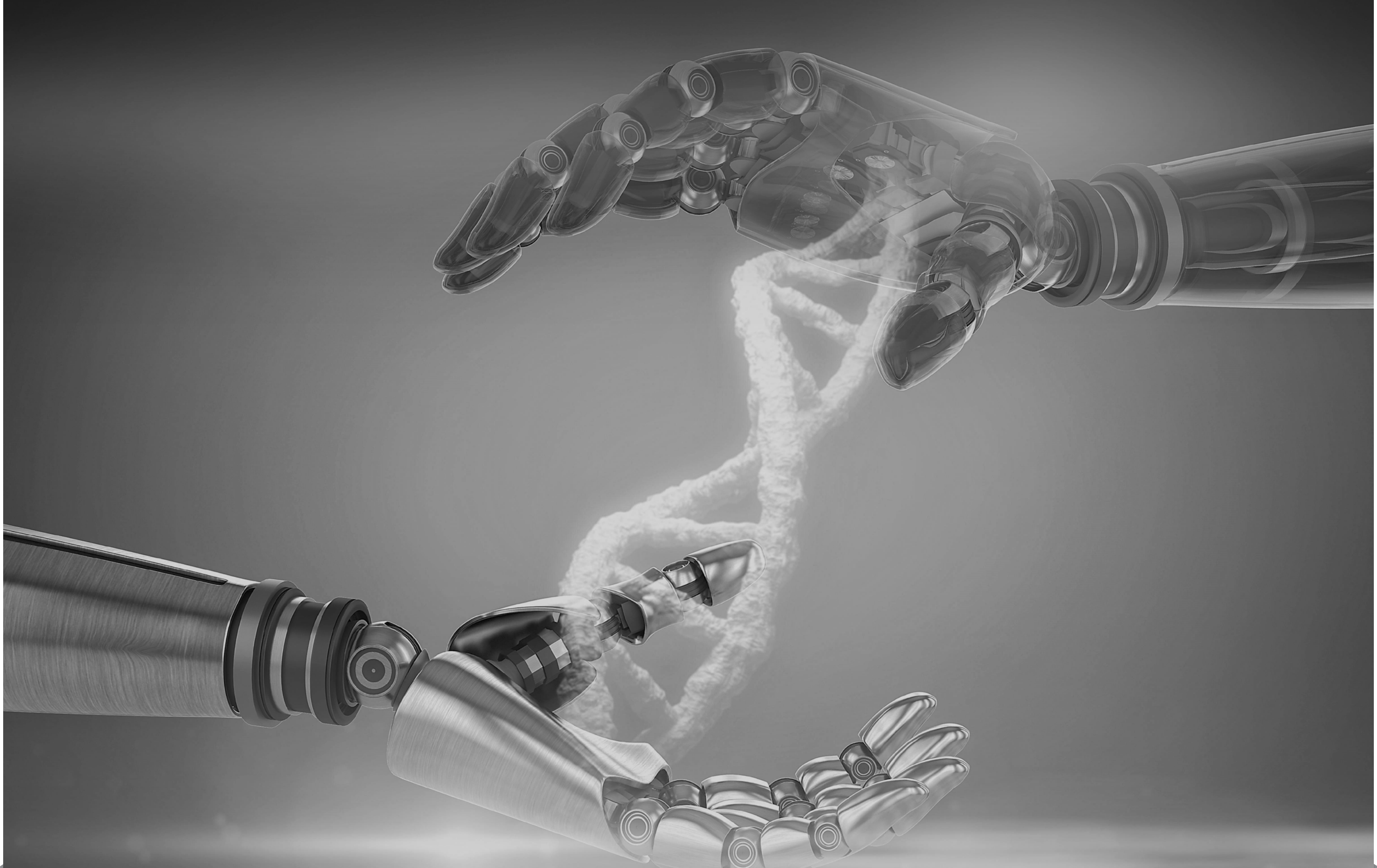
STOCKS DOWN UNDER

11 MAY 2021

Emerging Stocks Down Under

> *The world is neither unipolar, multipolar, nor chaotic — it is all three at the same time.*

- Joseph S. Nye, Jr. (b. 1937), American political scientist



KAZIA THERAPEUTICS
Tackling glioblastoma

LITTLE GREEN PHARMA
Not so little anymore

EDEN INNOVATIONS
An unknown land of innovation

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Stocks Down Under rating: ★★★★

ASX: KZA
Market cap: A$ 176M

52-week range: A$0.354 / A$1.88
Share price: A$ 1.38

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Share price: A$ 0.655

It seems like Little Green Pharma has a finger in every part of the cannabis pie. Apart from growing its own produce, the company is engaged in generating better access for patients to its existing pipeline of products while expanding into an overseas market hungry for Australian cannabis. While education about the benefits of medical cannabis is key to the company's current success, LGP understands the value of constant clinical improvement, which is why its long-term mission is to develop high-grade products to achieve its expansion dreams.

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Share price chart

Source: Tradingview

A complicated issue

Kazia is working on early and late-stage cancer drugs, specifically brain cancer, a disease with unique treatment challenges and high mortality rates. The company's lead candidate, Paxalisib, was designed to overcome the challenges in brain cancer treatment in what is still a largely uncompetitive field. Paxalisib is about to enter Phase 3 for glioblastoma – a type of malignant tumour that can spread rapidly, making early treatment difficult.

Despite the advancements in this arena, brain cancer remains a challenge. The five-year survival rate for all brain tumours – including benign tumours – is 33%, and that number drops to 5% for glioblastoma. Brain tumours are challenging because of their complexity: they're protected by the brain's natural blood-brain barrier (BBB), which absorbs nutrients and protects against harmful materials entering the brain, including actual cancer drugs. Tumours can also exhibit multiple mutations and are often resistant to single-approach treatments, making recurrence after therapy more common.

Paxalisib works to modulate the P13-K pathway, which is a signalling pathway important in regulating the cell cycles. P13-K becomes disordered in most cancers – around 85% in glioblastoma cases – making the pathway a priority target in new brain cancer therapies. Early animal studies show Paxalisib as an inhibitor of P13-K distortion with the added ability to successfully cross the blood-brain barrier.

Collaborating glioblastoma study

Paxalisib is fulfilling the unmet need in current treatment options, which means it's directly competing with three other cancer drugs, including Temozolomide, the only FDA-approved treatment for glioblastoma. As Paxalisib can pass the blood-brain barrier and has limited toxic side-effects, this could give it leverage in clinical settings where patients have shown resistance to Temozolomide (which is ineffective in 65% of glioblastoma cases). Especially now that the company's Phase 2 data shows a median overall survival rate of 17.7 months compared to existing Temozolomide therapy. It should be noted that while P13-K treatments exist, few are designed to bridge the BBB, providing Kazia with a substantial commercial opportunity with very little competition. Although glioblastoma affects only about 133,000 patients globally (and 12,500 in the US), the market opportunity to address those unmet needs is US$1.5bn. There are also expansion opportunities into other forms of brain cancers, secondary cancers and other cancers with disordered P13-K pathways.

Naturally, that opportunity depends on the ability to fund Phase 3 clinical trials. At the moment, Kazia has a six-part clinical program at various stages looking at primary and secondary brain cancer treatments. Still, it's the pivotal glioblastoma study, called GBM AGILE, which offers the fastest path to registration. GBM AGILE is sponsored by the Global Coalition for Adaptive Research, a non-profit organisation based in the US, helpfully reducing Kazia's cost of participation, while Paxalisib is being evaluated in hospitals throughout the US and Canada (and later Europe and China).

The company's collaboration in the two-to-three-year study takes care of the necessity of building 100% of the funding and support in a competitive space, especially as short-term revenue can be limited for smaller biotech companies. Since GBM AGILE is one study of six, Kazia is already cementing partnerships, including a US$281m licensing deal with Simcere Pharmaceutical Group to develop Paxalisib in Greater China. China is not an insignificant market and this deal makes Paxalisib's future global roll-out a little easier.

Brain cancer research takes precedence

The Simcere licensing deal has become the icing on the cake for Kazia's share price recently, with a spike back in April. But it could get a lot better if other partnerships emerge before the data from the clinical programs roll out. That extra revenue could have a secondary function with Cantrixil, designed as a cancer stem cell-targeting treatment for ovarian cancer. Cantrixil was handed down to Kazia by its former iteration Novogen. While the drug candidate shows early promise, the company has sold the rights to Swedish company Oasmia Pharmaceuticals so it can focus on brain cancer research.

We think that's a smart move for a company with Paxalisib's promising outlook. Ovarian cancer has similar problems in early detection, high recurrence and poor survival rates, meaning Kazia would be looking at similar funding and clinical programs to rival its current schedule. By keeping its current focus, Kazia is not betting only on itself or its drug candidate, but the emerging field of brain cancer treatments as a whole and that is demonstrated by the GBM AGILE collaboration. Four stars from us.

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Australia's first local producer

Little Green Pharma is one a few cannabis companies that actually cultivate and produce the little green plant. Its facility in Western Australia has a cultivation capacity of about 3 tonnes of flower (or 300,000 bottles of cannabis oil per annum). Now that the company is vertically integrated – operating across the supply chain through the manufacture, product development and sales of its own line of branded medicines – LGP is executing on a growth strategy that may see production capacity doubling. At the same time, the company is working with medical professionals and other distributors to enable greater patient access to its products. The company currently has five cannabis oil products (and one THC flower formulation) in the Australian market.

One clear advantage for LGP is its clinical research partnerships. The company is working with Curtin University in the development of its ARISE technology (which stands for Atomised Rapid Injection for Solvent Extraction) that will allow cannabis medicines to be more readily absorbed in the body. While not the same, ARISE technology has a similar purpose to Avecho Biotechnology's TPM technology, where greater absorption leads to better-targeted treatment. As with Avecho, we believe LGP's ability to produce more available and targeted CBD treatments will help give the company increased product confidence and further avenues to revenue.

Safe, affordable, effective

Although LGP has only been listed since February 2020, its quick integration into domestic and overseas markets is largely based on its commitment to patient access and education as much as its development strategy. The company's partnership with Curtin and its QUEST initiative with the University of Sydney – set to be the longest longitudinal study of the effect of cannabis on quality of life for patients with chronic pain – are meant to drive customer awareness of its products whilst increasing patient and professional engagement. The stats from the last quarter suggests the engagement is working: the company managed to sign up 150 GPs and brought in 4,900 new patient subscriptions for its products over the December quarter. That work has resulted in a fivefold increase in revenue to $3.7m, compared to just $700,000 in the December 2019 quarter. The majority of that is domestic sales, but engagement has now reached patients and suppliers in Germany, France and the UK. The new deals in Germany and France drove LGP's share price to a high of 92 cents in late February.

While that kind of distribution engagement is essential, improved products come first. Now that Australia's drug regulator, the TGA, is treating many medicinal cannabis products as worthy pharmaceuticals, the regulation for effective products is getting tighter and one of LGP's cannabis oil products has previously been picked up by the regulator for having 'too little CBD'. If this sounds negative, we believe it only presents more stringent regulation that could be better for companies like LGP and the wider market in the long run. It also acts as another push for the kind of treatments the partnership with Curtin intends to produce.

Aside from clinical trials, patient access for LGP's products is largely limited to the Special Access Scheme and the Authorised Prescriber Scheme, meaning that patients often have great difficulty obtaining any CBD medicines. As regulations toward non-prescription CBD medicines change gears, LGP is another company striving to compete on a pharmaceutical level.

Get high

The expanded capacity at the WA facility has given LGP the chance to distribute its products into new jurisdictions (chiefly South America and Europe) as well as supplying cannabis oil and produce in a few more clinical trials, including a 3,000-patient clinical trial in France. As more companies become interested in working with the company, the more likely it is LGP can reach its goal of global expansion. However, we believe local markets should remain a key priority. The successful application of cannabis to the ARISE technology should add another level of prestige to a company which is not all that little anymore.

Given the number of arms LGP has, a little more funding might also be in order. The company recently did a capital raise of $22.1m at a price of $0.65 per new share to help with increased patient acquisition at home and expand sales and distribution overseas.

In the longer term, the focus will be on expanding its pipeline of high-grade pharmaceuticals beyond flower and oils. We believe there is a great opportunity for LGP to produce competitive products and drive patient growth further. Additionally, its popularity overseas is certain to provide a lot of positive news flow in the future, as well as increased sales. Four stars.

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Share price chart

Source: Tradingview

Innovating Eden

Back in 2004, Eden and the University of Queensland believed current methods of creating hydrogen through steam-methane (natural gas) reformation was inefficient and formed a partnership to create a new approach to achieve the same thing. The resulting Pyrolysis method does not use precious metals as a catalyst and generates no other by-products besides hydrogen and carbon. In practice, this spin on steam-methane reformation is not only better for the environment, but produces greater economic returns. What's truly impressive about this method, though, is the ability to change what solid form the carbon takes: a nanofibre or nanotube. The development of this process, now 100% owned by Eden, led to three of Eden's four products: Hythane, EdenPlast and EdenCrete.

While Eden is not currently producing hydrogen, during 1HY21 several (unspecified) companies did commence discussions with Eden regarding the use of the Pyrolysis method. Hythane is a premium version of natural gas fuel currently sold in India, featuring a mixture of hydrogen and natural gas.

EdenPlast is a collaborative research project with the University of Queensland to find a new way of incorporating Polypropylene (plastic) into high concentrations of carbon nanotubes. EdenPlast received its first patent on 21 August 2019, which covered the United States, a large potential market.

Eden's test performance of its new material has proven that not only is it low-cost, but it has superior ductility (elongation-at-break), stiffness and yield stress compared to other competitors on the market. While EdenPlast is not generating revenues yet Eden provided a Japanese plastics manufacturer with a masterbatch for testing in 1HY21, while the Argil Group began discussions for the product.

A lot of revenue upside

As of 1HY21, only EdenCrete and OptiBlend are fully commercialised and generating revenue. In total, these two products generated $1.6m in revenue, an increase of 33% year-over-year. EdenCrete is available worldwide, although the primary focus is on the US market. This product is a rather clever carbon nanotube enriched admixture for concrete. Basically, allowing carbon nanotubes to fill the nanoscopic spaces of air in concrete results in a significant increase in flexibility, strength, durability, heat resistance and permeability compared to normal concrete. In total, this product generated revenue of $878,000 during 1HY21, representing a year-over-year increase of 24%.

However, we expect this growth rate to significantly increase during 2HY21 and 1HY22 based on two updates provided to the market on 25 March and 1 April 2021. Eden's concrete mixtures EdenCrete and EdenCrete Pz have received additional approvals and are now for sale in 21 and 16 US states, respectively. Additionally, EdenCrete has seen significant growth in Georgia, with five highway repair projects and one waste transfer station using the product. With the major infrastructure projects being promoted by both political parties in the US, we believe demand for these products will continue to grow at an accelerated rate.

Eden's other revenue-generating product, OptiBlend, is a proprietary air-gas mixer, allowing conventional diesel engines to transition to natural gas as their primary fuel. OptiBlend generated $703,000 in revenues for Eden in 1HY21, an increase of 47% year-over-year. The OptiBlend system requires no engine or fuel system modification and was developed outside of the Pyrolysis Project. The product is currently sold in the United States and India, although Indian sales account for most of the revenue ($587,000). India also accounted for most of the products' growth during the period due to recent changes to Indian environmental standards, banning diesel generator sets in Delhi, Noda, Ghaziabad, Faridabad and Gurugram as of the 15 October 2020.

Unfortunately, COVID-19 has reared its head in India, completely overwhelming the country's healthcare system. On 9 May 2021, India reported 366,499 COVID-19 cases. However, it is currently impossible to tell just how bad the situation is as Prime Minister Modi's government has repeatedly been caught engaging in cover-ups and manipulating official COVID-19 statistics. Fortunately, OptiBlend is a required technology as India continues to crack down on pollution, so we don't think there is a risk of long-term harm to sales.

Worth the risk to visit Eden

Due to a lack of company guidance and market forecasts, we have to resort to Eden's trailing 12-month EV/Revenue ratio to get a sense of the company's valuation. At of 20.5x it seems very high. However, the 1HY21 revenue growth of 33% doesn't yet include any revenues from EdenPlast and the Pyrolysis Project, which have yet to be fully commercialised. And the US market seems to be hungry for EdenCrete and OptiBlend.

So, even though we are slightly concerned about the risks to Eden's 2HY21 revenue growth from its Indian operations, we believe the overall outlook for the company is very solid. Additionally, the company is working hard to get to break even, decreasing its Net Loss After Tax by 30.6% year-over-year to $2.8m in 1HY21. Therefore, just like the biblical Eden, we believe this company is a hidden gem that deserves four stars. Be mindful, though, of the volatile share price. It may not be to every investor's liking.

Pitt Street Research Pty Ltd

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