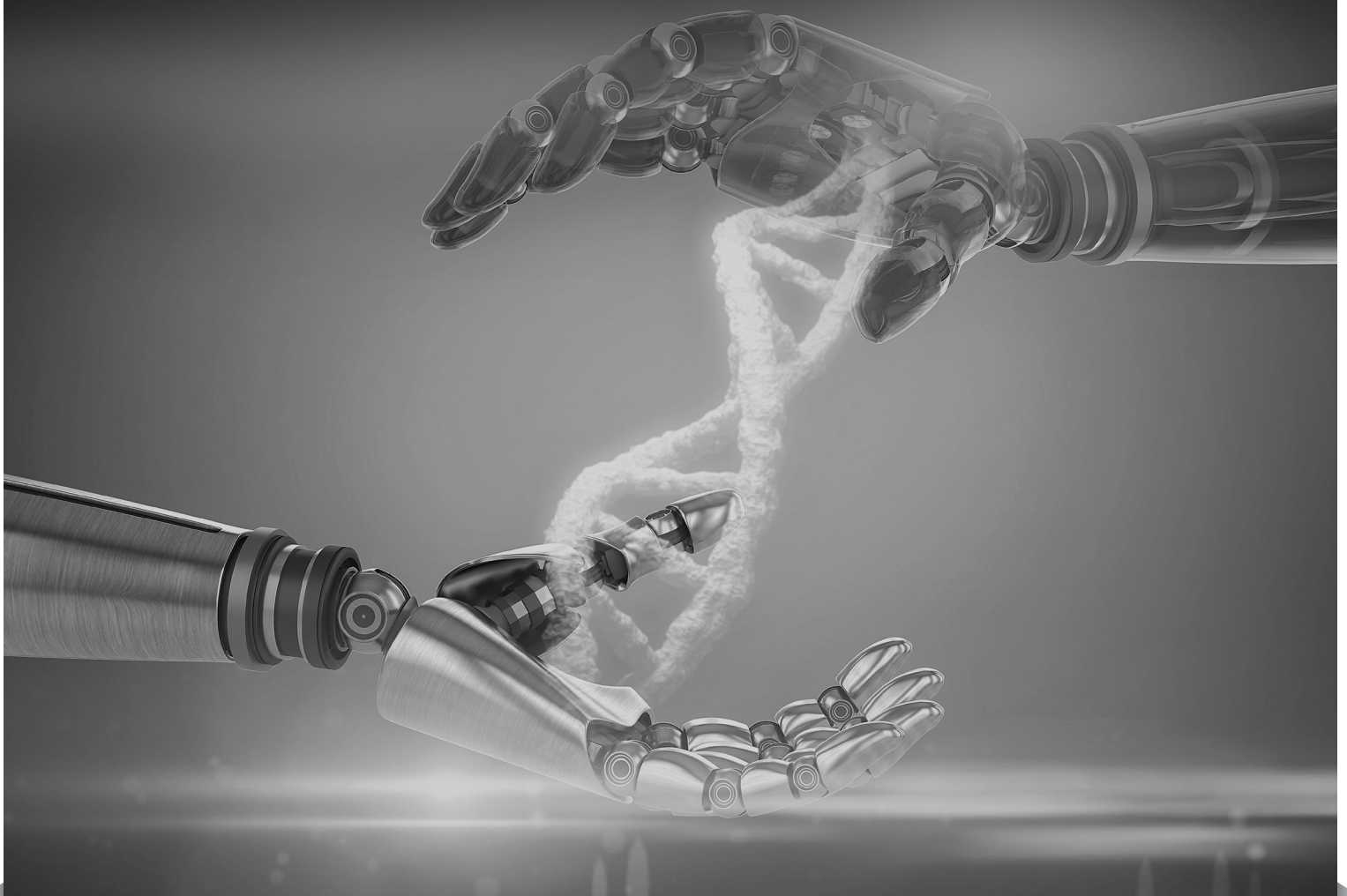




# Emerging Stocks Down Under

📖 *There is no real ending. It's just the place where you stop the story.* 📖

- Frank Herbert (1920 - 1986), Science-fiction author



**ISLAND PHARMACEUTICALS**

Anticipating IND approval

# ISLAND PHARMACEUTICALS

Anticipating IND approval

Stocks Down Under rating: ★★☆☆

**ASX: ILA**  
**Market cap: A\$6.1M**

**52-week range: A\$0.12 / A\$0.29**  
**Share price: A\$0.14**

Island Pharmaceuticals (ASX:ILA) is the only ASX-listed Biotech that is focused on mosquito diseases, primarily Dengue fever. Mosquito diseases, such as Dengue, are expensive to treat and are expected to proliferate due to climate change and the consequential boom in the mosquito population. But maybe Island Pharmaceuticals can help.

## Share price chart



Source: Tradingview

## Meet Island Pharmaceuticals and ISLA-101

Island Pharmaceuticals' flagship drug ISLA-101 was developed by Johnson and Johnson and initially purposed against cancer. After dozens of clinical trials, the biotech giant eventually retired the drug and donated the rights to the National Cancer Institute in the US. Pre-clinical work at Monash University identified the molecule's potential to be an anti-viral drug. ISLA-101 works by inhibiting the nuclear uptake (propagation) of flaviviruses that include dengue, among other mosquito diseases, such as Zika and yellow fever, although not malaria because malaria is parasitic and not viral.

Island Pharmaceuticals was founded in 2017 by American biotech entrepreneur David Foster who was living in Puerto Rico at the time and saw the impact of Zika first-hand. Foster is still managing director and CEO of the company today.

His aim was to develop molecules for the prevention and treatment of mosquito infections. It listed at 25c a share in April 2021, raising \$7.5m in the process, and went as high as 67c on the opening day. Notable investors include former Race Oncology chairman William Garner, who is the largest shareholder with a 26% stake, and private equity firm Kesa Partners with a 13% stake.

## **Dengue is a growing problem**

Dengue infects 390m people annually and ~500,000 of these are severe. The severe version of the virus, dengue haemorrhagic fever, kills 25,000 people per year. A further three billion people - nearly 40% of the planet's population - are deemed to be at risk. Both figures are expected to rise in the future due to climate change.

Dengue has recently been observed in areas where it isn't formally expected, such as in France. Even traditional hotspots have seen rising case numbers – Singapore for instance has recorded 1m cases in 1HY22 alone, up 106% from 1HY21.

It is also expensive to treat dengue fever. The typical hospitalisation cost in the US is US\$7,040. Even then, no treatment is guaranteed to work, let alone a vaccine. This is where Island Pharmaceuticals has been keen to make a difference.

## **Phase II likely to begin soon after IND**

Since listing, Island Pharmaceuticals has moved towards its goal of starting a Phase II trial in the USA. Just before Christmas, it obtained ethics approval and filed an Investigational New Drug (IND) application. An IND is a request from a clinical study sponsor to the FDA to obtain approval to administer an investigational drug or biological product to humans. The only criterion the FDA examines at that point is that research subjects will not be subjected to unreasonable risk. The company has told shareholders to expect patient screening and enrolment to occur imminently if and when the FDA approves the IND application.

The FDA responded 10 days ago by placing the application on a Clinical Hold. It has stated that that amendments to the protocol may be needed in order to obtain an approval. The company is anticipating a formal hold letter to be issued within 30 days from January 20. Once received it will have a clearer idea of what needs to be addressed and it will work to resolve the issues. The case study of Paradigm Pharmaceuticals (ASX:PAR) in 2021 depicts that a Clinical Hold is not 'Game Over' for a biotech, and IND is possible once outstanding issues are resolved.

Also on ILA's to do list is ensuring that the drug can be produced in sufficient quantities for a clinical trial. Throughout 2022, the company encountered supply chain challenges in obtaining the Active Pharmaceutical Ingredient (API) to be used in manufacturing the clinical product. By the end of the year, however, it had identified an alternative source and secured sufficient API for the upcoming trial. It engaged Florida-based company Sofgen to manufacture the product to be used in the clinical trial.

## **A risk, but one that could pay off**

The key risk with Island Pharmaceuticals is that there's no Plan B if ISLA-101 fails at any stage of the process. You need only look at the example of Factor Therapeutics back in 2018 to see what happens to single-asset Biotechs that fail at Plan A. Keep in mind that there's a long way to go before ISLA-101 is commercialised. It is also not certain that even if this eventually happens, ILA will be the company to make it happen. Back at its IPO, the company said the question of whether or not it commercialises the drug will depend on the results of Phase II and the potential costs of a Phase III trial. And as a clinical stage Biotech, Island Pharmaceuticals' short-term share price will be vulnerable to investor sentiment towards the broader industry.

For those comfortable with the risks of clinical stage Biotechs, we think Island Pharmaceuticals is four stars for two reasons. First, the unmet need for mosquito disease treatments. Second, the company's solid investor register and management, as we outlined above. Despite the delay in approval for its IND, we think this is a company investors should watch closely over the next few months.



## **Pitt Street Research Pty Ltd**

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