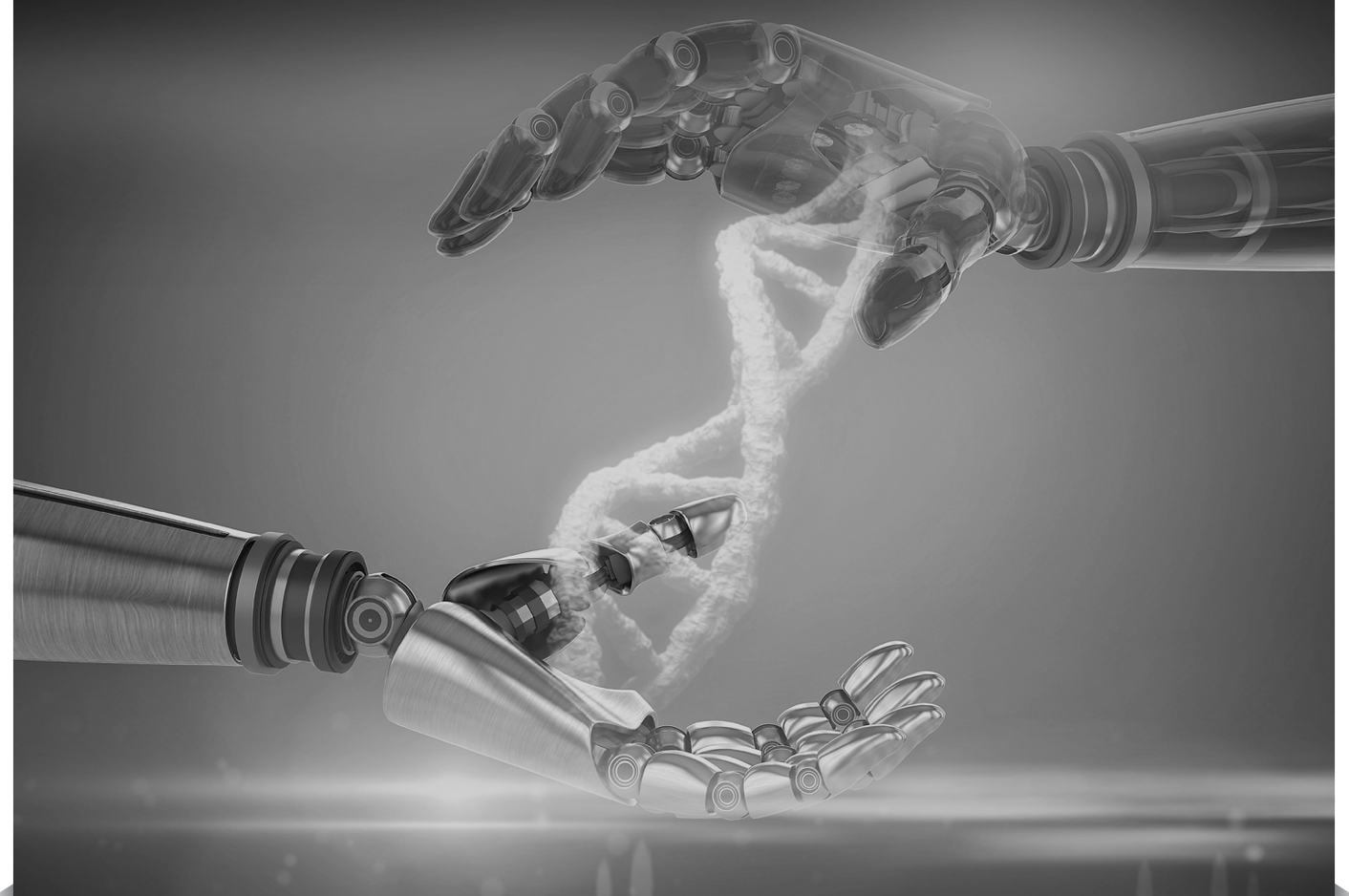
STOCKS DOWN UNDER

26 APRIL 2022

Emerging Stocks Down Under

> *All intelligent investing is value investing - acquiring more than you are paying for.*
>
> - Charlie Munger (b.1924), Vice-Chairman of Berkshire Hathaway



INVEX THERAPEUTICS

A biotech taking a shortcut to market

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Stocks Down Under rating: ★★★★

ASX: IXC
Market cap: A$53.7M

52-week range: A$0.50 / A$0.82
Share price: A$x.xx

Charlie Munger's partner Warren Buffet said that the stock market is a device of transferring wealth from the impatient to the patient. Arguably no sector proves this more than the Life Sciences sector, in which companies can make substantial money when they commercialise products. But it can take years to get products to market. This is because companies typically have to conduct multiple clinical trials and make their case to regulators. But Invex Therapeutics is one company taking a non-conventional path to market, re-purposing a drug already on market for a different condition.

Share price chart

Source: Tradingview

Relieving intracranial pressure

Invex Therapeutics listed on the ASX in July 2019, raising $10m at 40c a share. The company was founded as a general vehicle to commercialise research by University of Birmingham medical professor Alexandra Sinclair. Its main asset is a drug called Presendin (a properietary, sustained-release forumulation of an approved drug called Exenatide) that has conventionally been used to treat diabetes. But the company is striving to repurpose exenatide treat neurological conditions caused by intracranial pressure (ICP).

Invex is targeting a condition known as idiopathic intracranial hypertension (IIH) which is caused by accumulation of fluids inside the skull and on the brain tissue. Naturally IIH causes headaches, but it can even cause permanent vision loss. There is no known cause and no approved drug therapies that directly treat the disease (rather than the symptoms), but the annual market is estimated to be worth A$1.6 billion across the EU/UK and USA.

You're probably wondering how a diabetes drug could address a neurological disorder. Professor Sinclair found in her research that the same receptor agonists used in diabetes treatments (GLP-1), act on the choroid plexus in the brain to lower cerebral spinal fluid secretion and, consequently, ICP. Her work was validated in Invex's Phase II trial, which was completed in 2020 and delivered impressive results. Presendin met all endpoints and recorded a statistically significant and clinically meaningful reduction in ICP and an improvement in visual acuity.

A shortcut to market

Rather than taking Presendin through the conventional route of multiple clinical trials over several years, Invex is taking a shortcut. When a drug is already approved and has been commercialised for another condition, the safety profile is well known. Therefore, you can file for patent protection for the same drug to treat another condition as Invex has done, with issued patents in the US, Europe and Japan providing coverage beyond August 2035.

In addition, as IIH is a rare disease, Invex has also secured an Orphan Drug designation from the US Food and Drug Administraiton (FDA) and the European Medicine Agency (EMA) back in 2017. Consequently, Invex is able to start the clinical trial process at mid-stage clinical studies and this is what Invex has done with Presendin. As noted above, Invex's clinical work started at Phase II and it is proceeding to a single Phase III clinicial trial that meets the requirements (if successful) for a registration of Presendin in IIH for Europe, the UK and Australia.

Orphan drug designation provides exclusivity

The quicker path to market is good enough for shareholders knowing there'll be less time spent waiting and there'll be less dilutive capital raisings – if any are needed. But additionally, as we noted in our last report in Invex in September 2020, IIH has a low annual incidence in the Western World and has no approved medical treatments. This will make it possible to charge higher prices when Presendin is commercialised for IIH. The orphan drug designation will also grant it market exclusivity for 10 years in Europe and 7 in the US.

Invex is set to commence a Phase 3 trial which will be conducted across 37 clinical sites globally with 240 patients. The primary endpoint will be the mean difference in ICP from baseline at 24 weeks between patients receiving Presendin and those on placebo. With the trial designed to meet the requirements for market approval of Presendin in the EU, UK and Australia, the company hopes to have the drug on the market in 2024. The trial has not officially kicked off but that is due by the end of the June quarter. Invex also signed a long-term collaboration and manufacturing agreement with Korea-based biopharmaceutical company Peptron. The company has a solid balance sheet with $31.4m in net cash, meaning it is unlikely a dilutive capital raising will be required for some time yet. The company maintains current cash reserves are sufficient to complete the Phase III trial and secure a market approval for Presendin.

Another Race Oncology?

We think there are parallels between Invex and Race Oncology (ASX: RAC) in how these companies are pursuing a faster path to market. The latter, which we last covered in March 2021, has grown from 5 cents to ~$2.50 in 3 years off the back of clinical progress and expanding the indications its own orphan drug Zantrene could target. We also note that Invex's market capitalisation (~$55.2m at the time of this report) is lower than other companies with assets at Phase 3. For instance, Opthea (ASX: OPT) is at ~$355m and while it is focused on eye disease rather than brain disease, it too is targeting a vision loss caused by the build-up of fluid. And as we've seen recently with Neuren (ASX: NEU), positive Phase III results are a key catalyst for a company.

Let's assume the Phase III trial goes well, Presendin gets into market no later than 2025 only targeting IIH and no other indications are targeted for the foreseeable future – although the company is actively considering new ICP-related neurological conditions for Presendin. On this basis we think that Invex is one of the more appetising opportunities in the biotech space right now. It is not a foregone conclusion that the path will be smooth sailing, but the investment case is significantly de-risked. This is because Presendin is at a later clinical stage, has long term patent protection (well into the 2030s) and a manufacturing and supply agreement is all ready to go for when Invex is ready to commercialise the drug.

We also note that the company's management are all among the company's top shareholders and one other noteworthy backer of the company is Andrew Forrest's private investment vehicle Tattarang, which owns nearly 12%. So, it's four stars from us.

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