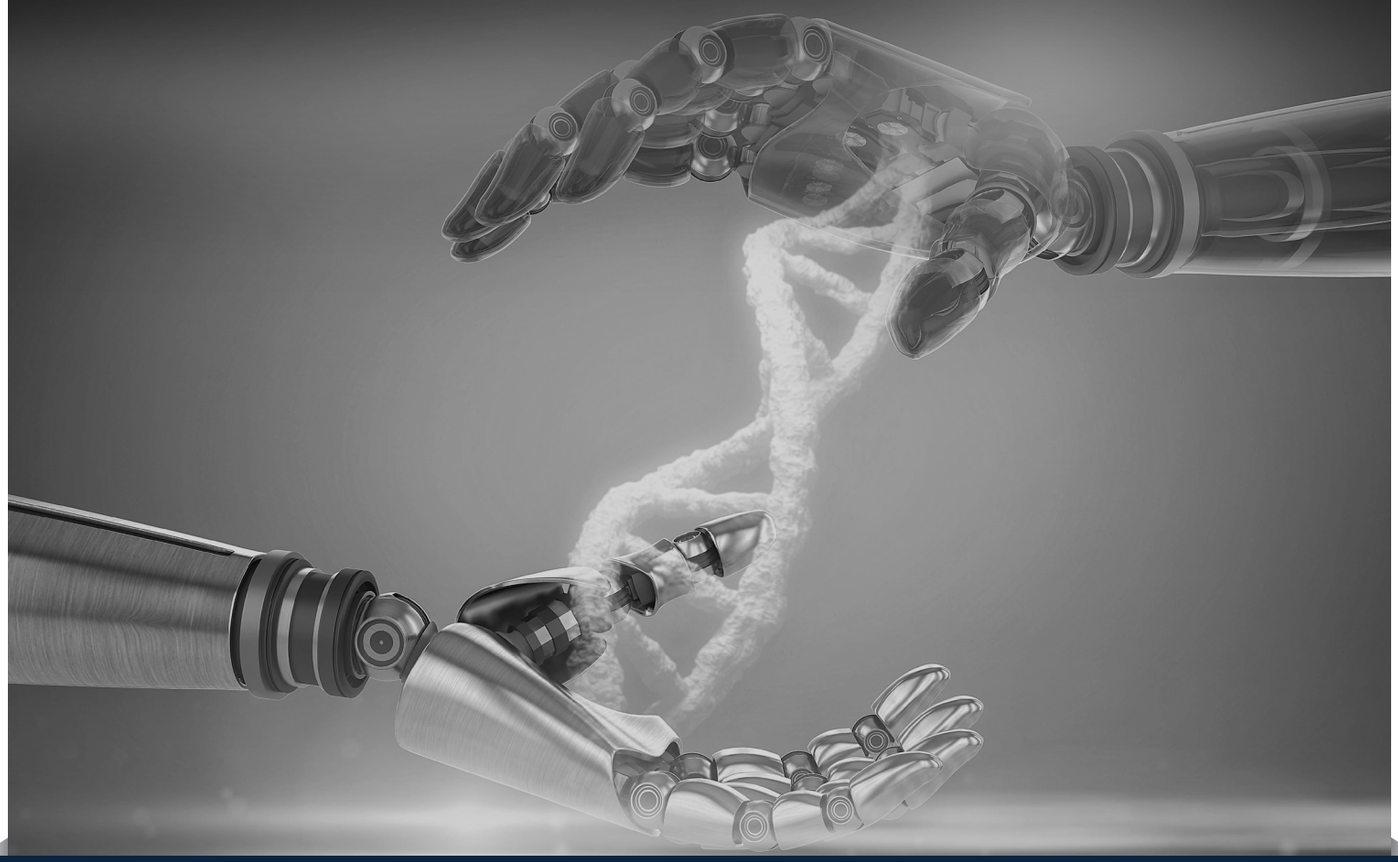
STOCKS DOWN UNDER

8 DECEMBER 2020

Emerging Stocks Down Under

"We are not made of drugs; we are made of cells."

- Cade Hildreth, Founder of BioInformant.com



CYNATA THERAPEUTICS

Stem Cell Revolutionary

NOVATTI GROUP

Ready, set, launch

ONCOSIL MEDICAL

Sirtex 2.0

CYNATA THERAPEUTICS

Stem Cell Revolutionary

Stocks Down Under rating: ★★★★

ASX: CYP
Market cap: A$ 91.4M

52-week range: A$0.58 / A$1.30
Share price: A$ 0.765

The Melbourne-based biotech Cynata Therapeutics is preparing for the day when the Stem Cell Revolution arrives. Stem cells represent one of the most powerful class of medicines yet developed. Cynata, with its Cymerus technology, has one of the best ways to make stem cells at low cost. With Cynata having completed its first partnering deal and rapidly building out its pipeline, we believe this is a four-star opportunity.

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ASX: NOV
Market cap: A$ 62.5M

52-week range: A$0.083 / A$0.43
Share price: A$ 0.275

Headquartered in Perth, the Novatti Group has one goal in mind, to become the one-stop-shop for all for things payment. Currently, the company operates digital banking through transaction processing, card issuance and payment acceptance solutions. The company has seen considerable growth over the last couple of years as it continues to expand globally. While Novatti is not yet profitable, the company is truly ramping up its business, although it's not yet clear when it will cross that all to important EBITDA profitability line.

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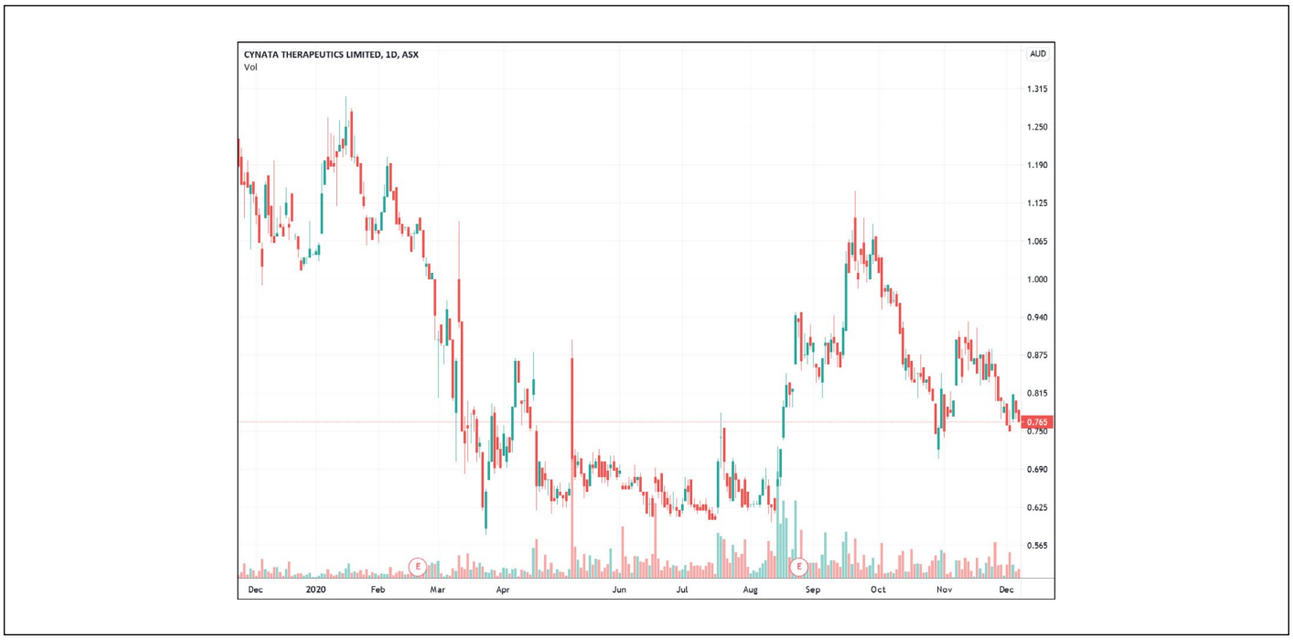
Share price chart



Source: Tradingview

Last month our sister company Pitt Street Research published an issuer-sponsored report on Cynata. You can download it for free at pittstreetresearch.com. If we may say so ourselves, it's not a bad primer on a rapidly emerging field of modern medicine, where that field could contribute to turning Cynata into a billion-dollar company down the track.

You know something is important when it makes the cover of Time magazine. That's happened a few times now for stem cells. On 2 August 2001, there was the cover that showed the American scientist James Thomson with the caption 'The Man who Brought you Stem Cells'. On 7 August 2006, there was, 'The Truth About Stem Cells: The Hope, The Hype and What it Means For You'. And we really liked this one from 8 February 2009: 'How the Coming Revolution in Stem Cells Could Save Your Life'.

This Revolution will not be televised

Stem cells are specialised cells that can differentiate into different tissue types and also secrete various therapeutically useful proteins. They're revolutionary, and therefore worthy of Time covers, because with some of these cells can actually repair and rebuild damaged tissue, not just paper over the cracks. We've known this for a while now. James Thomson became the 'Man who Brought you Stem Cells' by leading the team at the

University of Wisconsin-Madison, which isolated the first human embryonic stem cell line in 1998. That was controversial at the time, because of the word 'embryonic'. Well, 22 years later stem cells aren't controversial anymore, because of the emergence of two kinds of adult stem cells, one called 'Mesenchymal Stem Cells' (MSCs), the other 'induced Pluripotent Stem Cells' (iPSCs). Yeah, it sounds complicated, but stick with us for a moment.

We wrote about MSCs in our 30 July article on Mesoblast (ASX: MSB). MSCs originate primarily in the bone marrow, but you can also get them in other places, such as fat tissue. MSCs are not as powerful as embryonic stem cells, but they can still differentiate into multiple cell types and are known to be potent immune modulators. That capability in terms of treating disease conditions has propelled Mesoblast, which from the get-go in the early 2000s specialised in MSCs, into the leading position in the stem cell field today and a multi-billion-dollar company.

iPSCs + MSCs = $$$$ 4 CYP

iPSCs are a more recent stem cell development. They're normal adult cells reprogrammed so that they can once again differentiate into nearly all different cell types. The 2007 discovery by Japan's Shinya Yamanaka that this was possible was ground-breaking and led to a Nobel prize in 2012 because once a cell has been reprogrammed to the pluripotent state, it can expand in exceedingly large numbers just like embryonic stem cells.

This brings us to Cynata's Cymerus technology. What this company can do is use iPSCs to make large amounts of MSCs, which basically means the best kind of stem cell at consistent quality and the lowest possible price. Cymerus originates from work at the University of Wisconsin-Madison on a powerful MSC precursor called the 'mesenchymoangioblast'. The relevant intellectual property was licensed by Cynata, which in turn was backdoor-listed on ASX in late 2013. The company spent the next two years developing iPSC methods of making its mesenchymoangioblasts at scale. Since then the company has optimised the production process, validated it and tested it in laboratories and in the clinic.

Moving into Phase 3

To move its technology forward, Cynata first needed to prove that Cymerus MSCs worked therapeutically. The company chose Graft-versus-Host-Disease as its proof-of-concept indication and ran a maiden clinical study in 2017 and 2018. The data was so good, with better response rates and survival than what you'd expect, that Japan's Fujifilm, which wants to be a serious stem cell player, licensed the global rights in 2019. So far, so good.

The other thing Cynata needed to show that it was credible was a product pipeline. Beyond GvHD, Cynata now has multiple products in development, thanks to a rapidly growing body of work in indications such as Critical Limb Ischemia (CLI), asthma and heart attack. Cynata is now working on bringing these products into the clinic and a Phase 3 clinical trial will shortly to get underway in osteoarthritis. You read that right – thanks to Australian government funding, Cynata will soon be in a position to participate in a clinical study the size of a Phase 3. Next year the Fujifilm GvHD indication moves to Phase 2.

So, why can you still get Cynata for under A$100m, when comparable companies are in the billions? Maybe it was Cynata's decision in October 2019 to turn down Dainippon Sumitomo's offer to buy the company for A$204m. And maybe the recent decision by the FDA to turn down Mesoblast's application for approval of Remestemcel-l in GvHD hasn't helped either.

However, we're not worried all that much. Mesoblast is moving forward with its other late-stage products. Cynata is moving forward in conjunction with Fujifilm in GvHD. And Cynata's pipeline just keeps on growing, as does the evidence that its cells are therapeutically effective. All this warrants four stars, in our view.

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Share price chart

Source: Tradingview

The big five

Novatti operates under two main revenue streams: Novatti Platform and billing solutions & transaction services. While we are not provided with a breakdown of the geographical sales mix, the company does split out its revenue into Australia at $3.6m (FY19: $2m) and other countries at $7.5m (FY19: $6.4m). The company's total revenue for FY20 was $11.1m (FY19: $8.4m).

The Novatti Platform supports mobile and 'alternate' payment technology. 'Alternate' payments include gift cards and vouchers. The platform is considered one of the company's two 'principal activities.' This division saw flat growth during FY20 with $2.3m in revenue. However, despite the flat revenue, expenses grew drastically causing a 26.5% decline in EBITDA to a negative $2.2m. We are not concerned with this sharp increase in expense and will discuss this below.

Billing solutions and transaction services are the company's other 'principal activity' and produce the majority of Novatti's revenue and growth. The billing solutions segment is focused on the utility industry, where it earns yearly licencing fees for providing billing and customer information platforms. During FY20 the billings segment produced $2.2m in revenues and the company's only positive EBITDA of $294,662.

The transaction segment is significantly broader and earns revenue from four specific avenues: fees from its software suite, the processing of top-up vouchers, settling financial transactions and the fees from the company's 'Prepaid' reloadable cards provided by its banking services arm. This segment provides the majority of the total company's revenue at $6.5m after growing 68%.

Transaction services came very close to producing an EBITDA profit during this period after reducing its loss from $1.8m during FY19 to $94,420 in FY20. This does mean that FY20 was the first year that the billing solutions and transaction services division generated a total EBITDA profit. This is a rather significant development and we remain confident that FY21 will see both of this division's segments produce EBITDA profitability.

Expense increases, no cause for alarm

The company's expenses are a bit more complex than they appear at first, while Novatti operates two main revenue divisions, the company actually has three operating divisions: Novatti Platform, billing solutions & transaction services and banking services. The total company produced an EBITDA loss of $8.5m during FY20, a 100% increase year-over-year.

While we believe billing solutions & transaction services will produce an EBITDA profit during FY21, this is only possible due to most of the company's revenue being allocated to this division without the expenses. For example, included in the transaction segment's revenue is the transaction fees from the 'Prepaid' reloadable cards. The expenses related to the cards are placed on the banking services division's books. This is one of the reasons the largest driver for the company's EBITDA loss is the banking services division at a loss of $4.7m for FY20.

Although the company's overall expenses increased strongly in FY20, most of them are directly related to Novatti's expansion, i.e. staff hire, hosting fees etc. Novatti is currently undergoing significant expansion through the development of a broad range of strategic partnerships. Therefore, we believe these expense increases are necessary to prepare the company for future growth and are no cause for concern.

Ready, set, launch

FY21 has already seen a number of significant developments as Novatti put its growth engine into overdrive. For example, on 2 October 2020 the company announced it had received regulatory approval to issue and manage means of payment in New Zealand. This will allow it to expand fully into New Zealand, a new and open market.

Another major event happened on 2 November 2020 when the company announced a partnership with Google Pay and Samsung Pay allowing Novatti's Visa Prepaid cards to be supported through these company's in-app and online payment devices. We believe this will be a significant value add for both the company's existing clients and the pitch given to prospective ones.

Lastly, on 23 November 2020, Novatti announced a significant partnership with UnionPay. This partnership has allowed Novatti to become a UnionPay acquirer, which means UnionPay customers will have full access to Novatti's range of services in Australia. We believe this is another significant reason for businesses to sign-up with Novatti as it opens to door to many Chinese-Australian consumers that use UnionPay.

It's still early days, but we are bullish

Novatti is still in its early stages of development and its market cap of $62.5m really shows it. The company achieved 46% revenue growth during 1Q21 and stated that it is 'continuing (the) trend of average annual revenue growth of around 44%.' Using the company's 44% revenue growth target as a guide to FY21 results, this values the company at an FY21 EV/Revenue ratio of 4.2x. Combined with the fact that 1Q21 produced the company's first-ever positive EBITDA result of $101,000, we believe the market currently undervalues Novatti. Four stars from us.

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Share price chart

Source: Tradingview

Traditionally when it comes to cancer, there have only been three ways to deal with it – surgery, chemotherapy and radiotherapy. More recently we've seen a fourth way emerge, which is immunotherapy. However, it's the radiation part where OncoSil Medical believes it has created new value. Time was that the patient referred for radiotherapy was placed under an 'external beam' of radiation which would do a lot of collateral damage while also killing cancer. With OncoSil (and other competing products), the surgeon can place radioactive beads at the site of the tumour and the therapy is much more targeted. They call this new style of radiotherapy' brachytherapy', the 'brachy' part coming from the Greek word βραχύς, meaning 'short'.

100 shades of gray

If you've heard about brachytherapy before, it was probably because of Sirtex Medical. That company ultimately made it to over A$200m in revenue and A$75m in EBITDA with beads called 'SIR-Spheres' made of radioactive Ytrrium-90 (the 'SIR' part stood for 'Selective Internal Radiation'). The data that got the company started dated from the late 1990s, but by 2018, after a bidding war with America's Varian, the Chinese alternative asset management firm CDH Investments was paying A$1.9bn for Sirtex.

OncoSil is a little like the Sirtex from 20 years ago, but for pancreatic cancer. The beads implanted at the site of the tumour are radioactive Phosphorous-32. Over the next 81 days, those beads emit 100 'grays' of radiation, which is a lot of radiotherapeutic firepower. In patients where the cancer is inoperable and locally advanced (that is, serious but still only in the pancreas), and where those patients are also on chemo, the beads produce a median overall survival of 16 months in one key, 50-patient, study called the PanCO study, for which data was published in July. Okay, in PanCO there was no control arm, but the 16 months is about double the eight months which other studies suggested you'd get with just chemotherapy. It was OncoSil's data, and, importantly, the safety profile it established, that allowed OncoSil to get CE Mark approval for Europe back in April 2020.

A US$3bn market opportunity

Pancreatic cancer is, thankfully, relatively rare, with only 58,000 cases in America in 2019, but it's an aggressive one, with life expectancy of only a little over a year from diagnosis. The data that OncoSil has obtained on the effectiveness of its device, therefore, suggests a significant opportunity with a global addressable market probably north of US$3bn.

The CE Mark allowed OncoSil to start tapping that US$3bn for the first time in a serious way. Other jurisdictions have cleared the device since the April breakthrough – New Zealand in May, Singapore in July, Malaysia in August and Switzerland in November. Australia and Hong Kong are coming in 2021.

However, we are still more or less at the start-line in terms of sales – this company's first commercial sale was only made in late October, for a patient in New Zealand. Why isn't OncoSil booming yet? Well, selling medical devices is a complicated business, so it takes a while from initial approval to when the supply chains are all set up and the sales reps can start to knock on doors. However, once the word gets out in 2021 that there's an effective therapy on the market, we think sales will start to creep upwards. OncoSil is well funded for the interim – it held $20.5m cash per the end of September 2020.

Plenty of room to evolve this one

A big deal for OncoSil will be the all-important US market. The company used the existing data to file in July 2020 under that Agency's 'Humanitarian Device Exemption' rule and it expects to hear back from the Agency by early next year. The approval there will be specifically for cancer of the pancreatic bile ducts, but obviously there's room to increase the indications as more data is gathered.

Which brings us to another important aspect of the OncoSil story – the fact that it's potentially useful outside the locally advanced setting that was the basis for the current approvals. You could use these beads where the tumour has metastasised but where you want to shrink the primary tumour, thereby cutting the pain level of the patient. Or you could use it to shrink a tumour that is still operable to make the surgeon's job easier. We expect that as OncoSil matures, it will look into these new indications.

Currently, OncoSil stock is trading way below its potential, capitalised at only about $120m of which, as we noted above, $20.5m is cash. Companies gaining approval for devices as powerful as OncoSil's are generally not this cheap on Nasdaq and elsewhere and it's strange that OncoSil should be this inexpensive when the current Chairman is Dr. Chris Roberts, the man who took Cochlear to new heights when he was CEO between 2004 and 2015.

OncoSil's problem is that people have been waiting seven years for the company to get this far and investors have become somewhat fatigued. That's nothing US approval and a gradual increase in non-US sales in 2021 can't overcome. Ahead of that, OncoSil is four stars for us.

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.

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