

# Emerging Stocks Down Under

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- Epictetus (50 CE ~ 135 CE), Greek Stoic philosopher



## ANTISENSE THERAPEUTICS

Beginning to make sense

### IXUP

UP in the name, DOWN in the game

## **EXOPHARM** Ahead of the curve

## **ANTISENSE THERAPEUTICS**

Beginning to make sense

#### Stocks Down Under rating: $\star \star \star \star$

#### ASX: ANP Market cap: A\$121M

52-week range: A\$0.076 / A\$0.27 Share price: A\$0.22

The name Antisense may seem a bit confusing, but in medicine antisense makes a lot of sense. Antisense Therapeutics uses an antisense construct made out of nucleic acids to block the 'sense' of a disease-causing gene. The company has spent the last 20 years working with the legendary lonis Pharma to develop an antisense drug and reckons it's getting closer to having one in late-stage clinical trails. We believe the upside could be significant.



## IXUP

UP in the name, DOWN in the game

Stocks Down Under rating:  $\star \star$ 

#### ASX: IXU Market cap: A\$109M

#### 52-week range: A\$0.019 / A\$0.23 Share price: A\$0.16

Based in Paramatta, NSW, IXUP is a software company active in data management and handling. With data becoming a very precious asset, it has become increasingly difficult for companies to protect their data while sharing it with business partners. IXUP allows companies to not only analyse and store their data, but also to prevent misuse through constant tracking and oversight.



## **EXOPHARM**

Ahead of the curve

Stocks Down Under rating:  $\star \star \star$ 

ASX: EX1 Market cap: A\$73.8M 52-week range: A\$0.23 / A\$1.00 Share price: A\$0.47

Exopharm is a Melbourne-based clinical-stage biotech company we last covered in Friday Beers with Marc & Stuart on <u>23 April 2021</u>. The company's focus is exosomes, or, more specifically 'Extracellular Vesicles' (EVs), which are tiny bubbles secreted naturally from almost all cells that traffic molecules from one cell to another. Exopharm previously focused on Naïve EVs (NEVs) with potential application in regenerative medicine. It has since shifted its focus to Engineered EVs (EEVs) for use in drug delivery. With a substantial advantage over its competitors due to its proprietary LEAP technology, Exopharm is currently looking to further develop its well-diversified pipeline and license out its technology.



## **ANTISENSE THERAPEUTICS**

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#### Share price chart



Source: Tradingview

#### An arduous testing process

Essentially, antisense drugs make use of non-coding genes as a template for mRNA to direct protein synthesis. For the most part, antisense refers to the act of silencing genes. If a drug is able to successfully silence a particular disease-related gene, e.g. the gene associated with Multiple Sclerosis (MS), then the drug can be used to treat that disease.

Antisense has access to the rapid drug discovery process of Ionis Pharmaceuticals (Nasdaq: IONS), the pioneer of antisense drugs for the treatment of genetic-based diseases, now capitalised at north of US\$5bn. Using Ionis' processes, a drug candidate can be designed within hours. You read that right...hours. After that, the development process will still take years, with clinical trials and all, but well-designed drug candidates are a walk in the park for this company.

Antisense currently has three drugs in its pipeline: ATL1101 to treat prostate cancer, ATL1102 for MS, Duchenne Muscular Dystrophy (DMD) and asthma, among other diseases, and ATL1103 to to stop certain kinds of hormone growth (e.g., insulin). Eventually, the company believes that ATL1103 could also be used for cancer treatment.

ATL1102 and 1103 are much further along in their development process than ATL1101 right now. Numerous trials for ATL1102 have been run, some of them in collaboration with Teva Pharmaceuticals (TLV: TEVA),

the Israeli pharmaceutical company. ATL1102 was licensed to Teva in February 2008 and they conducted a phase IIa clinical trial to see the effects of the drug on MS. A IIa clinical trial is an important step in any drug's development, usually referred to as a 'proof of concept study'. During this trial, a small number of human patients are used to test the efficacy and safety of the drug.

The results from the trial were a mixed bag. While ATL1102 showed promise in treating MS, it was not enough to keep Teva on board, resulting in the license being terminated in 2010.

The ATL1103 phase II clinical trials began in April 2013, with a focus on treating acromegaly. The results were quite successful and Antisense began to plan a phase III trial in late 2014, while looking for a partner to help further develop the drug.

#### **Partners and licensing**

Antisense received approval to conduct an ATL1103 study with a higher dosage in December 2014. Using this approval, Antisense signed an agreement to license the drug to US-based Strongbridge Biopharma (NASDAQ: SBBP), known at the time as Cortendo AB, in May 2015, who started the trial in September of that same year. By this time, Antisense had communicated to its shareholders that its main strategy would be to license its drugs to other companies in hopes of getting them to market quicker.

During this time, Antisense had been working on improving ATL1102 and its ability to treat MS. An early access program was initiated in October 2015 with MyTomorrows, a Dutch healthcare company specialising in linking patients with developing treatments.

Antisense also filed an IND application for phase IIb trials in April 2017, which the FDA granted. However, the company was only allowed to use a low dosage due to concerns that the FDA had after reviewing previous trials. During this time, the company began to test ATL1102 for DMD, a disease that has symptoms like MS, but affects the body in a significantly different manner.

Phase II DMD clinical trials began in July 2018 and switched the Antisense's focus from MS to DMD as these trails produced stellar results. Antisense began to file applications for the use of ATL1102 in children with DMD. Having received the pediatric disease designation in September 2020, ATL1102 could be on the fast track to market approval.

#### When the stars align

It seems that everything is finally falling into place for Antisense. The company is well on its way to securing all the relevant patents and regulatory approvals, and it seems likely that ATL1102 will soon move on to phase III trials.

We believe this grant Antisense a huge competitive advantage. Companies targeting DMD treatment are few and far between, but there are many companies treating MS (e.g., Neuroscientific Biopharmaceuticals ASX: NSB | see 25 May 2021 report).

The FDA will often prioritise paediatric drugs. Therefore, using its paediatric designation, the company has submitted a Fast-Track Designation request for its US Phase IIb and III studies. If accepted, the timeline for the commercialisation of ATL1102 would be shortened by a considerable amount. On top of that, Antisense succeeded in listing ATL1102 as an orphan drug in Europe, which grants the company exclusive rights to the drug for ten years once it hits the market. Antisense expects to finalise its IIb trail design of ATL1102 in non-ambulant DMD patients in Europe during the third quarter of 2021.

We must also remember that other use-cases for the ATL1102 and 1103 are still being researched and the company still holds the rights to ATL1101. As such, we believe that Antisense can now begin capitalising on its research and testing and is finally beginning to make sense as an investment.

With slightly over \$10m in cash, Antisense has enough runway for over two years at its current burn rate. The company has not aggressively raised capital so far, but investors should expect one as ATL1102 gets closer to a market release, although management expects its R&D costs to be eligible for the Australian Government's R&D Tax incentive with an approximate 43.5% rebate of costs. Based on all the aforementioned factors, we believe Antisense is a four-star investment that has potential for exceptional returns. But be mindful of the risks, which could be significant, specifically the risk of the company not being able to bring ATL1102 to arket.

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#### Share price chart



Source: Tradingview

#### **First world problems**

One of the major difficulties faced by companies in modern times is the handling of data. It doesn't matter whether you run a chain of retail stores or a tech start-up, you almost certainly have data that contains trade secrets and other information that would be damaging if it was leaked. While it is not that difficult to safeguard your data if you are keeping it stored offline, security is an issue if you want to store and share sensitive data online.

This is where IXUP comes in with its platform to "unlock the true value of your data" as stated by IXUP itself. For example, one of the main features of the IXUP platform is the ability to perform analysis on encrypted data. Encrypted data is data that is hidden from the viewer unless they have a decryption key. IXUP uses the AES-256 protocol, considered the industry standard due to its extreme difficulty in breaking it using today's computing technology.

IXUP has a special focus on privacy and collaboration. The two main use cases for the platform are comarketing and multi-party analytics. Co-marketing allows one or more companies to effortlessly share and analyse data without compromising the privacy of their customers and the integrity of the data. All the companies collaborating have full control over their data and the way it is handled and shared.

In multi-party analytics, government agencies can combine their data sets to create better policies. Or companies can compare their customer base and market data with another company to see if they are a potential fit for a merger.

Simply put, IXUP solves the first-world problem of privacy and security when it comes to online data. We live in a world where information is a very important commodity and IXUP can ensure that companies can generate maximum value from their data while keeping it secure.

#### Forming partnerships

IXUP was founded in 2011 and listed on the ASX in 2017. Since its inception, IXUP has been targeting both companies and government agencies. It has tried to focus specifically on the healthcare sector given that collaboration in the healthcare space, for instance between departments and hospitals, is complicated due to the sensitivity of patient records and associated privacy issues. This is the main selling point of IXUP's platform as it provides a means of in-depth, AES-256 encrypted, highly controllable collaboration that ensures a patient's privacy.

To that end, IXUP presented its technology at the Healthcare Leaders Forum in August 2018, outlining the benefits of data collaboration in the healthcare sector. The company also became an approved cloud services supplier of the Australian government in June 2019, although it has struggled to land contracts with government agencies so far.

What we find more interesting, though, is that IXUP spent the better part of 2019 and 2020 developing relationships with companies in Australia, New Zealand and the US. It was selected for Austrade's Landing Pad program in November 2019. Landing Pad is a US-based hub that provides advisory services to start-ups and small companies looking to expand in the US. It also signed a trial agreement with the NIB Group (ASX: NHF | see 14 December 2020 report), the Australian health insurance company.

Having achieved the so-called Five Safes data framework capability (that allows handling of confidential and sensitive government data), IXUP is planning to achieve significant growth in the next few years.

That said, we are a little bit cautious about IXUP's ability to sign new customers. Until now, the company has had trouble forming revenue-yielding partnerships. There have been plenty of partnerships to further develop the company's technology and to explore potential new revenue streams, but the increase in revenues is yet to materialise.

IXUP has been trying to address that. In order to improve its services, the company acquired DATAPOWA in May 2021. DATAPOWA is a marketing analytics company that should help IXUP improve its platform for comarketing services by providing its clients with more powerful tools to collect and analyse data. The company believes that DATAPOWA would be beneficial for almost all of its revenue streams and could unlock US\$1tn in value.

#### Share price is well ahead of revenues

For IXUP, the biggest problem is finding companies that are willing to go the distance, i.e. from trial or partnership all the way to generating revenue for IXUP. So, while we do not doubt that IXUP has a viable product that could be useful to a lot of companies, we have failed to find any plausible reason why IXUP should suddenly achieve explosive growth. We believe that the DATAPOWA acquisition, while definitely beneficial, will only slightly accelerate the company's growth. Growth that is currently moving at a snail's pace.

While we do think that IXUP's revenues may lift off at some point, we believe that meaningful and impactful growth is still quite far away. And much of it has already been factored into the current share price, judging by the current market cap of \$109m with revenues of less than \$100k in the 12 months through December 2020. As such, we see IXUP as a two-star investment that has had trouble growing in the past and will continue to struggle going forward.

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#### Loading and leaping

If you've been following the field of stem cells over the last decade or so will likely already have heard of exosomes. Many thought leaders in the regenerative medicine space think that the therapeutic power of stem cells lies in the exosomes secreted by such cells. A few years ago, Exopharm founder Dr. Ian Dixon and his colleagues set out to find a better way to make exosomes. Historically, this field was held back due to the difficulty of isolating and purifying the exosomes from biological matter. This problem was solved with a technology called Ligand-based Exosome Affinity Purification, or LEAP for short. LEAP is really just a version of the 'affinity chromatography' that science has been using for decades to pull substances of interest out of a biological sample, but in terms of producing exosomes there's no technology as effective.

When Exopharm went public on the ASX in 2018, the intention was to use LEAP to build a pipeline of regenerative medicine products. However, in mid-2020 the company made a big pivot from producing Naïve Extracellular Vesicles (NEVs) for regenerative medicine to producing Engineered EVS (EEVs) for drug delivery. Reading about various licensing deals in the exosome space, Exopharm realised the big money was going to be in drug delivery, not in regenerative medicine. A good example was a deal that Takeda (TYO: 4502), a major Japanese Pharmaceutical company, did with a privately held exosome technology company called

Evox Therapeutics in March 2020. The two companies agreed to work on various rare diseases using Evox's technology, and, if all goes to plan, Evox picks up US\$882m in upfront, development and commercial milestone payments. That's right, US\$882 million from the world's tenth-largest pharma company.

In order to get a piece of that action, Exopharm went out and licensed two technologies that would allow drugs to be loaded into its LEAP-produced EVs and allow those EVs to target cells of interest. The technology to load drugs is called – you guessed it – 'LOAD', while the targeting technology is called 'EVPS'. LEAP, LOAD and EVPS are why Exopharm thinks it can become the new leader in the exosome space.

#### Better than the competition

Exopharm currently has three EEVs in the works – Fortrexo-CoV, for treating COVID-19 infection, Cognevo for neurodegeneration and PlexoDox for cancer. Fortrexo-CoV is particularly interesting because it has the potentially to be an anti-COVID agent. Fortrexo-CoV isn't a vaccine, but rather the product is designed to be administered after a patient has already been infected. Still, Fortrexo-CoV is not unlike the Pfizer and Moderna vaccines as they deliver RNA from the virus wrapped in artificial Lipid Nanoparticles (LNPs). The product can target COVID-infected cells, because it's attached to a copy of the virus' 'spike' protein. With COVID-19 likely to be with us for a while yet and strains, like Delta, emerging that the first generation of vaccines might not be able to deal with so well, we believe Exopharm's programme has got potential.

Exopharm can manufacture EEVs with relative ease, proving to us the company's technological superiority over its competitors in the EV space. But obviously the products have to work in terms of hitting their target and this is where Exopharm seems to be able to deliver the goods. During an in vitro study, PlexoDox – an EEV that can deliver the cancer drug Doxorubicin – killed a significantly higher number of cancer cells than standard Doxorubicin delivery methods. While considered a highly effective chemotherapy agent, Doxorubicin has numerous side effects that PlexoDox could potentially decrease.

#### **Onwards and upwards**

Exopharm has made it very clear that its focus is the EEV space and the company is looking to form partnerships with companies that have new or old drugs in need of better delivery solutions. The company also plans to make its proprietary LEAP technology available for other players to license, something that we believe will result in a stable revenue stream in the years ahead.

To help achieve its EEV vision, Exopharm raised \$12m at 72 cents in April 2021, funding the company until at least the end of 2022. By this time, Exopharm may have secured the first of its potential licensing deals. Based on the number of possible applications for exosome-based medications and the clear advantages brought about by the LEAP technology, we believe Exopharm is ahead of the curve when it comes to the EV space. When we combine this with the fact that investors can pick up shares for 35% less than when the company last raised capital, and an unlikely need to raise more soon, Exopharm is a clear four stars for us.

#### Pitt Street Research Pty Ltd

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