer in 2016, buying paxalisib from Roche subsidiary Genentech, then making its most recent name change in 2017. The company is also unique among ASX biotechs in being dually listed on the NASDAQ.

As we noted in our last report on this company 12 months ago, brain cancer is deadlier than other types of cancer, especially for glioblastoma, which is the main indication Kazia is targeting. This deadly nature is because of the brain's natural blood-brain barrier (BBB), which prevents cancer drugs from being effective, even drugs that are effective against other cancers.

Additionally, survival rates are low at 3-5% in five years. For comparison's sake, breast cancer has a 90% survival rate. And there's been no improvement in prognosis for two decades despite approved treatments existing. Even temozolomide, the only FDA approved drug for glioblastoma, is ineffective in 65% of cases.

But paxalisib is clinically proven to pass the BBB and has limited side-effects. It works by modulating the P13-K pathway, which is a signalling pathway important in regulating the cell cycles and is activated in over 85% of cancer cases. Paxalisib has already passed a Phase 2 against glioblastoma with flying colours. The

Phase 2 studies showed a five-month median extension in overall survival to 17.7 months compared with 12.7 months and progression free survival time (meaning the tumour not spreading) extended from 5.3 months to 8.4 months.

Another trial...then more trials targeting other conditions

Since January 2021, Paxalisib has been in a Phase 3 study - GBM Agile. The good news is that the trial being sponsored by the Global Coalition for Adaptive Research. It is taking place across the US and Canada, and will expand to Europe and China. The bad news is that it will not be a one-on-one study of paxalisib against the placebo, but two other drug candidates will be tested too – VAL-083 from Kintara Therapeutics and regorafenib from Bayer.

But keep in mind, cancer is often treated with multiple therapies, so it won't necessarily be a case of "winner takes all". If paxalisib can pass the primary endpoint, which in this study is improved survival rates, this will be the pivotal study for regulatory approval. The data is expected in the second half of 2023.

Deals on the side

Still, the company isn't just sitting back and watching this trial go by. It is looking for deals to help it with commercialisation, mainly through licensing deals. The most prominent deal Kazia has achieved to date was a US$281m licensing deal with Simcere Pharmaceutical Group to develop paxalisib in China. With Phase 3 data due next year, commercialisation is not too far away. The company will then seek regulatory approval thereafter. It estimates the disease is a US$1.5bn market.

The company has seven other studies ongoing of paxalisib against other forms of brain cancer including brain metastases, primary CNS Lymphoma and diffuse intrinsic pontine glioma (DIPG). Only a few weeks ago it showed positive preclinical data against the latter indication. It is expecting interim data from several of its clinical studies before 2022 is done. Kazia has other assets as well, including EVT801 – a cancer therapy licensed from Evotech that inhibits VEGFR3 and thereby starves cancer tumours of vital nutrients. It recently commenced a Phase 1 trial for EVT801.

Eventual commercialisation

When it reaches commercialisation, paxalisib has four noteworthy advantages. First, the drug is easy to administer being a 15mg capsule taken once daily. Second, it has strong IP protection extending into the early 2030s thanks to its FDA designation as an orphan drug. Third, it can be manufactured at a low cost and with excellent stability at an ambient temperature. And fourth, it has limited potential for harmful interactions with other drugs. As shareholders of other companies, such as Pharmaxis (ASX: PXS), know all too well, interactions can be a make-or-break issue for drugs.

We also note that the company's cash reserves are sufficient to complete the current Phase III trial, so it won't need to raise capital any time soon. And we think it could sign further licensing deals for other jurisdictions. Such deals could be a catalyst for the share price in the same way the Simcere deal was, particularly for the lucrative US market.

In our view, Kazia is four stars. We acknowledge the market for biotechs is not hot right now, but we think there'll be plenty of news flow out of the company in the months ahead to prevent shareholder boredom and consequential turnover in the company's investor register.

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