



# Emerging Stocks Down Under

📖 *Any new technology tends to go through a 25-year adoption cycle.* 📖

- Marc Andreessen (b. 1971), co-founder of venture capital firm Andreessen Horowitz

## IMUGENE

A cancer therapy set to go viral

## HARVEST TECHNOLOGY GROUP

Convertible notes are a ticking time bomb of dilution

## INVEX THERAPEUTICS

No pressure

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Stocks Down Under rating: ★★★★★

ASX: IXC  
Market cap: A\$ 73.7M

52-week range: A\$0.52 / A\$2.05  
Share price: A\$ 0.95

The drug developer Invex Therapeutics had a nice re-rating off the Corona Crash low. The stock rose from 53.5 cents on 23 March to \$1.67 on 22 May, after which it cooled off for a while. The Life Sciences sector is like that – when you're hot, you're hot. While Invex stock may drift down for a while yet, we are optimistic about its prospects at repurposing an old diabetes drug called Exenatide.

## Share price chart



Source: Tradingview

In the Life Sciences game patience is generally a virtue, because developing a new drug or medical device can take a long time, like somewhere between 10 and 20 years. There are, however, shortcuts and one of them is to take an old drug that is now off-patent and 'repurpose' it for a rare disease condition. To repurpose a drug, you discover a new potential use for that drug, file for patent protection over the new use and start again. Since the drug is already well known, it will be easy to manufacture. More importantly, since it has already been on the market before, the safety profile of the drug is well known. So, you can move quickly to mid-stage clinical studies. That's what Invex Therapeutics is doing with its Presendin drug, which just completed Phase 2.

## A monster of a drug

Presendin is simply the old diabetes drug Exenatide, but repurposed for a condition called Idiopathic Intracranial Hypertension, or IIH for short. If you have type 2 diabetes you may have encountered Presendin/ Exenatide before. The original drug gained FDA approval way back in 2005 as Byetta. It's a synthetic version of a hormone naturally produced by the Gila Monster. That's right – the clues to a great diabetes drug were found in the saliva of a large, venomous lizard.

Over the years to 2011, Lilly built Exenatide up to blockbuster status, before the original developer, the San Diego-based Amylin Pharmaceuticals, got the rights back again. In its heyday Byetta was a big deal in diabetes because it is an 'agonist' (that is, an activator) for GLP-1, which is produced in the human gut to control levels of glucose and insulin. It basically worked better than any other pill that had come before and pioneered a drug class that continues to be worth billions today. Which is why, in 2012, the pharma giants BMS and AstraZeneca bought Amylin for a cool \$7bn. They wanted the upside from Bydureon, which is a once-weekly version of Byetta.

### **A new use for an old drug**

All good things, including patent life, come to an end. Byetta may have been a blockbuster, but it's now a has-been that went generic in 2017. AstraZeneca's loss, but Invex's gain. Some years ago, Professor Alexandra Sinclair at the University of Birmingham in the UK figured out that the GLP-1 receptor agonists were good at reducing intracranial pressure, where fluid build-up inside the head starts to put pressure on the brain. She studied Exenatide in rats and found that it would modulate the cerebrospinal fluid secretion that was causing the problem. Patent protection for this novel use of Exenatide was obtained and Invex was formed to take the project forward. It went public on the ASX in July 2019 after raising \$12m at 40 cents per share. The stock quickly went to \$1.49 on the assumption that an eventual approval in Idiopathic Intracranial Hypertension was a no-brainer.

Idiopathic Intracranial Hypertension is where the Intracranial Pressure happens for no apparent reason. It's a rare condition but thanks to Invex there might be a great drug for it soon. Last May Invex delivered some Phase 2 data on IIH showing that Alexandra Sinclair was on to something. There were only 16 patients in the study, but it was the kind of randomised, placebo-controlled stuff that gives you an idea if a drug can work or not. In this case it seemed to work, with the treated patients experiencing a >10% reduction in Intracranial Pressure at 2.5 hours, 24 hours and 12 weeks, and the patients also registering a reduction in the days in which they experienced headaches as well as having improvements in their visual acuity. In the case of the 2.5 and 24 hour reduction in Intracranial Pressure the results were deemed 'statistically significant' (i.e. unlikely to be due to chance), as was the reduction in headaches and the visual acuity gains. To get statistical significance in a study this small was truly amazing.

### **Orphan drug but potential big profits**

Sure, Idiopathic Intracranial Hypertension is an Orphan condition – annual incidence in the Western world is only about 1 person in 100,000 – but that's actually good news for Invex because Orphan drugs are big business these days thanks to the high pricing one can charge and the faster path to market made available by the Orphan Drug Act in the US and related legalisation elsewhere.

After this Phase 2 Invex is now working towards its Phase 3 registration study. Phase 3 is the Grand Final of drug development and it's the stage where the share price of drug developers can seriously re-rate. Invex reckons it can get its Phase 3 data in IIH about 2023 and have the drug approved in that condition by 2024. Wow!

As we noted above, Invex stock has eased back since May and it may do for a while yet, but the March-May re-rating and the July 2019 positive reception shows you this stock has fans. Given the quality of the data to date, we're fans too. Four stars from us.

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