Research Update: Island Pharmaceuticals (ASX:ILA)

Regulatory Alignment and Strategic Partnerships Accelerate Galidesivir Toward Animal Rule Approval

Share Price: $0.425
ASX: ILA
Sector: Healthcare
05 March 2026

Island Pharmaceuticals (ASX: ILA) has delivered several significant developments since our last report, most notably the U.S. Food and Drug Administration (FDA) has confirmed the key scientific parameters underpinning the company's Animal Rule development program, including the viral strain, animal model and challenge dose required for approval. This confirmation establishes a clearly defined two-stage development pathway, significantly reducing regulatory uncertainty and enabling Island to progress toward a pivotal confirmatory study required for approval.

In parallel, Island has secured $9 million in strategic funding from institutional and sophisticated investors, extending the company's cash runway and fully funding Galidesivir through its two-stage Animal Rule development pathway and potential New Drug Application (NDA) submission for Marburg.

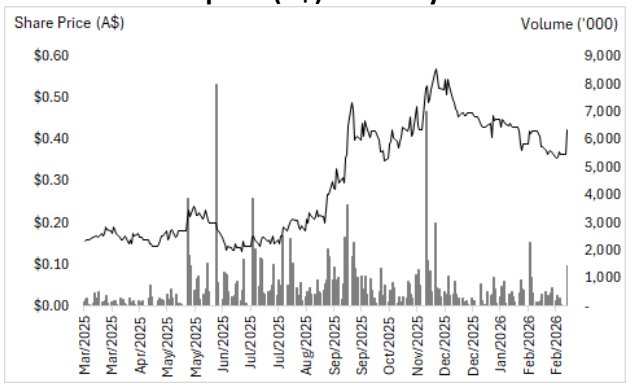
Further strengthening the program, Island has entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Geneva Foundation, two organisations deeply embedded in the U.S. biodefence ecosystem. The collaboration will support the design and execution of the non-human primate studies required to advance Galidesivir toward regulatory approval under the Animal Rule.

With regulatory alignment established, funding secured, and collaboration with leading biodefence research institutions now in place, Island has entered what management describes as the execution phase of its Animal Rule development strategy. If successful, approval under the Animal Rule could unlock eligibility for U.S. Strategic National Stockpile procurement, while also generating a Priority Review Voucher (PRV), which have recently sold for approximately US$200 million.

Market cap. (A$m)	125
Shares on issue (m)	295
Shares fully diluted (m)	343
Market cap full dil. (A$ m)	146
52-week high/low (A$)	$0.12/$0.63
Co. Website	islandpharmaceuticals.com

Source: Iress

12-month share price (A$) and daily volume



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Potential Near-Term Catalysts

Catalyst	Timeframe
Dose optimisation and pharmacokinetic studies in non-human primates	Q1-Q2 CY26
Pivotal confirmatory Animal Rule efficacy study	Q3-Q4 CY26
Potential progression toward New Drug Application (NDA)	CY27
Strategic National Stockpile procurement discussions	Post approval

Table 1: Upcoming Catalysts

Register to Receive Future ILA Research Notes

Two-Stage Development Pathway for Galidesivir

Following discussions with the FDA, Island has been provided with a defined two-stage development pathway to advance Galidesivir toward potential approval for Marburg Virus Disease.

The first stage involves dose optimisation and pharmacokinetic (PK) studies conducted in a limited number of non-human primates. These studies are designed to determine:

- the minimum effective dose
- how the drug behaves in the body
- the optimal timing for treatment following infection

The second stage is the pivotal confirmatory study, which provides the primary efficacy data required for regulatory approval. The confirmatory study will evaluate survival outcomes and disease progression in infected animals treated with Galidesivir using the optimised dosing parameters determined in the first stage.

The FDA's recommendation to adopt a staged approach is intended to reduce the risk of failure in the pivotal study. By first refining the optimal dosing and treatment timing in a smaller exploratory study, the confirmatory trial can be designed with greater precision. This approach helps avoid the need to repeat large, complex animal studies and ensures that the pivotal experiment is conducted under conditions most likely to demonstrate efficacy.

Top Shareholders

Shareholder	Ordinary Shares Held	% Held
Dr William James Garner	41,690,073	14.14%
Mr Jason Alan Carroll	32,074,930	10.88%
Dr Daniel Tillett	20,973,789	7.12%
MWP Partners Limited	19,264,773	6.54%

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

Role of USAMRIID and the CRADA Collaboration

Island recently entered into a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Geneva Foundation.

USAMRIID is widely regarded as the U.S. military's premier biodefence research institute, with more than five decades of experience studying high-consequence infectious diseases. The institute operates highly specialised Biosafety Level 4 (BSL-4) laboratories, which are required to safely handle and study pathogens such as Marburg and Ebola. These facilities represent the highest level of biological containment and are limited in number globally.

Under the terms of the CRADA, Island, USAMRIID and the Geneva Foundation will collaborate to design and conduct the non-human primate studies required to progress Galidesivir toward regulatory approval for Marburg Virus Disease. The agreement has an initial term of three years and includes optionality to expand the collaboration if additional studies are required.

The involvement of the Geneva Foundation is also strategically significant. The organisation specialises in managing government-funded medical research programs and coordinating collaborations between

defence agencies, academic institutions and industry partners. With approximately US$383 million in annual research funding and collaborations across numerous U.S. Department of War installations, the foundation provides expertise in navigating complex government research programs and regulatory frameworks.

From a strategic perspective, this collaboration further integrates Island into the U.S. biodefence ecosystem, which may prove important if Galidesivir progresses toward potential procurement by government agencies such as those responsible for the Strategic National Stockpile. Access to leading biodefence researchers and high-containment laboratories also strengthens the company's ability to execute the specialised studies required for approval under the Animal Rule.

Strategic Funding and Program Execution

ILA recently completed a $9 million placement to institutional and sophisticated investors, providing additional capital to advance the Galidesivir program through its defined Animal Rule development pathway.

The capital will be used to:

- conduct the required non-human primate studies
- manufacture additional drug supply
- progress regulatory and preclinical work associated with additional biodefence opportunities such as Ebola and Sudan virus

Importantly, this funding significantly strengthens the company's balance sheet and extends its operational runway at a critical stage of development. Combined with the company's existing cash balance of $6.87 million as at 31 December 2025, the capital raise is intended to fully fund the remaining studies required to advance Galidesivir through the two-stage Animal Rule development pathway and potential New Drug Application (NDA) submission to the FDA for Marburg Virus Disease.

This funding reduces near-term financing risk and allows the company to focus on executing the development pathway toward a potential New Drug Application with the FDA.

Investment Thesis

Island Pharmaceuticals (ASX: ILA) offers a compelling investment opportunity through its a broad-spectrum antiviral Galidesivir, 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.

With potential upside from Priority Review Vouchers valued at over US$200M each, strong insider alignment, and limited competition, Island is strategically positioned to potentially deliver outsized returns.

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].

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 ~$445m.

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].

[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/

[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

Galidesivir History

Galidesivir was originally developed by BioCryst Pharmaceuticals (NASDAQ:BCRX) (Mkt Cap ~$2.2B) 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.

The Animal Rule

The FDA has confirmed that Galidesivir is suitable for the 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].

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

[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

[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

drug or sell the PRV to another company. Recent PRVs have sold for more than US$100m[10].

Investment Highlights

Clinical development for Galidesivir 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.

Recent regulatory engagement with the FDA has provided a clearly defined two-stage development pathway, confirming the key scientific parameters required for approval and significantly reducing regulatory uncertainty surrounding the program. With alignment established on the viral strain, animal model and challenge conditions required for testing, the remaining work is largely executional in nature

Island has strengthened its strategic positioning within the U.S. biodefence ecosystem through a Cooperative Research and Development Agreement (CRADA) with the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Geneva Foundation. This collaboration provides access to specialised high-containment research facilities and expertise required to conduct the non-human primate studies necessary for approval under the Animal Rule.

Island has the potential to operate in an untapped market. There are no licenced treatments for Marburg, only supportive care.

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[11].

If proven effective against Marburg, Galidesivir could potentially be adapted for use against viruses such as Ebola[12], yellow fever[13], Zika[14], and Rift Valley fever virus[15].

Potential source of non-dilutive funding. Should Galidesivir be granted FDA approval it is eligible for a priority review voucher which have recently sold in excess of US$200m[16].

Infectious diseases like Marburg have some of the highest success rates. A 2021 study looked at over 12 thousand clinical and regulatory phase

[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://pubmed.ncbi.nlm.nih.gov/30310233/

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

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

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

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

[16] https://www.fiercepharma.com/pharma/fortress-sells-fda-voucher-205m-after-zycubo-approval-last-month

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[17].

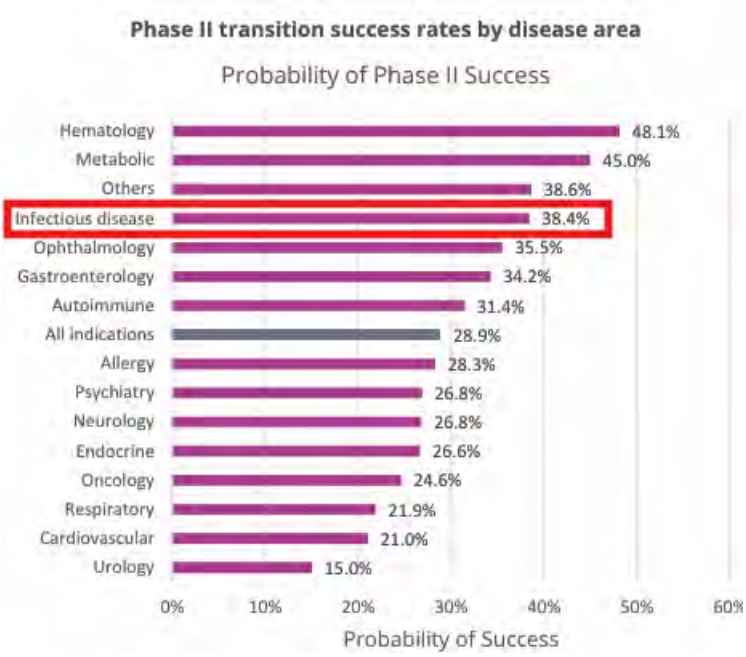

Figure 1: Phase II transition success rates by disease area. Source bio.org

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 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.
- **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

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

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 Entropy Neurodynamics (ASX:ENP).

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	254,623,427
ILAAL	OPT EXP VAR DATES EX VAR PRICES	17,100,000
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	1,895,834

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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