November 25, 2025

KEEPING STOCK

Stock code:	ILA AU
Price:	A$0.56
Market cap:	A$143m
Average daily turnover:	A$0.27m
Index inclusion:	N/A

Price performance

(%)	1M	3M	12M	3Y
Absolute	38.3	160.5	239.4	215.0
Rel ASX/S&P200	43.6	165.6	236.6	196.9

Source: IRESS

Iain Wilkie

+61 7 3334 4521

iain.wilkie@morgans.com.au

Scott Power

Analyst(s) own shares in the following stocks mentioned in this report:

– Island Pharmaceuticals

Island Pharmaceuticals

The Marburg Mission

- Island Pharmaceuticals (ILA) is small ASX listed pharmaceutical developer with two antiviral assets for indications across a variety of serious to deadly diseases.
- In July, ILA acquired Galidesivir, an antiviral with proven activity against serious infections including Marburg, Ebola and Zika.
- The FDA has confirmed Galidesivir will follow a fast-tracked clinical program using the rare Animal Rule pathway, and may be eligible for a Priority Review Voucher (PRV), which have recently sold for over US$150m.
- ILA is expected to complete one pivotal well-controlled animal study showing a clear survival benefit in Marburg infection with previous studies showing a 94% survival rate in treated subjects.
- If successful, ILA could have an approved drug within 12 to 18 months, secure a valuable PRV, and potentially supply the US Strategic National Stockpile as a Marburg antiviral.

Who is Island Pharma?

- Island Pharmaceuticals is an ASX-listed biotechnology company focused on repurposing established antiviral drugs for new infectious disease indications. By acquiring compounds with proven safety profiles and advancing them into areas of high unmet medical need, ILA aims to reduce both the time and cost typically associated with drug development. The company's two lead assets, Galidesivir (Marburg virus) and ISLA-101 (Dengue Fever), are positioned to address significant global health threats, with several near-term regulatory and commercial catalysts.

Galidesivir

- ILA owns the rights to two antiviral assets. Its historical asset ISLA-101 has achieved solid results as a prophylactic (preventative) and therapeutic (treatment post infection) against Dengue Fever, but its most recent asset Galidesivir has attracted significant attention due to its historical clinical success and near-term pathway to major clinical and regulatory catalysts.
- Galidesivir is a broad-spectrum antiviral agent developed by BioCryst Pharmaceuticals (BCRX.NAS). It is a nucleoside analogue that blocks a key enzyme called RNA-dependent RNA polymerase, which viruses use to replicate their genetic material and disrupts the virus' ability to multiply and spread within the host. This mechanism is common across a wide range of RNA viruses, which explains Galidesivir's activity against over 20 different pathogens, including Marburg, Ebola, Zika, and Yellow Fever.
- The FDA recently confirmed that Galidesivir may follow a highly streamlined clinical program, making use of the seldom-used Animal Rule pathway for potential regulatory approval for Marburg, along with its eligibility to claim a PRV on success – which holds significant secondary market value and often on-sold with recent transactions >US$150m.
- Looking forward, ILA is likely only required to complete a single, well-controlled pivotal animal study which shows a statistically significant difference in survival post infection with the Marburg virus. The drug has been tested in a similar study before, showing a 30-day survival rate of 17 of 18 (94%) treatment subjects versus 0 of 6 (0%) in placebo controls.
- Pending study commencement, ILA has potential to have an approved drug on market within 12-18 months, a valuable asset in PRV, and a likely US Strategic National Stockpile (SNS) contract as a Marburg antiviral.

Catalysts to watch

- Final FDA feedback (1Q'CY26) / Start of pivotal NHP trial (1Q'CY26) / NHP trial results (2Q'CY26) / NDA submission (2H'CY26) / Potential FDA approval and PRV (CY27) / Possible first SNS sales (CY27).

Risks

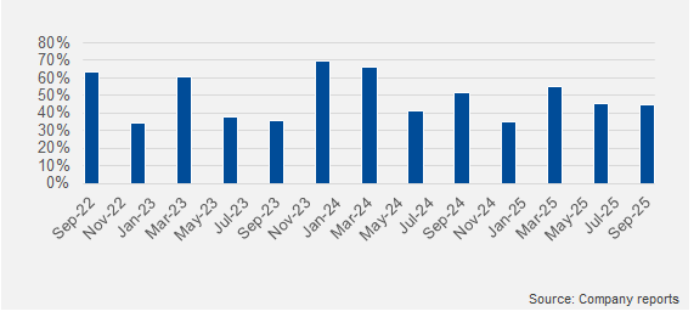
- All typical micro-cap pharmaceutical developments risks apply: Regulatory, clinical, funding, market, and operational risks.

Island Pharmaceuticals

Price (A$):	0.56	Industry:	Pharmaceuticals
Market cap (A$m):	143	Index inclusion:	N/A

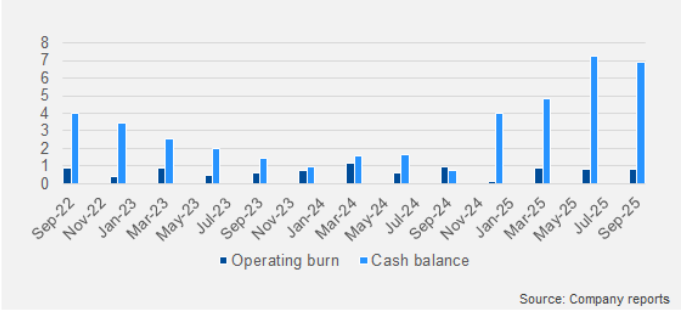
Island (ASX: ILA) is focused on areas of unmet need for drugs that can address urgent viral diseases, public health or biosecurity threats. The Company is executing a dual development strategy for its assets, ISLA-101 and Galidesivir. ISLA-101 has a well-established safety profile, being repurposed for the prevention and treatment of dengue fever and other mosquito (or vector) borne diseases. Galidesivir is a clinical-stage antiviral molecule with a broad spectrum of activity in over 20 RNA viruses, including high-priority threats such as Ebola, Marburg, MERS, Zika and Yellow fever – viruses with significant unmet medical needs and that may contribute to national security threats.

R&D as % of operating cost bcase (ex rebates)



Source: Company reports

Historical Operating cash burn and cash balance levels (A$m)



Source: Company reports

High survival in animal models with delayed dosing

Animal Species	Virus	Dose Regimen	Key Results
Hamsters	Yellow Fever	100 mg/kg BID 7 days	100% survival initial dose 3dpi, 80% survival initial dose 4dpi*; 12.5% survival control
Rhesus NHP	Zika	100 mg/kg BID, 25 mg/kg BID 9 days	Substantial suppression of viral load following galidesivir treatment at day 3 post infection
Cynomolgus NHP	Marburg	15 mg/kg BID 14 days	100% survival initial dose 2dpi*; 0% survival control.
Rhesus NHP	Ebola	100 mg/kg BID loading, 25 mg/kg BID 10 days	100% survival initial dose 2dpi, 67% survival initial dose 3 dpi* ; 0% survival control.

Key terms	
BID	Twice Daily
2dpi	2 days post infection
3dpi	3 days post infection

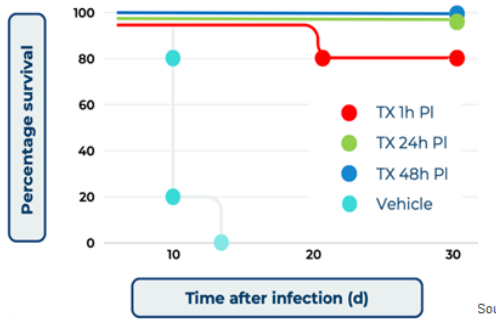
Source: Company reports

Milestones and catalysts ahead

Galidesivir specific milestones	Timeframe
Advance US Government engagement initiatives	November CY25
Sign research agreement with gold-standard BSL4 facility and develop clinical trial protocol	Q4 CY25
Submit clarifying questions on initial FDA feedback to assist in finalizing Galidesivir clinical program	Q4 CY25
Commence strategic appointments to establish Galidesivir Advisory Committee	Q4 CY25
Prepare proposed study protocol and submit to FDA for review	Q4 CY25 - Q1 CY26
Finalise proposed study design following FDA review	Q1 CY26
Commencement of Galidesivir's clinical development prior to NDA preparation	Q1 CY26
Advance opportunities for Galidesivir's broader development in other indications	Ongoing
Explore partnership and international government engagement opportunities	Ongoing

Source: Company reports

Galedesivir shows high survival rate well above placebo in Marbug



Source: Company reports

Galedesivir has shown activity across numerous RNA viruses

Virus Family	Virus	Strain/Variant
Filoviridae	Marburg	Musoke
	Marburg	Ci67
	Marburg	Angola
	Ebola	Kikwit
	Sudan	Boniface
Togaviridae	VEE	SH3
	EEE	FL93-939
	WEE	California
	Chikungunya	AF 15561
Bunyaviridae	Rift Valley Fever	ZH501
	LaCrosse encep	Wisc 1960
	Maporal virus	HV97021050
Arenaviridae	Lassa	Josiah
	Junin	Romero

Virus Family	Virus	Strain/Variant
Paramyxo	Nipah virus	Malaysia
	HRS	A2
	Measles	Chicago
Corona	SARS-CoV	Urbani
	MERS-CoV	Jordan
Orthomyxo	Influenza	pH1N1
Picornaviridae	Rhinovirus-2	HGP
Flaviviridae	West Nile	New York
	Yellow fever	17D
	Jap. Enceph.	SA14
	Powassan Virus	LB
	Dengue 2	New Guinea C
	Zika	PRVABC59

Source: Company reports

Bull points

Strong efficacy signals
Galidesivir has shown exceptional efficacy in preclinical studies for Marburg, with a survival benefit rarely seen in antiviral research.

Rare, but expedited pathway
The FDA's acceptance of the Animal Rule pathway could fast-track regulatory approval and commercialisation, potentially unlocking significant near-term value.

Eligible for PRV
If successful, Galidesivir may secure a Priority Review Voucher (PRV) and a contract with the US Strategic National Stockpile, both of which could deliver substantial financial upside.

Bear points

No approved assets
The pivotal animal study still needs to replicate previous results; any failure or unexpected outcome could delay or derail approval.

Pre-revenue
Island Pharmaceuticals remains pre-revenue and may require further capital raises, which could dilute existing shareholders.

Dependent on single customer
Commercial success depends heavily on government procurement and market uptake, with competition from other antiviral and vaccine programs a potential threat.

Island Pharmaceuticals

Background

Who is Island Pharma?

Island Pharmaceuticals (ASX:ILA) is an Australian biotechnology company focused on developing antiviral therapies for infectious diseases. The company's strategy centres on repurposing existing drugs with proven safety profiles to address urgent global health threats.

Company background

Founded in 2020 and listed on the ASX in 2021, ILA was co-founded by Dr David Foster (current CEO and Managing Director) and Dr William Garner (biotech entrepreneur and major shareholder). The company initially focused on ISLA-101 for dengue fever and expanded its portfolio in 2025 by acquiring Galidesivir, a broad-spectrum antiviral agent.

ILA's approach leverages the significant investment and research already undertaken by previous owners of its assets, allowing for a faster and more cost-effective path to commercialisation. The company operates with a lean structure, outsourcing manufacturing and commercial activities where possible.

Company operations

Island Pharmaceuticals runs a capital-light business model. Its operations focus on advancing late-stage clinical assets through regulatory approval and commercialisation. The company's immediate priorities are:

- Progressing Galidesivir through the FDA's Animal Rule pathway for Marburg virus.
- Continuing development of ISLA-101 for dengue, with a focus on prevention.
- Engaging with government agencies and potential commercial partners for future sales and licensing.
- Manufacturing is outsourced, and commercialisation strategies include direct government sales (for Galidesivir) and licensing agreements (for ISLA-101).

Risks

ILA faces several key risks typical of early-stage biotech companies:

- **Regulatory risk:** Success depends on meeting FDA requirements, particularly under the Animal Rule pathway for Galidesivir.
- **Clinical risk:** The pivotal animal study for Galidesivir must replicate previous strong efficacy results. Any unexpected outcomes could delay or jeopardise approval.
- **Funding risk**: As a pre-revenue company, ILA may need to raise additional capital to fund ongoing development and regulatory submissions.
- **Market risk:** Commercial success depends on government procurement decisions and market uptake, as well as competition from other antiviral and vaccine programs.
- **Operational risk**: Reliance on contract manufacturing and external partners introduces potential for delays or quality issues.

Clinical assets

What are the products or assets?

ILA's two lead assets are:

- **Galidesivir:** A broad-spectrum antiviral agent acquired from BioCryst Pharmaceuticals. It targets RNA viruses including Marburg, Ebola, Zika, and yellow fever. The initial indication is Marburg virus, a severe and often fatal haemorrhagic fever.
- **ISLA-101:** Formerly known as Fenretinide, this small molecule has demonstrated antiviral activity against mosquito-borne flaviviruses, especially dengue. It has a long safety record from previous oncology trials and is being developed primarily as a preventative treatment.

Regulatory pathway and clinical relevance

- Galidesivir is progressing through the FDA's Animal Rule pathway, a regulatory mechanism designed for drugs where human efficacy trials are not ethical or feasible. This pathway allows approval based on robust animal efficacy data and established human safety. The FDA has confirmed Galidesivir's eligibility for this pathway and its potential to receive a Priority Review Voucher (PRV) upon approval, which can be sold for significant value.
- ISLA-101 is advancing through traditional clinical trial phases, with a focus on prevention of dengue infection. The drug may also qualify for a PRV if approved.

Both assets target diseases with substantial unmet need and global health significance. Marburg is classified as a Category A biothreat by the US government, and dengue is a major cause of illness in tropical regions worldwide.

What is Marburg?

Marburg is a highly dangerous virus that causes Marburg Virus Disease (MVD), a severe and often fatal haemorrhagic fever. It belongs to the filovirus family, which also includes Ebola. The disease typically starts with sudden fever, headache, and muscle pain, and can quickly progress to vomiting, diarrhoea, organ failure, and internal and external bleeding. MVD has very high fatality rates, sometimes reaching up to 90% in outbreaks. There are currently no approved treatments or vaccines for Marburg, and controlling outbreaks relies on early detection, isolation, and supportive medical care. The virus is considered a major global health threat and is classified as a Category A biothreat by the US government.

Recent Marburg outbreaks and outcomes

In recent years, the Marburg virus has caused several outbreaks across Africa, highlighting its potential for rapid spread and high mortality. While most outbreaks have been contained quickly through public health interventions, the results have underscored the severity of the disease and the urgent need for effective treatments.

Key outbreaks include:

- Ethiopia (2025): The country reported its first-ever Marburg outbreak, with 8 confirmed cases and 6 deaths (APA news). Swift identification and response helped limit the spread, but the high fatality rate was a stark reminder of the virus's danger.
- Tanzania (2023 and 2025): Tanzania experienced two outbreaks, with one resulting in 10 cases and 10 deaths (100% fatality rate), and another with 9 cases and 6 deaths. These events demonstrated how quickly Marburg can escalate in the absence of effective countermeasures.
- Equatorial Guinea (2023): 17 cases were reported, with 12 deaths, resulting in a fatality rate of 71%.
- Ghana (2022): 3 cases were confirmed, all of which were fatal.

- Rwanda (2024): 66 cases and 15 deaths were recorded, with a fatality rate of 23%.
- The largest recorded Marburg outbreak occurred in Angola in 2004 - 2005, with 374 cases and 329 deaths (88% fatality rate). This event led to Marburg being classified as a Category A biothreat by the US government.

These recent outbreaks reinforce the urgent need for effective antiviral therapies and highlight the potential impact of drugs like Galidesivir, which could help reduce mortality and improve outbreak management in the future.

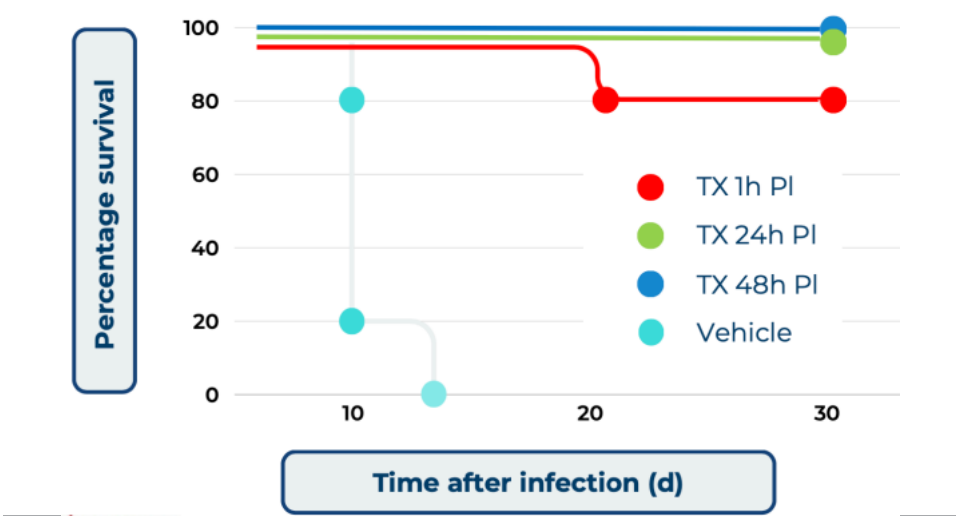
Clinical results history

Galidesivir

Preclinical Efficacy (Marburg Virus):

- Galidesivir's most compelling data comes from non-human primate (NHP) studies targeting Marburg virus, a highly lethal filovirus.
- In a landmark study published in Nature, 24 NHPs were infected with Marburg virus, 18 animals received Galidesivir at various time points post-infection, while 6 animals served as untreated controls.
- Of the treated group, 17 out of 18 survived for 30 days post-infection, equating to a 94% survival rate. In contrast, all 6 untreated animals died (100% death rate), demonstrating the drug's profound efficacy in this model.

Figure 1: BioCryst efficacy in NHP study. 94% survival on treatment



Source: Company data

- Based on those results, the probability of such an extreme split in survivors recurring by chance is extremely low, with about 1 in 19,000 (two-sided p-value of 0.000052). However, the small sample size (n=24) inflates uncertainty and creates wide confidence intervals however still highly significant and consistent with a strong treatment effect.
- The study also showed that Galidesivir was effective even when administered up to 2 days beyond initial infection (1hr / 24hrs / 48hrs), which is critical for real-world outbreak scenarios.
- Additional animal studies have confirmed Galidesivir's broad-spectrum activity against other RNA viruses, including Ebola, Zika, and yellow fever.

Figure 2: Galidesivir has shown activity in vitro in several RNA viruses

Virus Family	Virus	Strain/Variant
Filoviridae	Marburg	Musoke
	Marburg	Ci67
	Marburg	Angola
	Ebola	Kikwit
	Sudan	Boniface
Togaviridae	VEE	SH3
	EEE	FL93-939
	WEE	California
	Chikungunya	AF 15561
Bunyaviridae	Rift Valley Fever	ZH501
	LaCrosse encep	Wisc 1960
	Maporal virus	HV97021050
Arenaviridae	Lassa	Josiah
	Junin	Romero

Virus Family	Virus	Strain/Variant
Paramyxo	Nipah virus	Malaysia
	HRS	A2
	Measles	Chicago
Corona	SARS-CoV	Urbani
	MERS-CoV	Jordan
Orthomyxo	Influenza	pH1N1
Picornaviridae	Rhinovirus-2	HGP
Flaviviridae	West Nile	New York
	Yellow fever	17D
	Jap. Enceph.	SA14
	Powassan Virus	LB
	Dengue 2	New Guinea C
	Zika	PRVABC59

Source: Company data

Human Safety and Pharmacokinetics:

- Galidesivir has undergone Phase 1 clinical trials in healthy volunteers. These studies assessed both intramuscular and intravenous administration.
- The drug was found to be safe and well-tolerated at doses up to 20 mg/kg intravenously and 10 mg/kg intramuscularly, with no serious adverse events reported.
- Pharmacokinetic (PK) analysis indicated that Galidesivir achieves plasma concentrations suitable for antiviral activity, and its metabolic profile supports dosing regimens for acute viral infections.
- During the COVID-19 pandemic, Galidesivir was also evaluated in a randomised, placebo-controlled trial in Brazil for SARS-CoV-2 infection. While the primary focus has shifted to Marburg, these studies further reinforce the compound's safety in humans.

Regulatory Pathway and Next Steps:

- The FDA has confirmed that Galidesivir is eligible for the Animal Rule pathway, which allows approval based on robust animal efficacy data and established human safety.
- ILA is preparing a pivotal NHP (non-human primate) study designed to replicate the previous survival results. The protocol will be reviewed by the FDA, with feedback expected in early 2026.
- If the pivotal study demonstrates statistically significant survival benefit, Island can submit a New Drug Application (NDA) supported by both animal and human data.
- The streamlined regulatory process means Galidesivir could potentially reach market within 12 to 18 months, pending successful NHP results.
- The market for indications such as Marburg is as a biothreat stockpile and outbreak containment measures through programs such as the US Strategic National Stockpile (SNS). This aims to provide treatment coverage to >10k high-priority people to ensure continuity of government. This ranges from the president and cabinet down to essential infrastructure leaders (power grid, telco, transport, water).

Figure 3: ILA catalysts

Galidesivir specific milestones	Timeframe
Advance US Government engagement initiatives	November CY25
Sign research agreement with gold-standard BSL4 facility and develop clinical trial protocol	Q4 CY25
Submit clarifying questions on initial FDA feedback to assist in finalizing Galidesivir clinical program	Q4 CY25
Commence strategic appointments to establish Galidesivir Advisory Committee	Q4 CY25
Prepare proposed study protocol and submit to FDA for review	Q4 CY25 - Q1 CY26
Finalise proposed study design following FDA review	Q1 CY26
Commencement of Galidesivir's clinical development prior to NDA preparation	Q1 CY26
Advance opportunities for Galidesivir's broader development in other indications	Ongoing
Explore partnership and international government engagement opportunities	Ongoing

Source: Company data

ISLA-101

Preclinical and Mechanistic Data:

- ISLA-101 (Fenretinide) is a small molecule with antiviral activity against mosquito-borne flaviviruses, including dengue, Zika, West Nile, and yellow fever.
- The drug's mechanism involves inhibiting the nuclear entry of the dengue virus's non-structural protein 5 (NS5), which is essential for viral replication.
- Animal models have shown that ISLA-101 can prevent death in up to 70% of subjects exposed to lethal dengue virus strains.

Clinical Trials (Dengue):

- ISLA-101 has a long history of human exposure, having been tested in 48 Phase I, II, and III trials for cancer and respiratory diseases. While not efficacious in oncology, it was proven to be safe.
- ILA structured the Phase 2a/b PROTECT trial to assess both prophylactic (preventative) and therapeutic (treatment) use against dengue.
- In the Phase 2a arm, subjects received ISLA-101 or placebo before being exposed to an attenuated strain of dengue. Results showed a clinically meaningful reduction in viral load (viremia) and symptoms in the ISLA-101 group compared to controls.
- The Safety Review Committee found no safety concerns and recommended progression to Phase IIb.
- In the Phase 2b arm, subjects were treated after infection. While there was a reduction in viral load, the reduction in symptoms was less pronounced compared to the preventative arm.
- Overall, the data suggest ISLA-101 is more effective as a preventative agent than as a treatment for established dengue infection.

Current Status and Future Directions:

- ILA is reviewing the clinical data and seeking guidance on the next steps for ISLA-101's development. The likely path forward is to focus on its use as a prophylactic, with further trials planned.
- If approved, ISLA-101 may qualify for a Priority Review Voucher (PRV), adding further commercial value.

Scan here for a full list of our branches.
1800 777 946
info@morgans.com.au

Scan here to explore the stocks under coverage of our award-winning in-house research team.

Scan here for research coverage policy, research independence statement & recommendation structure.

Scan here for a glossary of terms used in Morgans research.