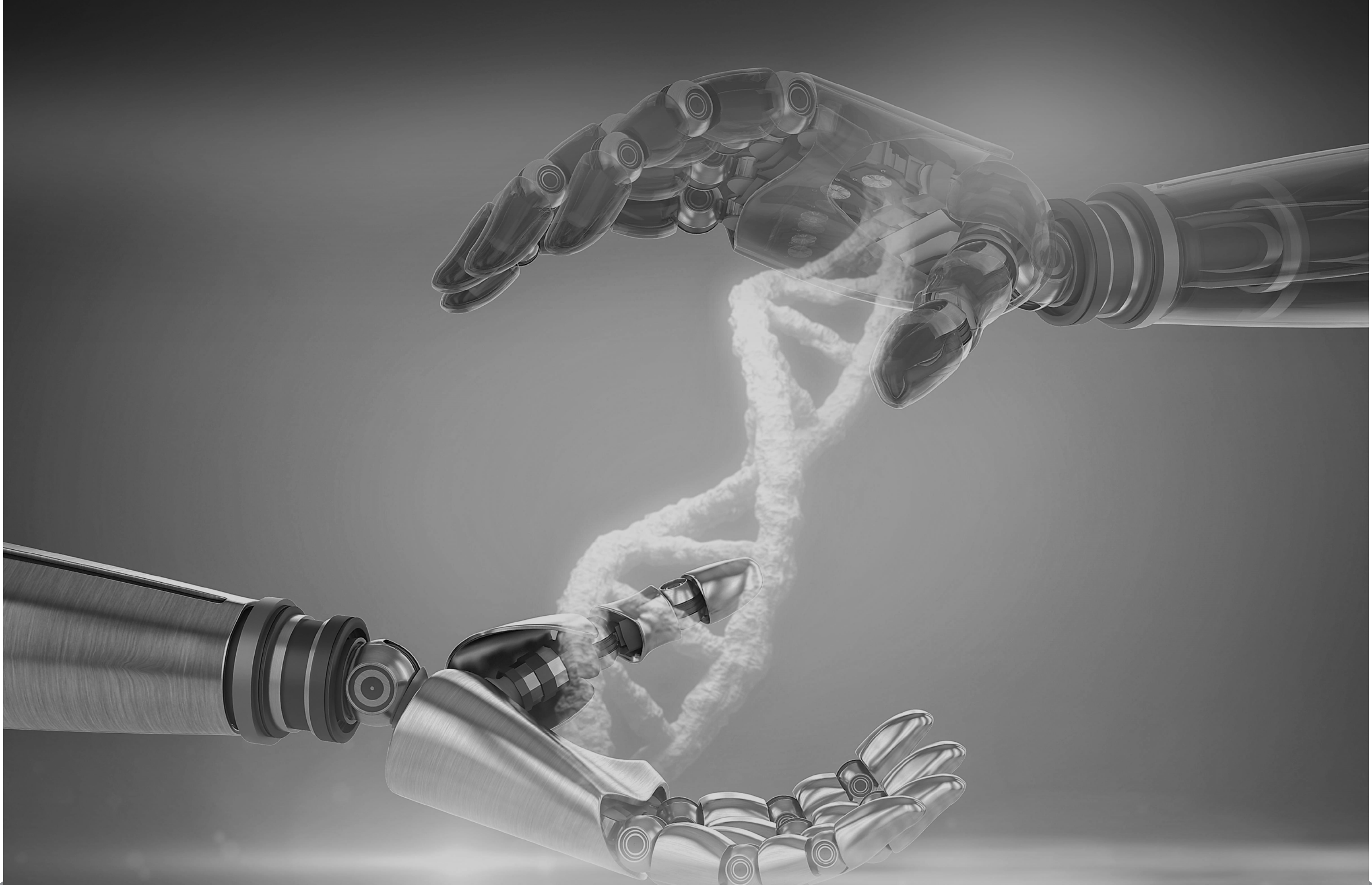
STOCKS DOWN UNDER

19 JANUARY 2021

Emerging Stocks Down Under

"If vampires ever spend less time playing theatrics and living down to their stereotypes, they might take over the world someday."

- Carrie Vaighn (b. 1973), American author



CLINUVEL PHARMACEUTICALS

One for the vampires

MYFIZIQ

Hot body scanner

MGC PHARMACEUTICALS

Beating COVID-19

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Stocks Down Under rating: ★★

ASX: CUV
Market cap: A$ 1.1BN

52-week range: A$12.92 / A$29.85
Share price: A$ 21.84

2020 has not been kind to the shareholders of Clinuvel Pharmaceuticals, the Melbourne-based drug developer whose company-maker is Scenesse, for the treatment of porphyria. On 15 January 2020 the stock was going for over $29. It went below $14 during the Corona Crash and has only recovered to around $21 from there. We think Clinuvel stock will stall for a while yet until the company figures out just what its Next Big Thing is going to be.

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Market cap: A$ 164M

52-week range: A$0.065 / A$1.50
Share price: A$ 1.22

You heard it first from our sister company Pitt Street Research. An issuer-sponsored research report on MyFiziq dated 22 May 2019 gave this Perth-based developer of body measurement software a valuation range of 91 cents to $1.08 per share. At the time MyFiziq stock was only 26 cents. Well, it took until August 2020, but investors who followed our optimism on MyFiziq have done well. The re-rating will likely last a while yet.

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Share price chart

Source: Tradingview

Tuesday 8 October 2019 was a landmark day in the history of the Australian Life Sciences sector. That was that day when America's FDA approved a drug called Scenesse, generic name afamelanotide, for the prevention of a condition called 'phototoxicity' that often occurs in people with a disorder called erythropoietic protoporphyria. It wasn't the first time that an Australian-developed drug had made a home run in terms of its clinical performance, but it was yet more proof that our Life Sciences sector was capable of this sort of achievement. Scenesse's developer, Clinuvel Pharmaceuticals, saw its stock go to an all-time high of $45 per share. Not bad when you could have bought it for under $1 at the end of 2013.

A 20-year overnight success story

Clinuvel had been working towards this moment for many years. Like, 20 of them. Afamelanotide, a synthetic hormone, had originally been worked on by scientists at the University of Arizona before the rights went to an Australian company called Epitan back in 1999. That company, which went public on the ASX in 2001, had wanted to develop afamelanotide as a tanning drug before it realised there were more lucrative opportunities available in various Orphan dermatological conditions. By the time Epitan became Clinuvel in 2006 the erythropoietic protoporphyria indication was firmly in its sights.

So, what the heck is erythropoietic protoporphyria, we hear you ask. Well, you've probably heard of porphyria before. When the body accumulates too many of the porphyrins — molecules the body normally uses to make oxygen-carrying haemoglobin – the result can be pain-causing sun sensitivity and skin redness, among other dermatological problems. The reason you will likely have heard of porphyria it is that it is sometimes associated with mental illness and its most famous patient may have been that mad king, George III of England.

There are eight different types of porphyria out there, of which erythropoietic protoporphyria is one. The 'erythropoietic' part refers to the fact that the process for making red blood cells is messed up, and the 'protoporphyria' part tells you that this is a condition where sun sensitivity is the biggest issue. It's speculated that the legend of vampires may have originated with EPP because people who had it would only go out at night and would drink blood in order to get their red blood cell count up.

This story got to Phase 3 seven years ago

The reason Clinuvel's drug could treat EPP was that it's an analogue of a naturally occurring hormone that increases skin pigmentation, by increasing melanin production in cells called the melanocytes. When EPP patients have more of that juicy melanin, their sunlight tolerance goes up. Clinuvel proved this in a Phase 3 trial for which results became available in November 2013 – when Clinuvel stock was, as we have seen, closer to $1 a share. In that study, Scenesse enabled patients to spend more time in direct sunlight without pain and increased the time to the appearance of the first symptoms of phototoxicity when you shone a standardised light source on their skin. Scenesse gained European approval in 2014, long before the 2019 FDA triumph.

Scenesse's clinical success in EPP turned Clinuvel into a billion-dollar company. These days in the pharmaceutical world the big money lies in so-called Orphan drugs that treat rare disease conditions. You can charge high prices for these drugs and there's less pushback from payers because there are no alternatives. So a small patient population doesn't matter too much, so long as enough of those patients live in countries with well-resourced healthcare systems. EPP may only afflict about 10,000 people around the world, but it tends to hit people with fairer skin, so most patients are in Europe and North America. Given that demographic, Scenesse can potentially become a blockbuster if it's marketed right.

Now comes the hard part…

The trouble for Clinuvel shareholders right now is that it will take a while before Scenesse's sales start to build. They're not bad now – revenue in the year to June 2020 was A$32.6m with NPAT of A$16.6m – but that kind of profitability ordinarily can't levitate a stock above a billion dollars for very long. We've seen this story play out on ASX and other markets many times before when it comes to Life Sciences companies: The stock rises while the drug is in development and then falls once the hard work of building a business is underway.

Now, Clinuvel isn't going to stay just a Scenesse-and-EPP story. There's a pipeline of other indications for Scenesse including variegate porphyria, where the patient gets blisters on sun-exposed skin. There are other products that are pre-clinical, most notably CUV9900, a second-generation alpha-melanocyte stimulating hormone analogue, that could be a more potent skin protector than Scenesse.

However, we don't think this pipeline can provide the excitement that propelled Clinuvel stock over $40. Clinuvel is well funded for the next stage of the journey, with $66.7m cash aa per June 2020. But investors should wait for a while on this one. So, it's only two stars in our book at the moment.

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Share price chart

Source: Tradingview

Every day after his morning run, one of our analysts steps on his Fitbit Aria, a Wi-Fi smart scale. Fitbit is a US-based developer of activity trackers and the Fitbit device on our man's wrist, plus the Aria scale, creates a whole lot of data up in the cloud that helps provide a picture of how he's going in terms of health-related measures, like sleep hours and Body Mass Index. He doesn't like what he sees there, but at least he can track how he's going. The fact that Google agreed to acquire Fitbit for US$2.1bn in November 2019 tells you that these kinds of tools are big business today.

The next Fitbit?

We argue that the Google/Fitbit deal points to the considerable future upside for MyFiziq. This company's MyFiziq smartphone app keeps getting better in terms of what it can measure. The original app just let you track your body dimensions by standing in front of your smartphone half-naked. That in itself was a big step forward because it meant you didn't have to buy any hardware for fitness tracking like Fitbit made you do. In addition, this app was ideal for, say, online apparel retailers because it potentially would ensure that the right size was ordered.

However, that is now all ‘very 2019’. In 2021 the MyFiziq app can also track a whole lot of other things. The fruits of several years of development efforts are now available in CompleteScan, which is basically the old BodyScan from the original app for body dimensions and composition, plus a FaceScan that can unlock various vital signs, most notably blood pressure, plus DermaScan that can track various skin conditions. This is no longer just another fitness app, but something that health and life insurers are going to be very interested in, because of all the data that can be obtained at low cost to catch the disease early. For instance, you can spot diabetes risk with this company’s technology. Put enough Artificial Intelligence and Machine Learnings smarts behind MyFiziq – which is what MyFiziq’s Toronto-based partner NuraLogix provides – and you can potentially jump way ahead of where Fitbit and its competitors have gone. Various multi-trillion-dollar market opportunities should therefore be in MyFiziq’s sights.

MyFiziq’s partners - All for one and one for all

The reason MyFiziq stock took off in a big way back in late August 2020 was because of Bearn. Bearn (bearn.co) is an unusual app where users get paid the more calories they burn while using the app. The thinking is that people are more incentivised to stay fit that way and Bearn can earn big bucks from all the data it collects (subject to the usual privacy regulations, obviously). When the folks at Bearn were creating their app, they put MyFiziq technology behind it, as per a January 2020 agreement. In August 2020 the combined Bearn/MyFiziq app became available in Google Play and the App Store where 25 million pre-registrations were waiting for it. That’s right, 25 million. Instantly there was a heck of a lot of extra would-be MyFiziq users in one fell swoop.

The following month MyFiziq announced that CompleteScan was being integrated into WellteQ, a corporate digital wellness platform. Given the proliferation of corporate digital wellness platforms in recent years, there was nothing particularly ground-breaking about this announcement.. However, we think the Bearn app launch had primed the market to pay attention to the progress MyFiziq was making with potential partners. Before September was out, MyFiziq stock had reached the valuation range Pitt Street Research’s May 2019 research had foreshadowed.

Revenue is coming, but it’s early days

It’s still early days for MyFiziq in terms of revenue, but the Bearn deal was one of the first partnerships where the partner is now live with a commercial app and will be paying MyFiziq US$2 per user per month. Not all of those 25 million pre-registrations will end up as paying customers and MyFiziq’s internal near-term target is only 400,000. But if this works and starts to scale, it will send a strong signal to the market on the viability of MyFiziq’s platform.

We think there’s more upside in the stock since MyFiziq’s recent return to favour. We noted above that Google agreed to pay a lot of coin to get hold of Fitbit. Interestingly, the deal has yet to close because of antitrust concerns, including in Australia, and this has created a lot of press around the digital fitness/wellness space. Once the market figures out that companies like MyFiziq may be the next cab off the rank, we think this story will become more widely known.

We’re a little cautious about the proposed Nasdaq listing since Nasdaq has a habit of requiring a valuation discount from stocks that are already trading elsewhere, as part of the price of entry. However, that’s nothing a good integration deal with another digital wellness or apparel retailing platform can’t overcome. So four stars from us.

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Share price chart

Source: Tradingview

As we all know, the thing that lands COVID-19 patients in hospitals is the storm of inflammation that hits their lungs post-infection. That has led to multiple clinical studies since March of drugs with anti-inflammatory properties. One such trial in Israel evaluated MGC's new ArtemiC drug, which is simply artemisinin plus curcumin delivered in an oral spray designed for better bioavailability. The trial was randomised and placebo-controlled, and the data, which became available on 15 December, was pretty good.

A COVID-19 drug from off your spice rack

In MGC's study, the patients treated with ArtemiC experienced a marked improvement in their COVID-19 clinical risk score. Over two weeks, they got better, whereas the control group worsened. The p-value that the biostatisticians used to compare the two groups was less than 0.04, which is very good. In statistics, if you get a p-value under 0.05, the result is considered 'statistically significant', that is, not very likely to have been caused by chance alone. If you can get it with only 50 patients in a Phase 2 trial, it's quite impressive.

How did MGC's investigators get so lucky? Well, artemisinin, which the doctors will have likely given you if you ever had the misfortune of getting malaria, has known anti-inflammatory properties. So does curcumin, which you can get without a doctor's help just by pulling that jar of turmeric you regularly cook with off the spice rack.

MGC's product delivered enough of both to pack a therapeutic punch, because it formulates them into little fat spheres called nanomicelles. Those nanomicelles improve 'bioavailability' so that more of the drug is available in the body where it's needed than a standard pill or spray.

Yes, MGC is still a medicinal cannabis company

The potential for MGC is obvious: We now have COVID-19 vaccines, but medicine still wants an armoury of anti-COVID drugs that can be used any time the wretched virus somehow regains a foothold. We predict MGC's new product will ultimately get to Phase 3. But what, we hear you ask, is a medicinal cannabis company doing mucking about with artemisinin and curcumin? Well, like any Life Sciences company worth its salt, the opportunity was there for the partnering, and the company had the know-how to take advantage of it back in March when the pandemic was getting underway. We think ArtemiC bodes well for future value creation at MGC in its core cannabis space.

If you've been following the medicinal cannabis space for a while, you may have heard of MGC Pharmaceuticals, because it's been ASX listed since a late-2015 backdoor listing, making it one of the first medicinal cannabis companies to show up here. MGC's technology allows strains of cannabis to be grown that are high in THC or in CBD, the two useful compounds in the cannabis plant. MGC has a laboratory in the Slovenian capital of Ljubljana that has developed two cannabis-based products for the treatment of epilepsy and for dementia, while the team is working on a pipeline of other indications.

The company also has a GMP-compliant production facility for its cannabis-based medicines in Slovenia and it's looking to set up another in Malta. Finally, the company distributes cannabis-based medicines in a number of countries. The latter activity is tiny, but the big money should come from the prescription products it is developing itself.

Going after the hard stuff

What CannEpil for epilepsy and CogniCann for dementia/Alzheimer's have in common is the basic research that went into the product. In each case, MGC specifically bred cannabis plants that would yield the right CBD-to-THC ratio – for CannEpil 20-to-1 and for CogniCann 2-to-3.

What these two products also have in common is MGC's willingness to push them further down the clinical research pathway than other medicinal cannabis companies. A Phase 2b study is now ongoing for CannEpil at Schneider Children's Medical Center in Tel Aviv, Israel's premier institution for paediatric medicine. CogniCann is being tried out in patients with mild dementia in a Phase 2 study at the University of Notre Dame Australia.

We believe CogniCann could yield an important commercial breakthrough. There's a lot of evidence emerging in science that CBD and THC in cannabis can not only be neuroprotective in Alzheimer's but also act against the amyloid plaques and neurofibrillary tangles that show up in the brains of Alzheimer's patients. The upside of this 50-patient study could be huge when you consider the dearth of decent Alzheimer's drugs out there and the millions of older people that are impacted these days. When looking at Actinogen Medical (ASX: ACW) on 1 December we noted that medicine is only now getting round to trying out drug candidates outside those that hit amyloid and another protein called tau. Cannabis-based medicines definitely fit that bill.

At Stocks Down Under we're bullish on medicinal cannabis and we like companies with science and clinical data behind their products. MGC is, therefore, a good candidate to review. Throw in the nimbleness illustrated by the ArtemiC venture and there's a lot to like about this company. And if the Notre Dame Australia study works out, it may prove unforgettable. Four stars.

Pitt Street Research Pty Ltd

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Pitt Street Research Pty Ltd is founded on more than 40 years of combined experience researching companies in a range of different sectors.