PITT STREET RESEARCH

Island Pharmaceuticals

Big things to come with ISLA-101 and Galidesivir

Share Price: A$0.21

ASX: ILA

Sector: Healthcare

27 August 2025

It is an exciting time for Island Pharmaceuticals (ASX: ILA) investors. ILA's biggest achievements in 2025 are completing and reporting results from its Phase 2 study of ISLA-101 for Dengue. Investors had a nuanced reaction to these results but have shown some enthusiasm for the company's promise with biodefence agent galidesivir.

Phase 2 was a success

The aim of the Phase 2 study was to deduce if ISLA-101 could work as a prophylactic (preventative) or treatment in patients infected with dengue. The initial review showed ISLA-101 was associated with both a reduction in viremia (viral load) and a clinically meaningful reduction in symptoms. ISLA-101 was the first small molecule to demonstrate a potential benefit in the robust dengue challenge model used for the study.

The data clearly showed an antiviral effect in both cohorts, albeit with more clearly pronounced results in the 2a (preventative) cohort. There is a clear path forward to develop ISLA-101 as a preventative and even if ILA only pursued ISLA-101 as a preventative mechanism, this is still a big opportunity. ILA will continue to evaluate data from the treatment arm.

Galidesivir another cause for optimism

ILA has completed the acquisition of galidesivir, an antiviral agent with longstanding clinical history and early-stage data of efficacy against many RNA viruses including Ebola, Marburg and Zika. ILA plans to undertake Galidesivir's second animal study in Marburg. ILA may be able to pursue a New Drug Application with just one additional animal study and thereafter plans to explore opportunities to sell the product into the US' strategic stockpile for bioterrorism.

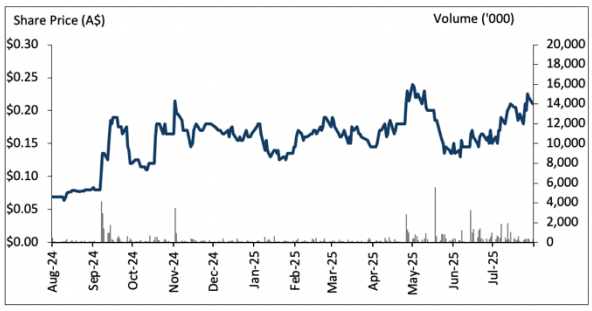
Valuation range of A$0.62-$0.78 per share

We update our valuation of ILA to $0.62 per share (or $167.5m) in a base case and $0.78 per share (or $211.6m) in an optimistic (or bull) case scenario. Please see p.11 for further details on our valuation and p.12 for key risks associated with an investment in ILA.

Market cap. (A$ m)	53.0
# shares outstanding (m)[1]	252.2
# shares fully diluted (m) [1]	297.1
Market cap ful. dil. (A$ m)	62.4
Free float	100%
52-week high/low (A$)	0.24 / 0.061
Avg. 12M daily volume ('1000)	326.6
Website	www.islandpharmaceuticals.com

Source: Company, Pitt Street Research

Share price (A$) and avg. daily volume (k, r.h.s.)



Source: Refinitiv Eikon, Pitt Street Research

Disclosure: Pitt Street Research directors own shares in Island Pharmaceuticals.

Analysts: Stuart Roberts, Nick Sundich

Tel: +61 (0)4 3483 8134

Stuart.Roberts@pittstreetresearch.com

Nick.Sundich@pittstreetresearch.com

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Re-introduction to Island Pharmaceuticals (ASX: ILA)

Island Pharmaceuticals (ASX: ILA) is a biotech company focused on repurposing drugs for viral infections. Its flagship drug is ISLA-101 that has completed Phase 2 and it has acquired Galidesivir which has significant upside in the near-term.

Island Pharmaceuticals (ASX: ILA) is a biotech company primarily focused on investigating treatments for flaviviruses (viruses caused by mosquitos).

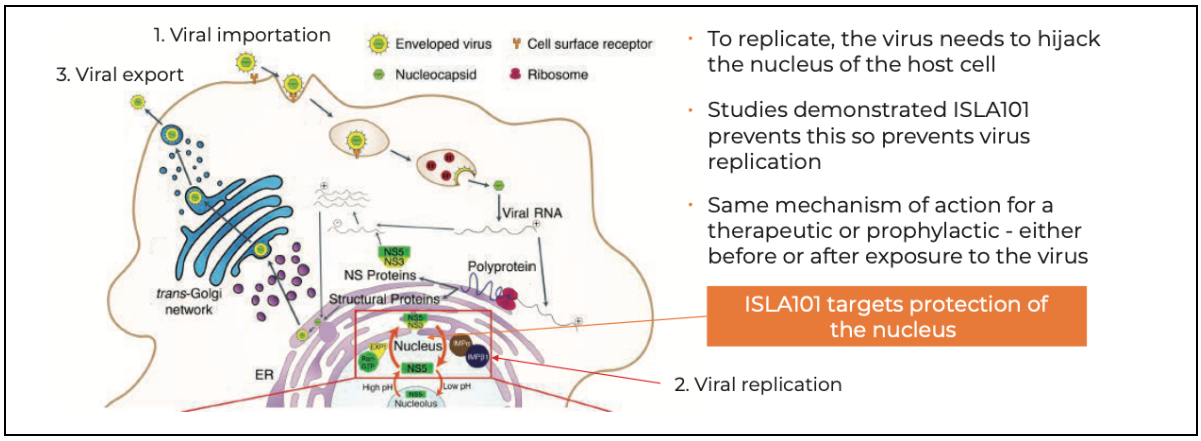
Its flagship drug is ISLA-101 (a repurposed version of fenretinide), and the key indication ILA is pursuing ISLA-101 against is Dengue fever, one of the world's prevalent flaviviruses, and it has just completed Phase 2.

Island now also has Galidesivir in its stable having formally acquired it after months of due diligence and is confident there is more upside in the immediate term as it may need to only complete one animal study before filing a New Drug Application. At first glance, an investor may think a drug about to undergo an 'animal study' has not been tested in humans and is several years away from commercialisation with long odds to make it. However, there is extensive clinical data which should enable a far quicker path to market, and a more unique one, than may appear to be the case.

Reintroduction to ISLA-101

Island licensed ISLA-101 in from Monash University, encouraged by research conducted at Monash which showed ISLA-101 had potential as an efficacious anti-viral drug. The research found that it prevents the nuclear entry of a particular viral protein into the host cell nucleus, acting as an NS5 nuclear transport inhibitor. In doing so, it prevents a viral infection and replication (Figure 1). It was found that in extremely lethal animal models, ISLA-101 prevented death in 70% of subjects. It was not just protective against dengue but in Zika too.

Figure 1: ISLA-101's Mechanism of Action



Source: Company

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Island's PROTECT trial

When Island Pharmaceuticals listed on the ASX in April 2021, its goal was to take ISLA-101 to a Phase II clinical trial. Although there were unanticipated delays for a variety of reasons, clearance was finally given in early-August 2024 and the trial commenced in early October 2024. The study was named PROTECT, short for PROphylactic and TrEatment Challenge Trial. It was conducted at SUNY Upstate Medical University in Syracuse, New York.

There were 2 cohorts:

- An A cohort with 4 subjects randomised 3:1 (Active:placebo) who would be a prophylactic or preventative cohort, and,
- A B cohort (Phase 2b) that will include 10 subjects randomised 8:2 (active:placebo) who would be a treatment arm. The A cohort is a prophylactic or preventative arm, whilst the B cohort will be a preventative arm.

ILA collaborated with the US Army to use its Dengue Human Infection Model (DHIM), with the Army manufacturing and providing an attenuated strain of the dengue virus that subjects will be exposed to.

An indication of a successful Phase 2a study came in late November 2024. The Safety Review Committee (SRC) observed evidence of antiviral activity in subjects treated with ISLA-101. However, the details of their observation remained unblinded until the recent completion of the study. That is to say although the company knew there was antiviral activity, it was not clear if it was an effect on general symptoms or specific indications like viremia. Nonetheless, there were no safety concerns that would have necessitated implementing changes to the study. And so, the SRC recommended that the trial proceed to the Phase 2b cohort.

Phase 2b showed positive results

ISLA-101 was associated with both a reduction in viremia (viral load) and a clinically meaningful reduction in symptoms.

Initial phase 2b results were released earlier in June 2025. Island told investors that ISLA-101 was associated with both a reduction in viremia (viral load) and a clinically meaningful reduction in symptoms. It was also associated with tangible drug effects. All subjects treated exhibited such reductions compared to the placebo treatment. When evaluating the maximum possible number of recorded symptoms, the control reported 63% of all potential symptoms while the ISLA-101 pre-treated subjects reported ~33% of all symptoms. In other words, those who received ISLA-101 got less sick than those who received the placebo (Figure 2).

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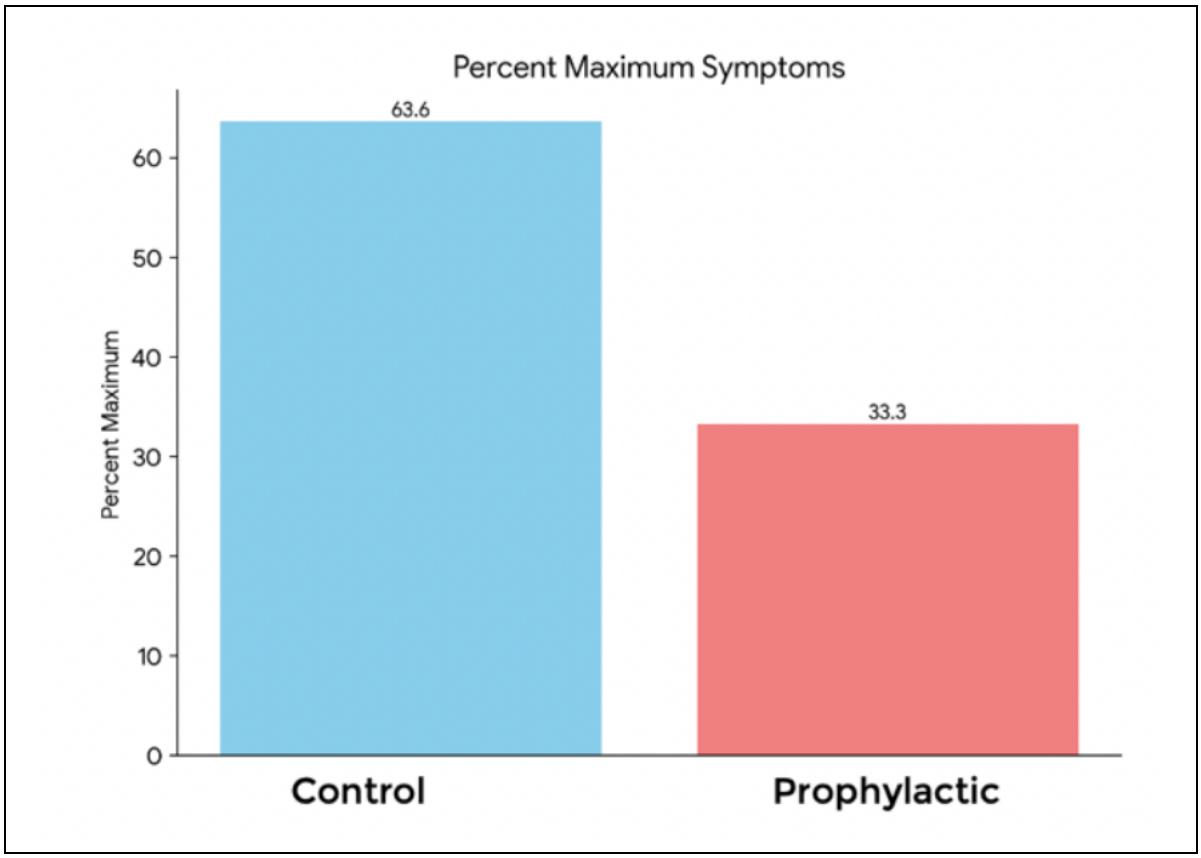
Figure 2: Phase 2b results



Source: Company

Although the path forward is unclear, the cumulative Phase 2 results to date provide reason for optimism.

ILA may end up only pursuing ISLA-101 as a preventative treatment rather than both as preventative and a treatment option.

Were the results really that good? And what's next for ISLA-101?

Overall the trial was a success because there was a reduced viremia and a reduction in the duration of symptoms. The market arguably interpreted the results as either not successful (in the sense that the difference it had on the symptoms was not substantially significant) or perhaps that subjects still had symptoms (33% still did). And the next step is uncertain, although there will almost certainly be a 'next step' even if that next step is unclear.

Specifically, ILA may end up only pursuing ISLA-101 as a preventative treatment rather than both as preventative and a treatment option. Moreover, it is true that more analysis needs to be undertaken on the results and it cannot be certain that it could be replicated in wild mosquitos since this was only an artificial form of the disease that could be studied in a well-controlled, hospital setting to reduce the risk to trial subjects.

Although those questions will need to be resolved, we don't think they justified the sell-off which we saw in the aftermath of the trial. The most important thing investors should have been looking for was that ISLA-101 saw a reduction in symptoms and this was shown.

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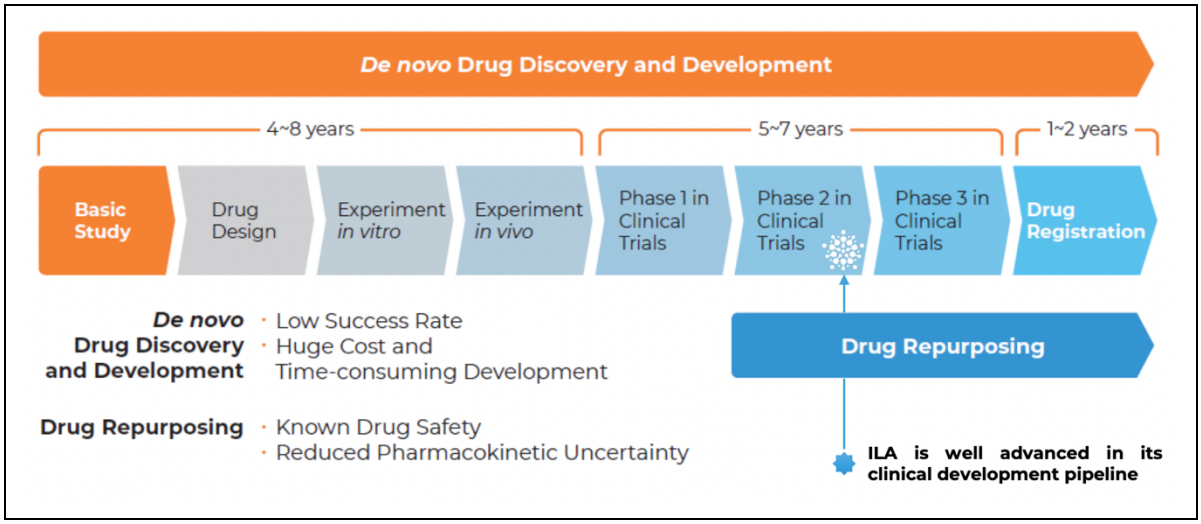
What next for ISLA-101?

Island is meeting with its Clinical Advisory Board to review the data and obtain guidance on the best path forward. The end goal is to clinically develop ISLA-101.

In our view, the next logical step would be a larger Phase 3 trial and perhaps only as a preventative treatment. It is plausible that it may take some months to make this happen – to secure FDA consent and funding/partnerships necessary for the trial. But there cannot be any denying that the overall Phase 2 results were a step forward (Figure 3).

Investors have shown some enthusiasm about Galidesivir and its potential and the company is eager – in fact, arguably more confident because there is a clearer path in the immediate term. Investors could be forgiven for being skeptical

Figure 3: Island's timeline



Source: Company

Island's risk is lower for it than other biotechs for many reasons including that anti-infective drugs generally have a higher probability of success and lower cost.

Some investors, even those who would acknowledge a Phase 3 trial is likely, may still be sceptical about commercialisation given success is not guaranteed and there'll be more time and money involved. The failure of Opthea (ASX:OPT) at Phase 3 does show that success is not guaranteed. But investors should bear in mind a few things:

1. It is estimated by JAMA Network and Biotechnology Innovation Organisation that the probability of a successful Phase 3 transition for infectious disease treatments increases to 64%.
2. Once at Phase 3, success there is usually more likely once a drug has passed Phase 2.
3. Infectious disease treatments have the third-highest probability of phase 2 success (38.4%), only trailing hematology (48.1%) and metabolic (45%) treatments
4. Anti-infective drugs tend to be the least expensive to develop and they always sit at the low end of the drug development cost curve across all therapeutic areas[1].

[1] Investor presentation 17 June 2025.

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5. Even if ISLA-101 is ultimately only utilised as prevention that is still a $1.5bn opportunity[2], even if is just prevention care for healthcare and travellers

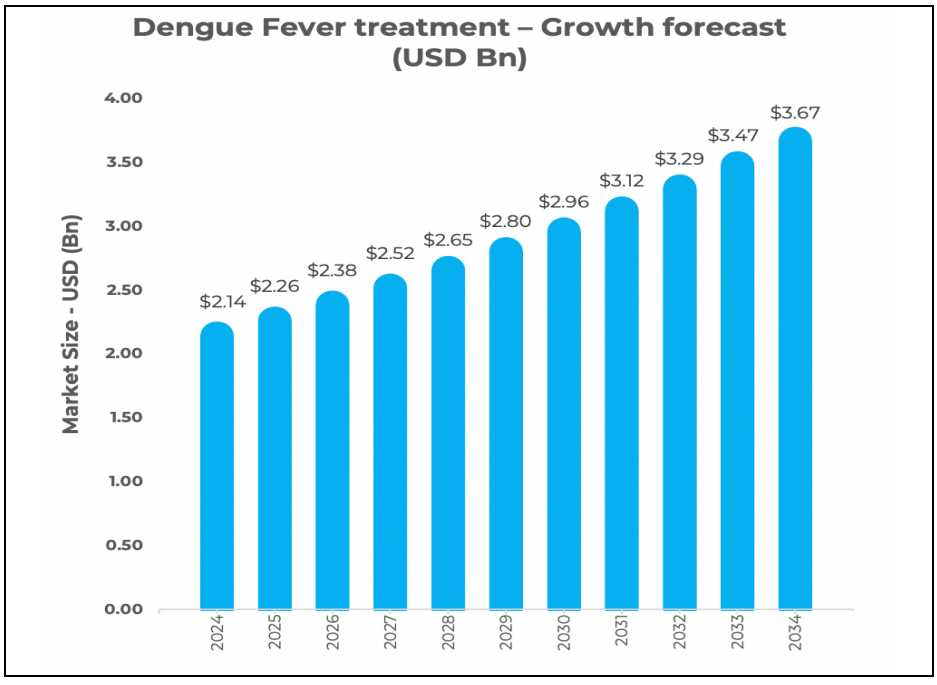
There's a big opportunity in Dengue for ISLA-101

Dengue (pronounced 'deng-gey') is a viral infection spread by two species of mosquito, Aedes aegypti and Aedes albopictus. Dengue affects infants, children and adults with symptoms developing between 3 and 14 days of a mosquito bitecan cause several symptoms including headaches, gastrointestinal bleeding, a reduction in blood platelets, seizures, itching, rashes and vomiting. Dengue is most frequently reported in the Caribbean, Central America, South America and Southeast Asia; but is increasingly occurring in areas not traditionally known for having endemic Dengue.

There were over 14 million Dengue cases in 2024 – a two-fold increase on 2023 and 12-fold increase on 2014.

Every year, it becomes a greater and greater problem. There were over 14 million cases in 2024 – a two-fold increase compared to 2023 and a 12-fold rise compared to 2014[3]. This is happening due to climate change and urbanisation that gets more and more vehement by the year. What's more is that there are no direct treatments. There are treatments that aid certain symptoms, and is only one approve vaccines for secondary infections (Sanofi Pasteur's Dengvaxia and Qdenga's dengue vaccine)[4], there is a need for treatments that can fight the disease. Herein lies a chance for ISLA-101. The Dengue Fever treatment market is expected to grow from US$2.1bn to US$3.67bn over the next decade (Figure 4).

Figure 4: The market opportunity for ISLA-101



Source: Company

[2] Company date
[3] Haider, N. et. al 2025, Global Dengue Epidemic Worsens with Record 14 Million Cases and 9,000 Deaths Reported in 2024. International Journal of Infectious Diseases, https://doi.org/10.1016/j.ijid.2025.107940
[4] Pasteur's Dengvaxia was mentioned as approved in earlier reports, but this drug was recently pulled from the market.

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Galidesivir is another opportunity for Island

Investors have warmly received the news that Island Pharmaceuticals has acquired galidesivir. Just over a year ago, in July 2024, Island signed a non-binding Letter of Intent with then owner BioCryst for an option to acquire this asset and then sealed a binding Letter of Intent in September. On 9 July 2025, Island told investors it had completed due diligence and signed an Asset Purchase Agreement which resulted in the closing of the acquisition on 31 July, 2025. The company was so confident in Galidesivir and eager not to lose any time that it bought the asset straight away without an Option agreement or even an MoU.

Galidesivir is an antiviral molecule that has a broad spectrum of activity in over 20 RNA viruses, including high-priority threats such as Ebola, Marburg, MERS, Zika, yellow fever and SARS-CoV-2

We can see why investors are excited. Galidesivir is an antiviral molecule that has a broad spectrum of activity in over 20 RNA viruses, including high-priority threats such as Ebola, Marburg, MERS, Zika, yellow fever and SARS-CoV-2. Beyond its potential to work in the healthcare sector, there is also potential for its use in biodefence, with viruses like Marburg and Ebola as a possible risk. The US government has invested US$70m into Galidesivir towards its ongoing development to target Marburg, as well as Ebola, amongst other indications. Filoviruses such as Marburg and Ebola are one of only six Category A bioterrorism threats – the greatest to US National Security. Mortality rates are 25-90% and there are no effective treatments, meaning there is a need for them.

How does Galidesivir work? It works as a nucleoside analogue that mimics adenosine triphosphate (ATP) and inhibits viral RNA synthesis, allowing broad activity against many RNA viruses. Nucleoside analogues are basically 'monkey wrenches' that interfere with viral replication because they are incorporated into viral RNA by RNA-dependent RNA polymerase but, lacking 3'-hydroxyl group, cause RNA synthesis to halt because the phosphodiester bond that would link to the next nucleoside can't be formed. Examples of other nucleoside analogues successful on 'the front line' have included Remdesivir (used to treat COVID-19 during the pandemic), Vidarabine for Herpes in 1976 and Zidovudine for HIV in 1987.

What next?

Island plans to undertake a single animal study in Marburg using Galidesivir and complete it by Christmas 2025, pending FDA feedback. Upon hearing the phrase 'animal study', investors could be forgiven for thinking this asset is several years away from commercialisation and long odds to make it, thinking this is just the first step in a long journey of multiple clinical trials and likely hundreds of millions of dollars.

Island plans to undertake and complete a maiden animal study in Marburg using Galidesivir.

To the contrary, much of the hard work and investment has been done[5]. If the animal study results are successful, there's potential for ILA to submit a New Drug Application (NDA) under the FDA's Animal Rule and results could come before Christmas 2025 (Figure 5). The FDA's Animal Rule facilitates the approval of drugs in indications where human trials are unethical or not feasible (and this is the case here), provided safety is shown in humans and the disease is well modelled in animals. And it is, clinical data has shown Marberg can have a 100% fatality rate within just over 10 days from infection, but Galidesivir can lead to a survival rate of greater than 90% (Figure 6), 30 days from infection. Moreover, it has a clear impact on viral load (Figure 7).

[5] US$70m has been to date

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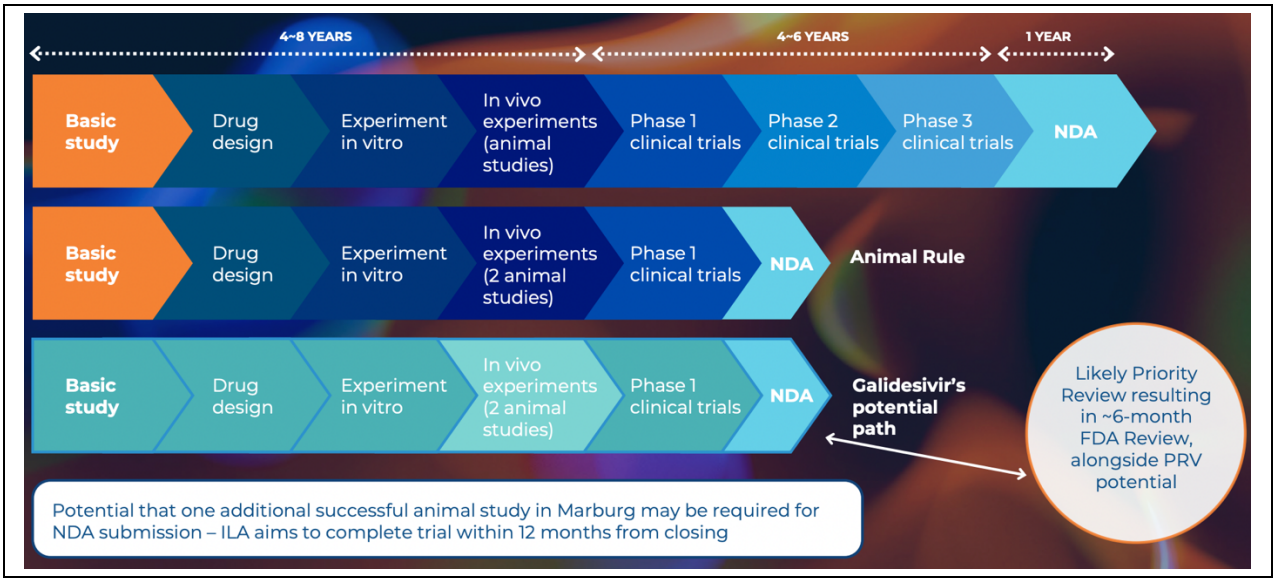
Figure 5: The path with Galidesivir



Source: Company

Figure 6: Results with Galidesivir (survival)

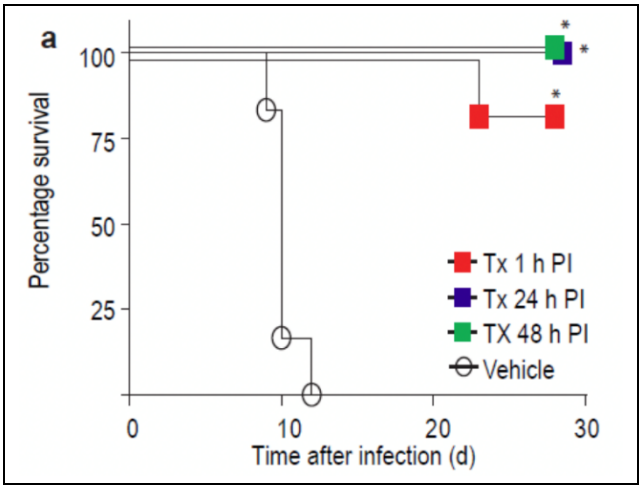
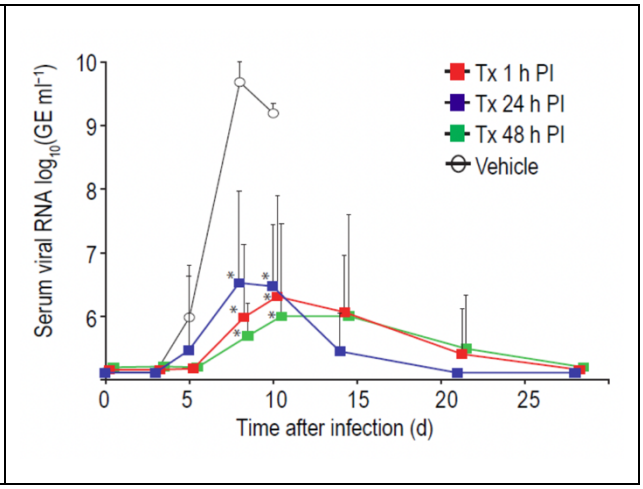


Figure 7: Results with Galidesivir (viral load)



Source: Company

Island believes all it has to do to secure an NDA is to replicate that same study and show similar results

Island believes all it may have to do to secure an NDA is to replicate that same study and show similar results. If they are anything like the results above (i.e. showing 100% mortality after 12 days without intervention but 100% survival with intervention) it is difficult not to see this happening. An NDA may provide Island with access to a Priority Review Voucher (PRV), which would be additional to any PRV given for ISLA-101. As we've noted in previous reports on Island, PRVs can sell for >US$150m if recent precedent transactions are any guide. Indeed, the most recent sale of a PRV was US$160m[6].

[6] It was sold by Bavarian Nordic to an unnamed buyer in June 2025, following the approval of Vimkunya – a vaccine for the prevention of chikungunya virus.

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Island plans for the US government to add Galidesivir to its Strategic National Stockpile and deliver it as required.

The ultimate plan is for Island's business partner to be the US government. Washington may add Galidesivir to its Strategic National Stockpile and have it delivered as required. The Stockpile reserves medical supplies and pharmaceuticals to respond to public health emergencies. Its assets include $500m worth of Ebola treatments, so a $100-200m take-up for Marburg (which we ultimately assumed in our modelling) would be arguably conservative. And this figure would not just be a one off – it would need to be replenished every 2 years just for Marburg. Moreover, Island could also conduct trials in Galidesivir for other indications like Ebola and measles and add it to the stockpile and this could potentially happen with just one animal study – although in such an instance there wouldn't be eligibility for PRV because of existing treatments.

One concern healthcare investors may have had is Donald Trump's Health Secretary Robert Kennedy being a vaccine sceptic, but this could work in ILA's favour – in that Galidesivir could address measles. Despite measles having been under control for decades, it is re-emerging due to herd immunity being lost by virtue of vaccination rates falling below 95%[7]. This is not necessarily because of anti-vaccination beliefs being more prominent but also that many younger generations are not anymore as childhood routine given the incidence had fallen. Measles is one of the most virulent of all viruses on earth – you can have no symptoms for 7-14 days and infect 12-18 people in that time[8]. For comparison's sake, the omicron COVID variant was estimated to be 4.2 people when it first emerged in South Africa in late 2021[9]. The Stockpile is an America First play first and foremost, so Elon Musk's short-lived DOGE did not touch it.

[7] https://www.health.harvard.edu/blog/measles-is-making-a-comeback-can-we-stop-it-202503063091

[8] Guerra, F. et. al 2017, *The basic reproduction number (R_0) of measles: a systemic review*, Lancet Infectious Diseases Dec; 17(12);e420-428. Doi: 10.1016/S1473-3099(17)30307-9.

[9] Karimizadesh, Z. et. al (2023) *The reproduction rate of severe acute respiratory syndrome coronavirus: 2 different variants recently circulated in humans: a narrative review,* European Journal of Medical Research, 28 no. 8. Doi: 10.1186/s40001-023-01047-0

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Our Valuation of Island Pharmaceuticals

We upgrade our valuation to $167.5m or $0.618 per share in our base case and $211.6m or $0.778 per share in our bull case.

Our previous valuation of Island Pharmaceuticals was A$83.0m in our base case and A$109.1m in our bull case, which represented $0.30 per share and $0.40 per share respectively in light of the company's capital raising in May 2025, purely based on ISLA-101 with no value ascribed to Galidesivir. We upgrade our valuation to $167.5m or $0.618 per share in our base case and $211.6m or $0.778 per share in our bull case using a SOTP valuation (Figure 8).

These figures are based on the company's diluted shares on issue (because of the high likelihood the company's options will be exercised in light of its recent share price growth) and also include probability weighting for both ISLA-101 and Galidesivir on top of the discount rates in our model. If there was no probability weighting, our valuation would be $327.9m or $1.20 in our base case and $416m or $1.52 per share in our bull case. Our assumptions for ISLA-101 as outlined in previous reports remain intact, but there has been an increase in our valuation by virtue of time passing since our initiation report last year which means the discount on our cash flows decreases despite maintaining the same WACC.

For Galidesivir, we have modelled a separate business selling to the US market with a US$200m opportunity (which is arguably conservative given stocks need to be replenished regularly, and the Stockpile has US$500m for Ebola alone). We assume $5m is spent on the study and regulatory efforts and that commercialisation begins in late FY27 with penetration ramping up over the next 3 years.

Our base case assumes a 25% pre-tax margin and our bull case assumes a 30% pre-tax margin. We employ a 14.7% WACC for Galidesivir cash flows as with ISLA-101, a 21% corporate tax rate and a 50% probability weighting, considering it hinges on binary decisions by the US regulator. We have assumed 10% tiered royalties to Galidesivir's vendors. For conservatism's sake, we have not assumed a PRV is issued in either case to show the business is valuable even if it does not obtain a PRV.

Figure 8: Our valuation of Island Pharmaceuticals (based on diluted shares on issue)

Sum of the Parts Valuation	Base Case		Bull case	
Drugs	**A$m**	**A$ps**	**A$m**	**A$ps**
ISLA	92.3	0.334	121.29	0.439
Galidesivir	68.1	0.247	83.13	0.301
rNPV	**160.3**	**0.581**	**204.4**	**0.740**
Cash (close of FY25)	7.2	0.037	7.2	0.037
Debt (close of FY25)	-	-	-	-
Equity Value	**167.5**	**0.618**	**211.6**	**0.778**
Current Price		0.210		0.210
Upside		194%		270%

Source: Pitt Street Research

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Key Risks facing Island Pharmaceuticals

We see the risk of failure of forthcoming trials as the biggest risks facing the company.

Other risks include:

- **Regulatory risk**. There is a risk that ISLA-101 or Galidesivir may not be approved by regulators. Even if data suggests efficacy, the FDA may not find the data acceptable, or decline to approve ISLA-101 or Galidesivir on other grounds such as the potential for negative interaction with other drugs. Even when approved, there is the risk that approval may be withdrawn, or that further regulations may be imposed on the company to be able to continue to market, manufacture and/or produce the drug.
- **Market acceptance risk**: There is the risk that even if the drug passes clinical trials, it will fail to be approved and/or attract a strong following in its applicable markets.
- **Key personnel risk**. There is the risk that the company may lose key personnel and be unable to replace them and/or their contribution to the business.
- **Capital risk**. Notwithstanding this risk has been significantly diminished with the recent placement and the prospect that Island could obtain a PRV, the prospect of Island needing debt or equity sources of funding cannot be entirely ruled out. In such an event, there is no guarantee that the company will be able to raise such capital, let alone on favourable terms. Even if successful, this would be dilutive to existing shareholders.

Risks related to pre-revenue Life Science companies in general.

The stocks of biotechnology and medical device companies without revenue streams from product sales or ongoing service revenue should always be regarded as speculative in character.

Since most biotechnology and medical device companies listed on the Australian Securities Exchange fit this description, the term 'speculative' can reasonably be applied to the entire sector.

The fact that the intellectual property base of most biotechnology and medical device lies in science not generally regarded as accessible to the layman adds further to the riskiness with which the sector ought to be regarded.

Caveat emptor. Investors are advised to be cognisant of the abovementioned specific and general risks before buying any the stock of any biotechnology or medical device stock mentioned on this report, including ILA.

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Appendix I – Analysts' Qualifications

Stuart Roberts, lead analyst on this report, has been an equities analyst since 2002.

- Stuart obtained a Master of Applied Finance and Investment from the Securities Institute of Australia in 2002. Previously, from the Securities Institute of Australia, he obtained a Certificate of Financial Markets (1994) and a Graduate Diploma in Finance and Investment (1999).
- Stuart joined Southern Cross Equities as an equities analyst in April 2001. From February 2002 to July 2013, his research speciality at Southern Cross Equities and its acquirer, Bell Potter Securities, was Healthcare and Biotechnology. During this time, he covered a variety of established healthcare companies, such as CSL, Cochlear and Resmed, as well as numerous emerging companies. Stuart was a Healthcare and Biotechnology analyst at Baillieu Holst from October 2013 to January 2015.
- After 15 months over 2015–2016 doing Investor Relations for two ASX-listed cancer drug developers, Stuart founded NDF Research in May 2016 to provide issuer-sponsored equity research on ASX-listed Life Sciences companies.
- In July 2016, with Marc Kennis, Stuart co-founded Pitt Street Research Pty Ltd, which provides issuer-sponsored research on ASX-listed companies across the entire market, including Life Sciences companies.
- Since 2018, Stuart has led Pitt Street Research's Resources Sector franchise, spearheading research on both mining and energy companies.

Nick Sundich is an equities research analyst at Pitt Street Research.

- Nick obtained a Bachelor of Commerce/Bachelor of Arts from the University of Sydney in 2018 and the certification Financial Modelling and Valuation Analyst from the Corporate Finance Institute. He has also completed the CFA Investment Foundations program.
- He joined Pitt Street Research in January 2022. Previously he worked for over three years as a financial journalist at Stockhead.
- While at university, he worked for a handful of corporate advisory firms

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