Research Update: FDA Meeting Granted Island Pharmaceuticals (ASX:ILA)

Critical Results Expected by End of Year

Share Price: $0.42

ASX: ILA
Sector: Healthcare
09 Oct 2025

Island Pharmaceuticals (ASX: ILA) intends to assess whether its small molecule antiviral, Galidesivir, is effective against the highly lethal Marburg virus. A successful outcome could enable FDA approval for Marburg treatment and open the door to U.S. government stockpiling contracts. The company aims to complete the animal study by December 2025

Since acquiring Galidesivir from BioCryst Pharmaceuticals Inc. (Nasdaq: BCRX) (Mkt Cap $1.5B) in July, Island Pharmaceuticals (ASX: ILA) has submitted and secured a meeting with the U.S. Food and Drug Administration (FDA) under the drug's existing Investigational New Drug (IND) application. The company expects to receive written feedback from the FDA on 12 November 2025 (U.S. time). The meeting will allow ILA to align with the regulator on the application of the FDA's Animal Rule pathway for Galidesivir's development and approval, while also seeking guidance on the proposed clinical study design and the drug's potential eligibility for a Priority Review Voucher (PRV).

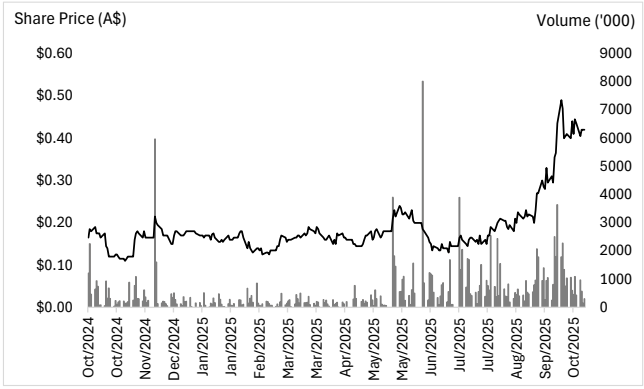
More on the FDA's Animal Rule and Priority Review Vouchers below.

In a previous non-human primate study, **Galidesivir achieved an overall survival rate of 94%**, including 100% survival when treatment commenced on day one or two post-infection. In contrast, the placebo group experienced 100% mortality within approximately 10 days of infection.

Market cap. (A$m)	107
Shares outstanding (m)	243
Shares fully diluted (m)	297
Market cap full dil. (A$ m)	125
52-week high/low (A$)	$0.51/$0.11
Co. Website	islandpharmaceuticals.com

Source: Iress

12 month share price (A$) and daily volume



Potential Near Term Catalysts

Catalyst	Timeframe
Sign research agreement with BSL4 facility and develop clinical trial protocol	October CY2025
Meeting with FDA to discuss Galidesivir Animal Rule applicability	November CY2025
Initiate animal study using Galidesivir in Marburg	November CY2025
Completion of Marburg animal study using Galidesivir	**December CY2025**
Preparation of NDA	Q1 CY2026

Table 1: Upcoming Catalysts

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Investment Thesis

Island Pharmaceuticals (ASX: ILA) offers a compelling investment opportunity through its recent acquisition of Galidesivir, a broad-spectrum antiviral targeting Ebola, Marburg, and other high-priority infectious diseases, with potential for accelerated approval under the FDA's Animal Rule and lucrative U.S. government stockpile contracts.

Additionally, its second asset, ISLA-101, has shown promising Phase 2 results for dengue fever, addressing a market of 400M annual infections with no approved antivirals, and could be extended to other flaviviruses like Zika and West Nile. A 2021 study of 12,000 clinical transitions found infectious disease programs were among the highest Phase II success rates, further strengthening the case.

With potential upside from Priority Review Vouchers valued at over US$100M each, strong insider alignment, and limited competition, Island is strategically positioned to potentially deliver outsized returns.

Top Shareholders

Shareholder	Ordinary Shares Held	% Held
Dr William James Garner	41,690,073	16.43%
Mr Jason Alan Carroll	31,100,000	12.25%
MWP Partners Limited	19,264,773	8.59%
Dr Daniel Tillett	14,010,000	5.52%

Table 2: Substantial holders as per last lodged substantial holder notice or Director Interest notice with ASX

Galidesivir

In July 2025 Island acquired Galidesivir from BioCryst Pharmaceuticals (NASDAQ:BCRX) as a potential treatment for Ebola and Marburg infections.

Ebola/Marburg

Ebola and Marburg are members of the filoviridae family and often lead to fatal Haemorrhagic Fever. Marburg has a fatality rate of around 50%[1], Ebola is even more deadly with a fatality rate of ~60%[2]. Because of their highly contagious and deadly nature US CDC classifies Filoviruses (Ebola & Marburg) as one of only six Category A bioterrorism threats, threats which pose the greatest risk to US National Security.

Marburg has a fatality rate of around 50%, Ebola is even worse with a fatality rate of ~60%.

Fighting Bioterrorism

Galidesivir could become part of the US government's fight against bioterrorism. While bioterrorism acts have been rare in recent history it is believed that biological agents such as anthrax, plague, smallpox, and viruses that cause viral haemorrhagic fevers such as Marburg and Ebola have been weaponised.

In an effort to protect its citizens, governments such as the U.S. stockpile drugs or vaccines to be distributed in the event of a biological outbreak. It's estimated that the US government spent $100bn on biodefence from 2000-2020[3].

[1] https://pmc.ncbi.nlm.nih.gov/articles/PMC10526840/

[2] https://www.sciencedirect.com/science/article/pii/S1876034123003581

[3] https://time.com/5898120/america-biodefense-covid/

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Supply contracts for antiviral drugs or vaccines can be highly lucrative, as demonstrated by SIGA Technologies (Nasdaq: SIGA). In 2010, SIGA secured a contract to provide 1.7 million courses of its smallpox treatment for the U.S. Strategic National Stockpile. The base contract was valued at approximately US$500 million in revenue, with the potential to reach up to US$2.8 billion if all options under the agreement were exercised by BARDA[4]. SIGA is listed on the Nasdaq exchange with a market cap of ~$590m.

Another stockpiling example is Emergent BioSolutions, who was awarded a 10-year contract with the Biomedical Advanced Research and Development Authority (BARDA), under the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), valued at up to $704 million. The contract covers the advanced development, manufacturing scale-up, and procurement of Ebanga™, an FDA-approved treatment for Ebola virus disease (EVD)[5].

Galidesivir History

Galidesivir was originally developed by BioCryst Pharmaceuticals (NASDAQ:BCRX) (Mkt Cap $1.5B) intended to treat hepatitis C. Since then, Galidesivir has shown efficacy against many viral pathogens, including Ebola, Marburg, yellow fever, Zika, and Rift Valley fever viruses. Additionally, it has exhibited broad-spectrum antiviral activity in vitro against more than 20 RNA viruses spanning nine viral families, such as coronaviruses, filoviruses, togaviruses, phenuiviruses, arenaviruses, paramyxoviruses, pneumoviruses, orthomyxoviruses, picornaviruses, and flaviviruses[6].

Galidesivir has undergone phase 1 studies in healthy volunteers included single and multiple ascending dose trials using intramuscular administration, as well as single ascending dose studies delivered intravenously[7].

A 2024 study tested the efficacy of treating Marburg virus with Galidesivir. Cynomolgus macaques were infected with a lethal dose of Marburg. There were 4 groups in the trial, each consisting of 6 macaques. The six infection-control subjects succumbed by day 12. All animals treated with Galidesivir whether treated 24 or 48 hours after infection survived. Five out of six (83%) animals treated beginning 1 hour after infection survived[8]. 17 out of the 18 macaques treated with Galidesivir survived.

All animals treated with Galidesivir whether treated 24 or 48 hours after infection survived.

[4] https://www.globenewswire.com/news-release/2010/10/13/431434/9738/en/SIGA-Selected-for-the-Procurement-of-Smallpox-Antiviral-Drug-for-the-Strategic-National-Stockpile-and-Responds-to-Small-Business-Size-Protest.html

[5] https://investors.emergentbiosolutions.com/news-releases/news-release-details/emergent-biosolutions-awarded-10-year-barda-contract-valued

[6] https://pmc.ncbi.nlm.nih.gov/articles/PMC8483777/

[7] https://ir.biocryst.com/news-releases/news-release-details/biocryst-completes-phase-1-clinical-trial-galidesivir

[8] https://www.mayoclinic.org/diseases-conditions/dengue-fever/symptoms-causes/syc-20353078

The Animal Rule

Galidesivir may benefit from the FDA's Animal Rule which allows drug approval for specific indications based on efficacy demonstrated in animal models, when human trials are unethical or impractical, provided the drug's safety is established in humans and the disease is reliably replicated in animals. Obviously, it would be unethical to inoculate humans with Ebola or Marburg and so the Animal Rule will likely apply. As mentioned earlier Galidesivir has undergone phase 1 studies in healthy human volunteers so there is potential that Galidesivir may be approved following one additional animal study.

The most recent animal rule approval came in 2024 when Amneal Pharmaceuticals LLC received approval for pyridostigmine bromide for pretreatment against the lethal effects of soman nerve agent poisoning in adults[9].

ISLA-101 – Dengue Fever

In parallel ISLA-101 (fenretinide), is being developed as a prophylactic and therapeutic for dengue fever. In mid-2025, Island reported highly encouraging Phase 2 trial results for ISLA-101, demonstrating meaningful reductions in dengue viral load and symptoms in a human challenge model. This data underscores the potential for ISLA-101 to become the first antiviral option for dengue, addressing a market of hundreds of millions of annual infections, multi-billions in potential revenue and a significant unmet need.

ISLA-101 (or fenretinide) has been tested in ~45 Phase I and II human clinical trials.

With both Galidesivir and ISLA-101 progressing through clinical development, the company is not reliant on the success of a single program. Each asset targets a distinct, high-need indication. One in biodefense (Marburg) and one in endemic global disease (dengue). With independent regulatory paths, market opportunities, and potential eligibility for Priority Review Vouchers, this diversification lowers binary outcome risk and increases the likelihood of at least one value-creating outcome.

Next Steps for ILA-101

The Company held a meeting with its Clinical Advisory Board to review the positive initial data and seek guidance on the next steps for the clinical development of ISLA-101. Additional trials are likely to be required, though they be shorter than typical studies due to the nature of dengue fever infections.

[9] https://investors.amneal.com/news/press-releases/press-release-details/2024/Amneal-Receives-U.S.-FDA-Approval-of-New-Drug-Application-for-Pyridostigmine-Bromide-Extended-Release-Tablets/default.aspx

Priority Review Vouchers

Both Galidesivir and ISLA-101 are eligible to receive Priority Review Voucher (PRV) upon approval. Meaning, if either of these drugs is granted FDA approval the company can expedite the approval process of another drug or sell the PRV to another company. Recent PRVs have sold for more than US$100m[10].

Investment Thesis

Clinical development for Galidesivir and ISLA-101 is expected to require less time and funding than typical drug programs. For Marburg virus, expedited approval may be possible under the FDA's Animal Rule, further reducing development timelines and costs. In the case of dengue, this is due to the short duration of infection, allowing for more efficient trial designs.

Island has the potential to operate in an untapped market. There are no licenced treatments for Marburg, only supportive care. Currently, there are no approved antiviral treatments available once dengue fever is contracted. While a few vaccines exist, their use is limited. Existing therapies are limited to managing symptoms rather than targeting the virus itself.

If proven effective against dengue fever, **ISLA-101 could potentially be rapidly adapted for use against other flaviviruses** such as West Nile, Zika, and yellow fever[11]. These viruses share a similar mechanism of action and exhibit comparable patterns of dissemination within the body. As a result, regulatory approval for additional flavivirus indications may be faster than typical timelines.

Island presents a lower risk profile compared to many pharmaceutical companies, largely because of its strategy of repurposing drugs with an extensive safety record. Repurposed drugs generally require less time and investment to progress through clinical development and have a reduced risk of failure in trials[12].

If proven effective against Marburg**, Galidesivir could potentially be adapted for use against viruses** such as Ebola[13], yellow fever[14], Zika[15], and Rift Valley fever virus[16].

[10] https://www.globenewswire.com/news-release/2025/06/18/3101184/0/en/Bavarian-Nordic-Announces-Sale-of-Priority-Review-Voucher-for-USD-160-Million.html

[11] https://journals.asm.org/doi/10.1128/aac.04177-14

[12] https://pubmed.ncbi.nlm.nih.gov/30310233/

[13] https://www.nature.com/articles/nature13027.pdf

[14] https://journals.asm.org/doi/10.1128/aac.03368-14

[15] https://europepmc.org/article/MED/27838352

[16] https://www.sciencedirect.com/science/article/pii/S0166354218301499

Potential source of non-dilutive funding. Should Galidesivir or ISLA-101 be granted FDA approval either could be eligible for a priority review voucher which have recently sold in excess of US$100m[17].

Infectious diseases like Marburg and Dengue have some of the highest success rates. A 2021 study looked at over 12 thousand clinical and regulatory phase transitions between 2011 and 2020. They found that trials focused on treating infectious diseases were among the most likely of a successful phase II trial[18].

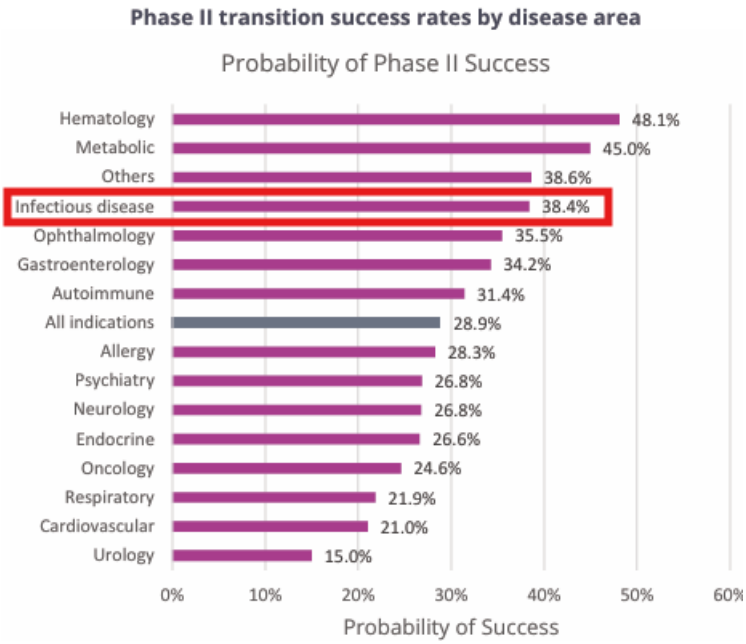

Figure 1: Phase II transition success rates by disease area. Source bio.org

Key Risks

The primary risk facing Island is the potential for lack of efficacy in future trials of Galidesivir or ISLA-101. However, risk is mitigated through Island's multi-asset platform. Further reducing this risk is the broad potential of both compounds, which have demonstrated activity across multiple indications, including Zika, Yellow Fever, and Ebola.

Additional risks include but are not limited to:

- **Regulatory Approval Risk**: There is a risk that **Galidesivir and** ISLA-101 may not receive regulatory approval. Even with supportive efficacy data, regulators such as the FDA may find the evidence insufficient or raise concerns over safety, drug interactions, or other factors that could delay or prevent approval.

[17] https://www.globenewswire.com/news-release/2025/06/18/3101184/0/en/Bavarian-Nordic-Announces-Sale-of-Priority-Review-Voucher-for-USD-160-Million.html

[18] https://go.bio.org/rs/490-EHZ-999/images/ClinicalDevelopmentSuccessRates2011_2020.pdf

- **Commercial Adoption Risk**: Successfully completing clinical trials does not guarantee commercial success. The drug may face challenges in gaining approval, physician adoption, or market penetration, particularly if there are competing therapies, limited awareness, or reimbursement hurdles.
- **Leadership & Talent Dependency Risk**: Island's success depends heavily on the expertise of its leadership and scientific team. The loss of key personnel could disrupt operations or strategic direction, and finding suitable replacements with comparable experience may be difficult.
- **Capital Availability Risk**: There is a risk that Island may require additional capital to fund ongoing operations or future development. There is no certainty the company will be able to raise the necessary funds, or that such capital can be secured on favourable terms. Any successful capital raising may result in dilution for existing shareholders.

Risks related to pre-revenue pharmaceuticals, biotechnology & Life sciences companies in general. The stocks of biotech/pharma and medical device companies without revenue streams should always be regarded as speculative in character.

Management and Key Personnel

Dr David Foster (CEO and Managing Director) - Dr. Foster brings over two decades of experience in the life sciences sector, having advised pharmaceutical, biotherapeutic, and diagnostic companies during his time in private legal practice. He previously served as Intellectual Property Counsel at Medarex, a mid-sized biotherapeutics firm later acquired by Bristol-Myers Squibb. Dr. Foster is a co-founder of several ventures, including the technology-focused law firm Roberts Foster LLP, the regional life sciences association BionorthTx, and multiple private biotechnology companies. Dr. Foster holds a Ph.D. from The University of Texas Southwestern Medical Center and a J.D. from Golden Gate University School of Law.

Jason Carroll (Non-Executive Chair) - Mr. Carroll has over 30 years of experience in the life sciences industry and has held senior leadership positions at several global pharmaceutical companies, including Johnson & Johnson, Janssen Pharmaceutica, and iNova Pharmaceuticals. His background brings deep expertise across both research and development as well as corporate strategy. He has led clinical product development programs, guided successful market access and reimbursement initiatives for new drug therapies, and executed regional M&A and business development strategies, with a particular focus on South-East Asia. Mr. Carroll is a significant shareholder in the company and currently serves as CEO of Tryp Therapeutics Inc. (ASX:TYP).

Chris Ntoumenopoulos (Non-Executive Director) - Mr. Ntoumenopoulos has over 20 years of experience in financial markets and is the Managing Director of Twenty 1 Corporate, an Australian-based corporate advisory firm. He was a founding director of ResApp Health Ltd (ASX:RAP), which was acquired by Pfizer, and Race Oncology (ASX:RAC). He currently serves as a Non-Executive Director of TrivarX Limited (ASX:TRI) and Tryp Therapeutics (ASX:TYP).

Prof Stephen Thomas MD (Scientific Advisory Board) - Professor Thomas, is an internationally recognised virologist and vaccinologist. He has authored numerous publications on infectious diseases, including dengue fever, Zika, and other viral threats, and is widely regarded as a global expert in his field. Prof. Thomas holds multiple leadership roles at the State University of New York (SUNY) Upstate Medical University, where he is Chief of the Division of Infectious Diseases, Professor of Medicine, Professor of Microbiology & Immunology, and Director of the Institute for Global Health and Translational Science (IGHTS). He also served for two decades in the U.S. Army Medical Corps, including key roles at the Walter Reed Army Institute of Research (WRAIR).

Dr Amy Patick (Scientific Advisory Board) - Dr. Patick is a scientific consultant with extensive expertise in antiviral drug discovery, development, and viral resistance. She has broad knowledge spanning emerging viral epidemics and translational medicine. Her previous roles include Vice President of Research at Adamas Pharmaceuticals, Vice President of Biological Sciences at Genelabs Technologies, Head of the Antiviral Biology Therapeutic Area at Pfizer, and Research Scientist at Bristol-Myers Squibb. Dr. Patick also served as President of the International Society of Antiviral Research. She completed her postdoctoral fellowship in immunology at the Mayo Clinic/Foundation in Rochester, Minnesota, and earned her PhD in Medical Microbiology from the University of Wisconsin–Madison.

Appendix I – Capital Structure

Security	Description	On Issue
ILA	Ordinary Fully Paid	253,776,761
ILAAL	OPT EXP VAR DATES EX VAR PRICES	6,000,000
ILAAP	OPT EXP 04-DEC-2025 EX $0.07	14,428,970
ILAAM	OPT EXP 28-APR-2026 EX $0.21	1,380,000
ILAAQ	OPT EXP 04-DEC-2026 EX $0.07	19,428,969
ILAAO	OPT EXP 21-MAR-2027 EX $0.12	2,075,834

Table 3: Issued Capital. Source: Iress

Appendix II - results from previous non-human primate study

94% overall survival rate			
Group	**Time post infection**	**Survival (no.)**	**Survival (%)**
Placebo (untreated)	-	0	0%
Galidesivir treated	1 hour	5/6	83%
	24 hours	6/6	100%
	48 hours	6/6	100%

Table 4: Results from a previous non-human primate study by BioCryst Pharmaceuticals Inc. (Nasdaq: BCRX) (BioCryst) using Galidesivir Galidesivir was administered one hour, 24 hours or 48 hours post Marburg virus infection. This led to an overall survival rate of of 94%, including a 100% survival rate when treatment began on 24 hours or 48 hours post infection. This is compared to the placebo group, which succumbed to infection within ~10 days. Source: Company

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