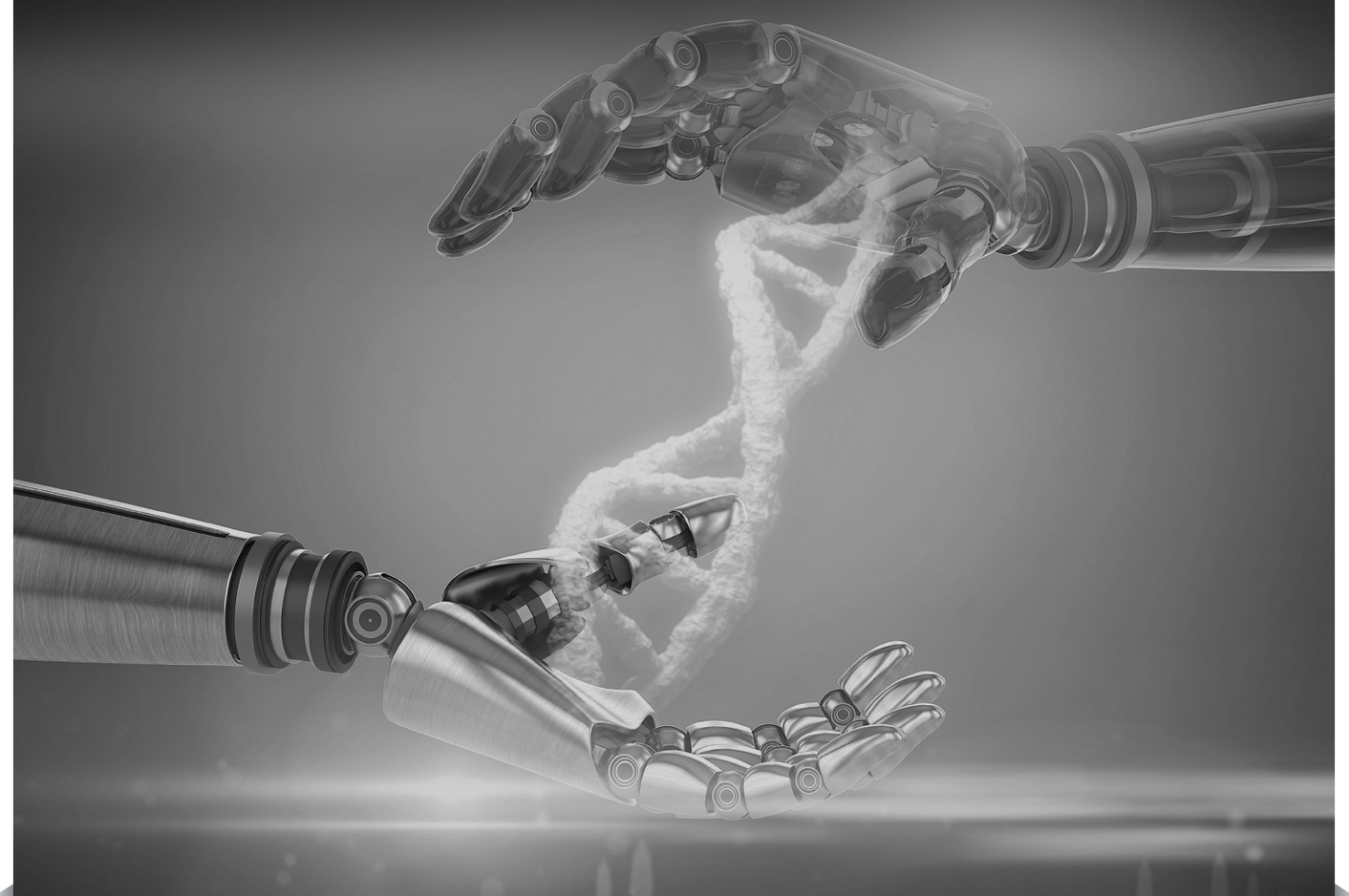
STOCKS DOWN UNDER

17 JAN 2023

Emerging Stocks Down Under

“Buy less. Choose well. Make it last.”

- Dame Vivienne Westwood (1941-2022), New Wave fashion designer



NEUREN PHARMACEUTICALS

FDA approval likely coming soon

NEUREN PHARMACEUTICALS

FDA approval likely coming soon

Stocks Down Under rating: ★★★★

ASX: NEU
Market cap: A$1.2BN

52-week range: A$2.93 / A$9.08
Share price: A$8.90

There are very few Biotechs that have more than doubled in the last year. Neuren Pharmaceuticals, however, is one such company. The company's flagship asset Trofinetide - also known as NNZ-2566 - has passed all clinical trial phases and is being examined by the FDA as a candidate drug to treat Rett Syndrome, a rare neurological disorder. A regulatory decision is due in the next couple of months and we think shareholders can be optimistic about the prospects of approval. We also think that Trofinetide's approval for Rett Syndrome can be just the beginning for this company's prospects, considering it has other candidate drugs in the clinic as well.

Share price chart

Source: Tradingview

It has been a long wait

Neuren listed on the ASX 18 years ago, in January 2005. Although it has been trying to develop Trofinetide ever since, it was in 2018 when things really got moving. It signed a deal with San Diego-based company Acadia Pharmaceuticals, giving Arcadia the North American rights to Trofinetide in the event of commercialisation. In return, Acadia agreed to fund a phase III trial for Rett Syndrome and commercialisation costs if and when it entered the market.

Rett syndrome is a rare brain disorder that leads to severe impediments, such as a loss of motor skills and language. Rett syndrome becomes apparent after 6-18 months of age and almost exclusively impacts females. There are currently no FDA-approved medicines for this disease.

The Arcadia-funded Phase III trial was a complete success, meeting the primary endpoints on a statistically significant basis. After the trial was concluded in late 2021, Neuren and Acadia made their case to the FDA during 2HY22. The companies are expecting a result by mid-March CY23.

The wait will be worth it

Given the experience of Cyclopharm (ASX:CYC) with the FDA, we cannot say with certainty Neuren has approval in the bag, although we still think it is more likely than not, considering how far Neuren has come. If the FDA gives the green light, a lucrative market opportunity awaits. Arcadia forecasts US$500m in sales for Rett alone and only in the US market. At a 12% royalty, this would equate to $85m in royalties. And with Arcadia covering all the costs, this would be a significant profit margin for Neuren.

For FY23, which is the calendar year for Neuren, consensus estimates expect $103.1m in revenue and $75m in EBITDA, well up from $15.1m in revenue and negative $6m in EBITDA expected for FY22. The company's FY23 EV/EBITDA and P/E multiples are 14.5x and 15.9x respectively. The exponential increases in revenue and earnings might be hard for some investors to believe, especially those unfamiliar with Biotechs. But when you consider the recent example of Telix Pharmaceuticals, which has made US$100.4m (A$149.7m) in just 9 months since launching its prostate cancer imaging agent Illuccix in the US, we think consensus estimates do not appear too unreasonable – assuming commercialisation goes to plan of course.

Not just a one trick pony

Neuren is also advancing Trofinetide in relation to Fragile X syndrome, currently in a Phase II clinical trial. Fragile X is another neurological disorder, impacting between one in 4,000 - 7,000 males and between one in 6,000 - 11,000 females. It is the most common inherited cause of intellectual disability and the most common cause of autism. As is the case with Rett Syndrome, there are currently no approved medicines.

Neuren's deal with Arcadia also covers Fragile X Syndrome, leaving the latter company with commercial rights for North America. Neuren would get double-digit royalties from the sale of Trofinetide and retains rights for the rest of the world, at least for now. After the USA, we think the next market Neuren will target is Europe, considering that the company successfully obtained Orphan Drug designation for Trofinetide in relation to both Fragile X syndrome and Rett Syndrome.

Neuren is not just reliant on the success of Trofinetide. It has another asset, NNZ-2591, that is in multiple clinical trials for multiple neurological diseases that are larger than the market for Rett syndrome. These include Prader-Willi syndrome, Pheland McDermind syndrome, Angelman syndrome and Pitt Hopkins syndrome. With a US$27m cash balance as of 30 September 2022, not counting the US$10m milestone payment received in October, we don't expect the company to need capital any time soon.

There's still some risk, but it's relatively low for a Biotech

The biggest risk with this company is that FDA approval is not given. Either the application could be rejected outright or the FDA could request further information. The recent example of Cyclopharm (ASX: CYC) illustrates that shareholders can regard the latter as being just as bad news as the former judging by CYC's share price drop following the FDA's request for more information. You could even argue that the impact would be worse on Neuren than Cyclopharm, given the latter has already commercialised its own technology in 60 countries other than the US, whilst Neuren has none at all.

There is also the risk of further shareholder dilution. We think it is inevitable that capital will need to be raised in due course to fund Phase III studies, and even though the company claims to be fully funded for its current Phase II programs, circumstances can change. We also note that investors may not like that this company will not be getting as big a share of revenues it would get if it commercialised Trofinetide all by itself. Be that as it may, the path to market would have been more difficult without the support of Arcadia, although obviously not impossible, as Telix Pharmaceuticals has shown.

But if you're an investor who is disappointed to have missed out on Telix and is looking for a similar opportunity, you'd be hard pressed to find a better one than Neuren. Some risk-averse investors may prefer to wait until FDA approval. We think there's not too much longer to wait either way and that there is substantial further upside from there as Trofinetide is commercialised in the US, and it progresses NNZ-2591 through the clinic. Four stars.

Pitt Street Research Pty Ltd

3 Spring Street, Sydney, NSW 2000, Australia

Stocks Down Under gives you an information advantage to better invest and trade in ASX-listed stocks!

Stocks Down Under (Pitt Street Research AFSL 1265112) provides actionable investment ideas on ASX-listed stocks. The Content is financial advice but is not (and cannot be construed or relied upon as) personal financial advice. No investment objectives, financial circumstances or needs of any individual have been taken into consideration in the preparation of the Content. Please make sure that investing in such products is suitable for your circumstances, and ensure you obtain, read and understand any applicable offer document.

Financial products are complex, entail risk of loss, may rise and fall, and are impacted by a range of unpredictable market and economic factors.

Stocks Down Under/Pitt Street Research directors and staff may own shares in the companies mentioned in our articles, videos, reports and analyses.

You are receiving this email because you subscribed to our newsletter.